15.99.05.W1.02AR WTAMU Institutional Animal Care and Use Procedure

Approved: August 15, 2010
Last Revised: October 4, 2023
Next Scheduled Review: October 4, 2028

Procedure Summary

Environmental Health and Safety at West Texas A&M University (WTAMU) is composed of two distinct but integrated environmental safety departments which report to the Vice President of Research and Compliance. Academic and Research Environmental Health and Safety (AR-EHS) is responsible for research and academic related compliance, which includes laboratory and academic research and the associated compliance committees. Fire and Life Safety (FLS-EHS) is responsible for fire related compliance and conducts fire and life safety inspections of campus buildings and assists with the testing of all fire detection and suppression systems.

Contents

Purpose

The *Guide for the Care and Use of Laboratory Animals* (*Guide*) strongly affirms the principle that all who care for, use, or produce animals for research, testing, or teaching must assume responsibility for their well-being. The *Guide* is created by scientists and veterinarians for scientists and veterinarians to uphold the scientific rigor and integrity of biomedical research with laboratory animals as expected by their colleagues and society at large.

The *Guide* plays an important role in decision making regarding the use of vertebrate laboratory animals because it establishes the minimum ethical, practice, and care standards for researchers and their institutions. The use of laboratory animals in research, teaching, testing, and production is also governed or affected by various federal and local laws, regulations, and standards; for example, in the United States the Animal Welfare Act (AWA 1990) and Regulations (PL 89-544; USDA 1985) and/or Public Health Service (PHS 2000) Policy may apply. Compliance with these laws, regulations, policies, and standards (or subsequent revised versions) in the establishment and implementation of a program of animal care and use is of utmost importance to West Texas A & M University (WTAMU). WTAMU Institutional Animal Care and Use Committee (IACUC) procedures implements the Health Research Extension Act of 1985, PHS Policy, *Guide for the Care and Use of Laboratory Animals* (*Guide*) 8th ed., Assurances, and the Animal Welfare Regulations.

The practical effect of these laws, regulations, and policies is to establish a system of self-regulation and regulatory oversight that binds researchers and institutions using animals. Both researchers and institutions have affirmative duties of humane care and use that are supported by practical, ethical, and scientific principles. This system of self-regulation establishes a rigorous program of animal care and use and provides flexibility in fulfilling the responsibility to provide humane care. The specific scope and nature of this responsibility can vary based on the scientific discipline, nature of the animal use, and species involved, but because it affects animal care and use in every situation this responsibility requires that producers, teachers, researchers, and institutions carry out purposeful analyses of proposed uses of laboratory animals. The *Guide* is central to these analyses and to the development of a program in which humane care is incorporated into all aspects of laboratory animal care and use.

WTAMU Institutional Animal Care and Use Committee (IACUC) is charged with overseeing all aspects of animal care and use at WTAMU and affiliated entities. The IACUC monitors the animal care and use program by conducting thorough reviews of the program and inspections of the animal facilities. After review and inspection, a written report (including any minority views) is compiled and provided to the IO about the status of the program including any recommendations. The IACUC may approve, require modification of, or withhold approval of a project. Animal use in the absence of IACUC approval is a serious violation of University procedure (SOP No. 15.99.05.W1.07AR WTAMU Potential Non-Compliance in the Course of Vertebrate Animal Care and Research) and a violation of federal law.

Roles and Responsibilities

The IACUC is responsible for oversight of the animal care and use program and its components as described in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) and the *Guide for the Care and Use of Laboratory Animals* (*Guide*). Its oversight functions include an ongoing assessment of animal care and use. IACUC responsibilities include:

- Meet as often as necessary to fulfill its responsibilities;
- Review, at least semiannually, the institution's program for the humane care and use of animals;
- Inspect, at least semiannually, the institution's animal facilities (including satellite facilities);

- Prepare reports to the Institutional Official (IO) of the IACUC evaluations;
- Review animal welfare concerns;
- Make recommendations to the IO on any aspect of the animal program, facilities, or personnel training;
- Review and approve, those components of PHS conducted or supported activities related to the care and use of animals;
- Review and approve, proposed significant changes to the use of animals in ongoing activities; and
- Be authorized to suspend an activity involving animals.

A.) **The CEO** is characterized as the highest operating official of the institution (such as the president of a university). The CEO is required to appoint members qualified to serve on the IACUC. The Institutional Official (IO) recommends a nominee to the President of the University for approval to serve on the IACUC.

B.) **The Institutional Official** (IO) for the University research efforts as defined under 9CFR 2.31 shall be the Vice President of Research and Compliance (VPRC) as appointed by the President (i.e. Chief Executive Officer of WTAMU) and the IO bears ultimate responsibility for the program. The IO has the authority to allocate the resources needed to ensure the IACUC's overall effectiveness. IACUC Program needs should be clearly and regularly communicated to the IO by the Attending Veterinarian (AV), the IACUC, and others associated with the Program (e.g., facilities management staff, occupational health and safety personnel, scientists). All Applications for Vertebrate Animal Use (AVAU's) and IACUC Committee reviews, and comments are available to the VPRC. All committee meeting minutes will be submitted to the VPRC.

The IO and Animal Research Protocols

The United States Department of Agriculture (USDA) Animal Welfare Act Regulations provide the IACUC with authority to approve animal activities on behalf of the institution. **The IO may suspend any animal activity for any reason without IACUC concurrence, but these officials do not have the authority to approve an animal activity in the absence of IACUC approval.**

Attending Veterinarian (AV)

The attending veterinarian (AV) is responsible for the health and well-being of all animals used in research, testing, teaching, or production at WTAMU. WTAMU must provide the AV with sufficient authority, including access to all animals, and resources to manage the program of veterinary care. The AV should oversee other aspects of animal care and use (e.g., husbandry, housing) to ensure that the IACUC complies with the *Guide*. There will be clear and regular communication between the IO, AV, and IACUC.

WTAMU's mission, programmatic goals, including the nature of animal use at WTAMU or associated entities, and animal welfare size will determine whether fulltime, part-time, or consultative veterinary services is needed. If a full-time veterinarian is not available on site, a consulting or part-time veterinarian should be available in visits at intervals appropriate to programmatic needs. Veterinary consultation must occur when pain or distress is beyond the level

anticipated in the protocol description or when interventional control is not possible. Veterinarians providing clinical and/or Program oversight and support must have the experience, training, and expertise necessary to appropriately evaluate the health and well-being of the species used in the context of the animal use at the institution. Veterinarians providing broad Program direction should be trained or have relevant experience in laboratory animal facility administration and management. In such instances, there must be an individual with assigned responsibility for daily animal care and use and facility management, which is the principal investigator of the research laboratory/facility.

Institutional Animal Care and Use Committee

The Institutional Animal Care and Use Committee (IACUC) ascertains the acceptability of proposed research involving animals and monitors the resultant research. The IACUC is responsible for assessment and oversight of the institution's animal welfare components and facilities. It should have sufficient authority and resources (e.g., staff, training, computers and related equipment) to fulfill this responsibility. The IACUC is advisory to the Vice President of Research and Compliance who reports to the President on all matters relating to research and compliance. The IACUC must consist of at least 5 members who are recommended by the (VPRC) to the CEO/President of the University for approval to serve on the IACUC. No more than three members shall be from the same administrative unit of the facility (9CFR2.31(b)(4)). The appointed members must be qualified through experience and expertise to provide oversight for the institution's animal programs, facilities, and procedures. IACUC members named in protocols or who have other conflicts must recuse themselves from decisions concerning these protocols. At a minimum the IACUC must include a veterinarian, a practicing scientist experienced in animal research, a person whose primary concerns are in a nonscientific area, and a person who is unaffiliated with the institution except as a member of the IACUC. Members shall serve three-year terms, and there are no limitations on the number of terms a person may serve, and have the following responsibilities:

The Committee Chairman

The Committee Chairman is appointed by the IO/VPRC and the chairman's responsibilities include:

- Calling IACUC meetings.
- Knowing all applicable regulations and procedures regarding animal welfare.
- Assigning each approved AVAU its appropriate approval number.
- Issuing the letter of approval to the PI as approved by the IACUC.
- Submitting reports of investigations and reviews to the IO.
- The IACUC chairman shall submit the semi-annual inspection and programmatic review using the "Memorandum to the IO" (Appendix F) to the IO for review and approval.

Committee Members

The Panhandle oriented "Cooperative Research, Educational and Extension Team (CREET)" is an inter-institutional collaboration between West Texas A & M University, Texas AgriLife Extension Service, Texas Veterinary Medical Diagnostic Laboratory (TVMDL) and USDA-Agricultural Research Service. Due to the cooperative research between WTAMU and CREET, in December 2011, WTAMU and CREET agreed to combine their Institutional Animal Care and

Use Committee (IACUC) project into one comprehensive program to be administered by WTAMU. CREET provides two qualified representatives to serve on the WTAMU IACUC committee. All members of the committee have the following responsibilities:

- Attend as many IACUC meetings as possible.
- Provide feedback on the Program.
- Decisions are based entirely on the welfare of the animals involved.
- Provide minority views which must be included in reports to the IO.
- May be excluded in any evaluation and report.
- IACUC members named in protocols or who have other conflicts must recuse themselves from decisions concerning these protocols.

The IACUC committee is comprised of the following members.

Voting Members:

1. Chairman, Jimmy Gray (2023-2026)
2. Attending Veterinarian, Dr. Richard Posey (until 2025)
3. One Representative non-affiliated with university, Jude Smith, U.S. Fish and Wildlife Service (2021-2024)
4. One Representative from non-science discipline: Rex Pjesky (2023-2026)
5. Representatives from science disciplines with experience in animal research
    a. John Richeson, Agriculture (2023-2026)
    b. Stephen Karaganis, Environmental Science (until 2025)
    c. Lance Baker, Agriculture (2023-2026)
    d. Maxine DeButte, Psychology (2023-2026)
    e. Biology, vacant seat
    f. Justin McBride, UPD Sargent (2022-2025)
    g. Matthew Beck, U.S. Department of Agricultural Research Service (USDA-ARS) (until 2025)
    h. Vinicius (Vinnie) Gouvêa, Agrilife Assistant Professor and Ruminant Nutrition Specialist (until 2025)
    i. Kelli Beavers, Veterinary Education, Research, & Outreach (VERO), Equine Veterinarian (2023-2026)

Non-Voting Members

1. Vice President for Research and Compliance
2. Director of Sponsored Research
3. Assistant Director of Academic and Research Environmental Health and Safety (AR-

EHS)

4. Research Compliance Coordinator

Environmental Health and Safety Program (EHSP)

The Assistant Director of the Environmental Health and Safety Program (EHSP) serves in a support role to the IO, IACUC chairman, and the IACUC as follows:

- Provides regulatory reviews and assessments of newly adopted AWA regulations and other applicable policies to determine applicability to the WTAMU IACUC and/or research activities for review by the IACUC and IO.
- Assists in the updating and revisions of SOPs to address required regulatory changes and programmatic changes.
- Assists the IACUC chairman and IO in the maintenance of the IACUC administrative records, files and applicable permits and permit deliverables.
- Provides and tracks IACUC, PI and research personnel training.

Procedure on Use of Animals and Lab Animal Care Facilities

The use of animals is essential to the teaching, extension, and research missions of West Texas A&M University. Significant benefits to the health and welfare of both animals and humans have resulted from animal use in research, and continued use is crucial to future advancements. Without the use of animals, adequate instruction of students in many programs such as agriculture, the biological sciences, and veterinary medicine would not be possible. However, those who utilize animals are morally and legally obligated to care for them properly and use them humanely. Each faculty member, staff member, or student involved in the use of animals is directly responsible for promoting and protecting their welfare within the instructional, extension, and research programs of the University. Those who use animals should assume this responsibility through precept and example. This procedure provides guidance for the proper care and humane use of animals within University programs.

(1) Animals should be used in teaching, research, and extension programs only as required to demonstrate principles, obtain new information, and achieve results which will ultimately benefit society. Whenever feasible, mathematical models, in vitro biological systems, demonstrations, and computer and audiovisual aids should augment, complement, or possibly replace animal use entirely, thereby reducing the number of animals needed. The procurement, care, and use of animals shall be in accordance with the regulations and terms of the federal Animal Welfare Act and the Health Research Extension Act of 1985 as applicable and subsequent revisions.

(2) All research projects and educational or extension activities using vertebrate animals under the jurisdiction or control of WTAMU shall be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC). In its reviews, the committee will apply standards and guidelines set forth in the Animal Welfare Act, the Health Research Extension Act of 1985 as applicable, and

subsequent revisions.

(3) The housing, care, feeding, and observation of all animals must be supervised by individuals trained in such matters.

(4) Animal use shall be planned and conducted so as to avoid or minimize pain and distress to the animals. Procedures involving animals must be performed by, or be closely supervised by, a faculty or staff member who is skilled in the procedure. Students taking part in such procedures must be appropriately instructed and supervised. If any experimental or demonstrative procedure or its consequences have the potential to induce significant and/or lasting pain, distress, or suffering, appropriate methods of tranquilization, anesthesia, and analgesia must be used. Any painful or distressful procedure, regardless of whether it can or cannot be obviated, must be reviewed and approved in advance by the IACUC.

(5) Procedures for euthanasia must be performed in a manner consistent with the latest recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, and all proposed methods must be approved in advance by the IACUC.

Any faculty member, staff member, or student of the University who has reason to know or believe that this procedure is being violated may submit a written request to the Chairman of the IACUC for review of the procedure or situation in question. The committee will use (SOP No. 15.99.05.W1.07AR WTAMU Potential Non-Compliance in the Course of Vertebrate Animal Care and Use Research) while conducting an investigation. The AVAU can be found at wtamu.edu and must contain the following:

- Identification of the species and the approximate numbers of animals to be used.
- A rationale for involving animals and for the appropriateness of the species and numbers of animals to be used.
- A complete description of the proposed use of the animals.
- A description of the procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals.
- A description of any euthanasia method to be used.

The WTAMU IACUC requires an approved Application for Vertebrate Animal Use (AVAU) as specified in this standard operating procedure and submission of an application and approval for all activities involving the use of animals (Appendix A: AVAU Application Instructions, and Appendix B: Application for Vertebrate Animal Use). “Use” includes activities such as research, teaching, public service; intramurally or extramurally funded grants or contracts regardless of source or amount. “Use” also includes animals being bred, conditioned, or held for future use. The AVAU is a form that allows the investigator to communicate to the Institutional Animal Care and Use Committee (IACUC) reasons for and methods of animal use. The investigator shall follow the conditions set forth in the AVAU. In the event that the investigator requires additions or changes, including extension or renewal of activities to the research activity that include regulated activities, the investigator must submit the Animal Care and Use Protocol Amendment (Appendix C) to the IACUC committee for approval prior to implementing those changes.

The person submitting an AVAU must be the principal investigator (PI). PIs are responsible for animal use by their students and staff. The PI heading a research group or teaching a course must have an approved application on file for each project or course under his/her supervision. Collaborators, technicians, and students must care for and use animals according to the protocols described in the approved applications. Deviations should be reported to the IACUC. PIs must become familiar with laws, rules, and regulations governing animal care and use as well as policies governing the review of animal care and use.

The IACUC chairman shall assign each AVAU a specific number indicating the sequential AVAU and the month and year submitted using the following format.

2022.01.001 (Indicating AVAU #1 in January 2022)

Based on the IACUC committee's recommendations for approval, the IACUC chairman will issue a letter of approval to initiate the requested research activities to the investigator using the designated letter of approval (Appendix E). The investigator and IACUC committee will use the assigned AVAU number on all future correspondence, applications, amendments, and review reports.

Special Considerations for IACUC Review

Certain animal use protocols include procedures or approaches that require special consideration during the IACUC review process due to their potential for unrelieved pain or distress or other animal welfare concerns. The topics below are some of the most common requiring special IACUC consideration. For these and other areas the IACUC is obliged to weigh the objectives of the study against potential animal welfare concerns. By considering opportunities for refinement, the use of appropriate non-animal alternatives, and the use of fewer animals, both the institution and the principal investigator (PI) can begin to address their shared obligations for humane animal care and use.

Experimental and Humane Endpoints The experimental endpoint of a study occurs when the scientific aims and objectives have been reached. The humane endpoint is the point at which pain or distress in an experimental animal is prevented, terminated, or relieved. The use of humane endpoints contributes to refinement by providing an alternative to experimental endpoints that result in unrelieved or severe animal pain and distress, including death. The humane endpoint should be relevant and reliable (Hendriksen and Steen 2000; Olfert and Godson 2000; Sass 2000; Stokes 2002). For many invasive experiments, the experimental and humane endpoints are closely linked (Wallace 2000) and should be carefully considered during IACUC protocol review. While all studies should employ endpoints that are humane, studies that commonly require special consideration include those that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicological effects, organ or system failure, and models of cardiovascular shock.

The PI, who has precise knowledge of both the objectives of the study and the proposed model, should identify, explain, and include in the animal use protocol a study endpoint that is both humane and scientifically sound. The identification of humane endpoints is often challenging, however, because multiple factors must be weighed, including the model, species (and sometimes

strain or stock), animal health status, study objectives, institutional policy, regulatory requirements, and occasionally conflicting scientific literature. Determination of humane endpoints should involve the PI, the veterinarian, and the IACUC, and should be defined when possible before the start of the study (Olfert and Godson 2000; Stokes 2000). Information that is critical to the IACUC's assessment of appropriate endpoint consideration in a protocol includes precise definition of the humane endpoint (including assessment criteria), the frequency of animal observation, training of personnel responsible for assessment and recognition of the humane endpoint, and the response required upon reaching the humane endpoint. An understanding of preemptive euthanasia (Toth 2000), behavioral or physiologic definitions of the moribund state (ibid.), and the use of study specific animal assessment records (Morton 2000; Paster et al. 2009) can aid the PI and IACUC when considering or developing proposed endpoints. When novel studies are proposed or information for an alternative endpoint is lacking, the use of pilot studies is an effective method for identifying and defining humane endpoints and reaching consensus among the PI, IACUC, and veterinarian. A system for communication with the IACUC should be in place both during and after such studies.

Unexpected Outcomes Fundamental to scientific inquiry is the investigation of novel experimental variables. Because of the potential for unexpected outcomes that may affect animal well-being when highly novel variables are introduced, more frequent monitoring of animals may be required.

With their inherent potential for unanticipated phenotypes, genetically-modified animals (GMAs) are an example of models for which increased monitoring for unexpected outcomes could be implemented (Dennis 1999).

GMAs, particularly mice and fish, are important animal models, and new methods and combinations of genetic manipulation are constantly being developed (Gondo 2008). Regardless of whether genetic manipulation is targeted or random, the phenotype that initially results is often unpredictable and may lead to expected or unexpected outcomes that affect the animal's well-being or survival at any stage of life. For example, in some instances genetic modification has led to unforeseen immunodeficiency, requiring the GMA offspring to be held under specialized bioexclusion conditions (Mumphrey et al. 2007); and the promoter sequences used to direct expression of transgenes to specific tissues have varying degrees of specificity ("leakiness") that can lead to unanticipated phenotypes (Moorehead et al. 2003). These examples illustrate the diversity of unanticipated outcomes and emphasize the need for diligent monitoring and professional judgment to ensure the animals' well-being (Dennis 2000). The first offspring of a newly generated GMA line should be carefully observed from birth into early adulthood for signs of disease, pain, or distress. Investigators may find that the phenotype precludes breeding of particular genotypes or that unexpected infertility occurs, situations that could lead to increases in the numbers of animals used and revision of the animal use protocol. When the initial characterization of a GMA reveals a condition that negatively affects animal well-being, this should be reported to the IACUC, and more extensive analysis may be required to better define the phenotype (Brown et al. 2000; Crawley 1999; Dennis 2000). Such monitoring and reporting may help to determine whether proactive measures can circumvent or alleviate the impact of the genetic modification on the animal's well-being and to establish humane endpoints specific to the GMA line.

Physical Restraint Physical restraint is the use of manual or mechanical means to limit some or all of an animal's normal movement for the purpose of examination, collection of samples, drug

administration, therapy, or experimental manipulation. Animals are restrained for brief periods, usually minutes, in many research applications.

Restraint devices should be suitable in size, design, and operation to minimize discomfort, pain, distress, and the potential for injury to the animal and the research staff. Dogs, nonhuman primates, and many other animals can be trained, through use of positive reinforcement techniques, to cooperate with research procedures or remain immobile for brief periods (Boissy et al. 2007; Laule et al. 2003; Meunier 2006; Prescott and Buchanan-Smith 2003; Reinhardt 1991, 1995; Sauceda and Schmidt 2000; Yeates and Main 2009).

Prolonged restraint, including chairing of nonhuman primates, should be avoided unless it is essential for achieving research objectives and is specifically approved by the IACUC (NRC 2003b). Systems that do not limit an animal's ability to make normal postural adjustments (e.g., subcutaneous implantation of osmotic minipumps in rodents, backpack-fitted infusion pumps in dogs and nonhuman primates, and free-stall housing for farm animals) should be used when compatible with protocol objectives. Animals that do not adapt to necessary restraint systems should be removed from the study. When restraint devices are used, they should be specifically designed to accomplish research goals that are impossible or impractical to accomplish by other means or to prevent injury to animals or personnel.

The following are important guidelines for restraint:

- Restraint devices should not be considered a normal method of housing, and must be justified in the animal use protocol.
- Restraint devices should not be used simply as a convenience in handling or managing animals.
- Alternatives to physical restraint should be considered.
- The period of restraint should be the minimum required to accomplish the research objectives.
- Animals to be placed in restraint devices should be given training (with positive reinforcement) to adapt to the equipment and personnel.
- Animals that fail to adapt should be removed from the study.
- Provision should be made for observation of the animal at appropriate intervals, as determined by the IACUC.
- Veterinary care must be provided if lesions or illnesses associated with restraint are observed. The presence of lesions, illness, or severe behavioral change often necessitates the temporary or permanent removal of the animal from restraint.
- The purpose of the restraint and its duration should be clearly explained to personnel involved with the study.

Multiple Survival Surgical Procedures Surgical procedures in the laboratory setting may be categorized as major or minor (USDA 1985). Whether a procedure is major or minor should be evaluated on a case-by-case basis, as determined by the veterinarian and IACUC.

Regardless of classification, multiple surgical procedures on a single animal should be evaluated to determine their impact on the animal's well-being. Multiple major surgical procedures on a single animal are acceptable only if they are (1) included in and essential components of a single research project or protocol, (2) scientifically justified by the investigator, or (3) necessary for clinical

reasons. Conservation of scarce animal resources may justify the conduct of multiple major surgeries on a single animal, but the application of such a practice on a single animal used in separate protocols is discouraged and should be reviewed critically by the IACUC. When applicable, the IO must submit a request to the USDA/APHIS and receive approval in order to allow a regulated animal to undergo multiple major survival surgical procedures in separate unrelated research protocols (USDA 1985, 1997a). Justifications for allowing animals not regulated by the USDA to undergo multiple survival procedures that meet the above criteria should conform to those required for regulated species. If multiple survival surgery is approved, the IACUC should pay particular attention to animal well-being through continuing evaluation of outcomes. Cost savings alone is not an adequate reason for performing multiple major survival surgical procedures.

Some procedures characterized as minor may induce substantial post-procedural pain or impairment and should similarly be scientifically justified if performed more than once in a single animal.

Food and Fluid Regulation Regulation of food or fluid intake may be required for the conduct of some physiological, neuroscience, and behavioral research protocols. The regulation process may entail *scheduled access* to food or fluid sources, so an animal consumes as much as desired at regular intervals, or *restriction*, in which the total volume of food or fluid consumed is strictly monitored and controlled (NRC 2003b). The objective when these studies are being planned and executed should be to use the least restriction necessary to achieve the scientific objective while maintaining animal well-being.

The development of animal protocols that involve the use of food or fluid regulation requires the evaluation of three factors: the necessary level of regulation, potential adverse consequences of regulation, and methods for assessing the health and well-being of the animals (NRC 2003b). In addition, the following factors influence the amount of food or fluid restriction that can be safely used in a specific protocol: the species, strain, or stock, gender, and age of the animals; thermoregulatory demand; type of housing; time of feeding, nutritive value, and fiber content of the diet (Heiderstadt et al. 2000; Rowland 2007); and prior experimental manipulation. The degree of food or fluid restriction necessary for consistent behavioral performance is influenced by the difficulty of the task, the individual animal, the motivation required of the animal, and the effectiveness of animal training for a specific protocol-related task.

The animals should be closely monitored to ensure that food and fluid intake meets their nutritional needs (Toth and Gardiner 2000). Body weights should be recorded at least weekly and more often for animals requiring greater restrictions (NRC 2003b). Written records should be maintained for each animal to document daily food and fluid consumption, hydration status, and any behavioral and clinical changes used as criteria for temporary or permanent removal of an animal from a protocol (Morton 2000; NRC 2003b). In the case of conditioned-response research protocols, use of a highly preferred food or fluid as positive reinforcement, instead of restriction, is recommended. Caloric restriction, as a husbandry technique and means of weight control, is discussed in Chapter 3 of the *Guide*.

Use of Non-Pharmaceutical-Grade Chemicals and Other Substances The use of pharmaceutical-grade chemicals and other substances ensures that toxic or unwanted side effects are not introduced into studies conducted with experimental animals. They should therefore be used, when available, for all animal-related procedures (USDA 1997b). The use of non-pharmaceutical-grade chemicals

or substances should be described and justified in the animal use protocol and be approved by the IACUC (Wolff et al. 2003); for example, the use of a non-pharmaceutical-grade chemical or substance may be necessary to meet the scientific goals of a project or when a veterinary or human pharmaceutical-grade product is unavailable. In such instances, consideration should be given to the grade, purity, sterility, pH, pyrogenicity, osmolality, stability, site and route of administration, formulation, compatibility, and pharmacokinetics of the chemical or substance to be administered, as well as animal welfare and scientific issues relating to its use (NIH 2008). All items must be ordered through the Environmental Health and Safety Office contact 806-651-2270 or ar-ehs@wtamu.edu for additional information.

Use of Activated or Inactivated Pathogenic Microorganisms and Extracted genomic material

As of November 7, 2014, APHIS requires a VS 16-6 permit for importation and interstate transport of live, inactivated, and killed microorganisms; and extracted genomic materials, such as DNA and RNA. Organisms that are not pathogenic to livestock or poultry do not require a VS 16-6 permit. All items must be ordered through the Environmental Health and Safety Office contact 806-651-2270 or ar-ehs@wtamu.edu for additional information.

Field Investigations may involve the observation or use of non-domesticated vertebrate species under field conditions. Many field investigations require international, federal, state, and/or local permits, which may call for an evaluation of the scientific merit of the proposed study and a determination of the potential impact on the population or species to be studied.

Additionally, occupational health and safety issues, including zoonoses, should be reviewed by the institution's health and safety committee or office, with assurances to the IACUC that the field study does not compromise the health and safety of either animals or persons in the field. Principal investigators conducting field research should be knowledgeable about relevant zoonotic diseases, associated safety issues, and any laws or regulations that apply. Exceptions to the above should be clearly defined and evaluated by the IACUC.

In preparing the design of a field study, investigators are encouraged to consult with relevant professional societies and available guidelines. Veterinary input may be needed for projects involving capture, individual identification, sedation, anesthesia, surgery, recovery, holding, transportation, release, or euthanasia. Issues associated with these activities are similar if not identical to those for species maintained and used in the laboratory. When species are removed from the wild, the protocol should include plans for either a return to their habitat or their final disposition, as appropriate.

The *Guide* does not purport to be a compendium of all information regarding field biology and methods used in wildlife investigations, but the basic principles of humane care and use apply to animals living under natural conditions. IACUCs engaged in the review of field studies are encouraged to consult with a qualified wildlife biologist.

Agricultural Animals The use of agricultural animals in research is subject to the same ethical considerations as for other animals in research, although it is often categorized as either biomedical or agricultural because of government regulations and policies, institutional policies, administrative structure, funding sources, and/or user goals (Stricklin et al. 1990). This categorization has led to a

dual system with different criteria for evaluating protocols and standards of housing and care for animals of the same species on the basis of stated biomedical or agricultural research objectives (Stricklin and Mench 1994). With some studies, differences in research goals may lead to a clear distinction between biomedical and agricultural research. For example, animal models of human diseases, organ transplantation, and major surgery are considered biomedical uses; and studies on food and fiber production, such as feeding trials, are usually considered agricultural uses. But when the distinction is unclear, as in the case of some nutrition and disease studies, administrators, regulators, and IACUCs face a dilemma in deciding how to handle such studies (Stricklin et al. 1990). Decisions on categorizing research uses of agricultural animals and defining standards for their care and use should be made by the IACUC based on both the researcher's goals and concerns for animal well-being. Regardless of the category of research, institutions are expected to provide oversight of all research animals and ensure that pain and distress are minimized.

The protocol, rather than the category of research, should determine the setting (farm or laboratory). Housing systems for agricultural animals used in biomedical research may or may not differ from those used in agricultural research; animals used in either type of research can be housed in cages, stalls, paddocks, or pastures (Tillman 1994). Some agricultural studies need uniform conditions to minimize environmental variability, and some biomedical studies are conducted in farm settings. Agricultural research often necessitates that animals be managed according to contemporary farm production practices (Stricklin and Mench 1994), and natural environmental conditions might be desirable for agricultural research, whereas control of environmental conditions to minimize variation might be desirable in biomedical research (Tillman 1994).

The *Guide* applies to agricultural animals used in biomedical research, including those maintained in typical farm settings. For animals maintained in a farm setting, the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (FASS 2010) is a useful resource. Information about environmental enrichment, transport, and handling may be helpful in both agricultural and biomedical research settings. Additional information about facilities and management of farm animals in an agricultural setting is available from the Midwest Plan Service (1987) and from agricultural engineers or animal science experts.

Population Management Identification Animal records are useful and variable, ranging from limited information on identification cards to detailed computerized records for individual animals (Field et al. 2007). Means of animal identification include room, rack, pen, stall, and cage cards with written, bar-coded, or radio frequency identification (RFID) information. Identification cards should include the source of the animal, the strain or stock, names and contact information for the responsible investigator(s), pertinent dates (e.g., arrival date, birth date, etc.), and protocol number when applicable. Genotype information, when applicable, should also be included, and consistent, unambiguous abbreviations should be used when the full genotype nomenclature (see below) is too lengthy.

In addition, the animals may wear collars, bands, plates, or tabs or be marked by colored stains, ear notches/punches and tags, tattoos, subcutaneous transponders, and freeze brands. As a method of identification of small rodents, toe-clipping should be used only when no other individual identification method is feasible. It may be the preferred method for neonatal mice up to 7 days of age as it appears to have few adverse effects on behavior and well-being at this age (Castelhano-

Carlos et al. 2010; Schaefer et al. 2010), especially if toe clipping and genotyping can be combined. Under all circumstances aseptic practices should be followed. Use of anesthesia or analgesia should be commensurate with the age of the animals (Hankenson et al. 2008).

Application Processing

Most Applications for Vertebrate Animal Use, AVAUs, are processed in approximately two weeks. On occasion, an individual protocol may require a longer period of time because of the nature of the proposed use or other complicating factors. Therefore, it is prudent to submit the forms to the IACUC as soon as the need is anticipated. The IACUC cannot expedite the review of an application because the investigator failed to submit it in time to meet various deadlines. It is the responsibility of the principal investigator to submit an AVAU with sufficient lead-time to meet all University and agency deadlines.

Application for Multiple Projects, Co-submission and Re-review

Under certain circumstances, it may be possible to cover vertebrate animal use for more than one project under a single AVAU. For example, resubmission of a grant within one year of approval of an AVAU to the same or another funding agency which may involve changes in title, size of project, or contain other changes, but for which the scope of animal use (procedures, numbers, duration) does not significantly change, does not require another AVAU.

Overseas and Field Research and IACUCs from Other Institutions

While the IACUC does not conduct inspections of field and overseas research sites, the use of vertebrate animals at those sites by PIs is expected to be in accordance with University procedure. That portion of vertebrate animal use conducted at WTAMU in collaboration with outside researchers must be reviewed by the WTAMU IACUC, even if it has already been reviewed by an IACUC or similar committee at the collaborating institution.

Principal investigators participating in vertebrate animal research conducted at other sites which has been reviewed and approved by IACUCs at other institutions may not be required to submit an application to the WTAMU IACUC. However, the WTAMU IACUC requires investigators to submit a copy of the IACUC approval from the other reviewing institution. The WTAMU IACUC must be allowed to assess whether or not an application is required under these circumstances.

With regard to collection of tissue samples (i.e. biopsies, blood, etc.), if samples are collected expressly for the purposes of a principal investigator's research or teaching projects, that investigator must file an application for vertebrate animal use with the WTAMU IACUC. For example, clinically necessary biopsies and blood samples may be split for research purposes without IACUC review, but no clinically unnecessary sample may be taken without IACUC review and approval. This procedure also applies to field studies in which samples are collected expressly for the purposes of an investigator's research or teaching projects, and to studies covered by government permits. The IACUC must review these projects.

Preparation and Review of Blanket Protocols

Principal Investigators (PIs) may wish to seek "blanket" approval for animal use where procedures can be described but specific treatments and/or animal numbers are not yet determined. The potential advantage of this approach is that only an amendment would need to be filed, once the additional details are known. However, the process for approving amendments that involve significant changes requires essentially the same steps as a new submission; therefore, there may not be significant time savings in review. On the other hand, if amendments include only non-significant changes, then those changes would generally be approved quickly.

If a PI has special need for a rapid turnaround time on a review of an Application for Vertebrate Animal Use (AVAU), s/he must contact the EHSP. Approvals for "rush" applications are handled on a case-by-case basis and only processed in extreme instances.

The IACUC requires a complete description of the animal-use activity. This description includes not only the procedures performed with/on animals, but also details of the experimental treatments: specific drugs, dosages (volume and mg/kg), and routes of administration; dietary manipulations; justification of animal numbers based on the experimental design; etc.

The above information may be supplied in some combination of AVAU and amendment form, and must be reviewed and approved by the IACUC before an animal activity begins.

If details of animal use are not available at the time of initial AVAU submission, then the AVAU should indicate specifically what additional information will be provided as an amendment.

For each amendment submitted, the IACUC Chairman decides whether the proposed changes are "significant." This decision is based on the IACUC Guideline, "Review Procedures for Significant Changes in an Approved AVAU."

AVAU Duration, Annual Reports and Renewal

The AVAU is approved for three years. The PI is required to submit an annual report updating any changes that may have occurred during the year. The Compliance Coordinator distributes the form for updates within sixty days of the annual renewal date. After three years, the AVAU must be re-written and undergo the entire review process again.

If changes are anticipated in an on-going project, a Protocol Amendment Form (Appendix C) must be submitted to the EHSP prior to initiation of these changes. However, total approval time for a single AVAU may not exceed three years. Consult the EHSP (phone 806-651-2270, e-mail ar-ehs@wtamu.edu) for information).

The AVAU can be obtained from the IACUC website: www.wtamu.edu . The application form must be typed. Each section must be answered in specific detail or noted "not applicable." It is not sufficient to answer a question by simply referring to a more detailed paper or reference or attached document. Syllabi are needed for teaching activities. Submit all applications through the EHSP (WTAMU Box 60217, Canyon, TX 79016, or e-mail ar-ehs@wtamu.edu). After review and approval, the Chairman of the IACUC will send the approval information to the PI for submission to the appropriate offices or federal agencies.

Tracking of IACUC Approval and Approved Animal Numbers

All use of vertebrate animals at WTAMU requires prior IACUC approval of the Application for Vertebrate Animal Use (AVAU). All animals must be accounted for in the AVAU, including all neonates (e.g., pre-weanling animals euthanized to standardize litter size or to cull unwanted genotypes or sex, and animals that are expected to die as a result of a harmful genotype). Use of prenatal, pre-hatch, embryonic, or larval stage animals does not require listing in the AVAU.

In accordance with federal regulations and WTAMU procedure, the AVAU requires the principal investigator to provide a rationale for the numbers of animals to be used. It is implicit from these requirements that there be an institutional mechanism to ensure that the animal use is approved and that the number of animals used is consistent with information in the approved protocol.

IACUC Meetings

The IACUC shall meet once every six months to review the research facility's program for humane care and use of animals, using title 9, chapter 1, subchapter A-Animal Welfare, as a basis for evaluation (9 CFR2.31(c)(1)). The IACUC meetings will be called by the IACUC chairman and will typically be held in May and November of each year. The IACUC committee will also complete a memorandum to the IO (Appendix F).

IACUC Inspections

The IACUC shall inspect, at least once every six months, all of the research and animal facilities, including animal study areas, using title 9, chapter 1, subchapter A-Animal Welfare, as a basis for evaluation, provided, however, that animal areas containing free-living wild animals in their natural habitat need not be included in such inspections (9 CFR2.31(c)(2)). In addition, the WTAMU committee will utilize the above guidance in the conduct of the semi-annual inspections. Appendix D: WTAMU IACUC Committee Review Checklist has been revised to include the requirements outlined under the 8th edition of the *Guide*.

IACUC Meetings and Inspection Reports

The IACUC shall prepare reports of its evaluations conducted as required by paragraphs (c) (1) and (2) of section 9CFR2.31 and submit the reports to the Institutional Official of the research facility (Vice President of Research and Compliance) (9 CFR2.31(c)(3). The IACUC may determine the best means of conducting the evaluations, providing:

i. No committee member wishing to participate in the evaluation is excluded.
ii. The IACUC may use subcommittees composed of a least two Committee members and may invite *ad hoc* consultants to assist in the evaluations.
iii. The IACUC remains responsible for the reports required under the Act.
iv. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views.
v. The reports shall be updated at least once every six months upon completion of the required semi-annual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request.
vi. The IACUC review and inspection reports must contain a description of the nature and

extent of the research facility's adherence to title 9, chapter I, subchapter A-animal Welfare, and must state the reasons for each departure.

vii. The reports must distinguish significant deficiencies from minor deficiencies.

viii. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals.

ix. If program deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency.

x. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS.

Furthermore, the IACUC shall

(i) Review and, if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees.

(ii) Make recommendations to the IO regarding any aspect of research facility's animal program, facilities, or personnel training.

(iii) Review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals, as specified in 9 CFR2.31 paragraph (d) of this section.

(iv) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

IACUC Proposed Activity Reviews

Prior to the IACUC review each member shall (per 9 CFR2.31 (d) (2))

- Be provided a list of proposed activities to be reviewed.
- Have available access to written descriptions of all proposed activities that involve the care and use of animals.
- Have the right to request a full committee review of those activities.
- If full committee review is not requested, at least one member of the IACUC, designated by the chairman and qualified to conduct the review, shall review those activities and shall have the authority to approve, require modifications in (to secure approval), or request full committee review of any of those activities.
- If full committee review is requested for a proposed activity, approval of that activity may be granted only after review, at a convened meeting of a quorum (majority) of the IACUC and with approval vote of a majority of the quorum present.
- No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g. is personally involved in the activity) except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum.

IACUC Committee Review Checklist

The IACUC Committee review checklist (Appendix D) addresses the following requirements of 9 CFR2.31(d);

(1) Procedures involving animals will avoid or minimize discomfort, distress, and pain to animals.
(2) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal and has provided a written narrative description of the methods and sources, e.g., the Animal Welfare Information Center, used to determine that alternatives were not available.
(3) The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments.
(4) Procedures that may cause more than momentary or slight pain or distress to the animals will
    a. Be performed with appropriate sedatives, analgesics, or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time.
    b. Involve, in their planning, consultation with the attending veterinarian or his or her designee.
    c. Not include the use of paralytics without anesthesia.
(5) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
(6) The animals' living conditions will be appropriate for their species in accordance with part 3 of subchapter D 9 CFR2.31 and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by the attending veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
(7) Medical care for animals will be available and provided as necessary by a qualified veterinarian.
(8) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
(9) Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medicine and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Non-major operative procedures and all surgery on rodents do not require a dedicated facility, but must be performed using aseptic procedures. Operative procedures conducted at field sites need not be performed in dedicated facilities, but must be performed using aseptic procedures.
(10) No animal will be used in more than one major operative procedure from which it is allowed to recover, unless
    a. Justified for scientific reasons by the principal investigator, in writing.
    b. Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian.
    c. In other special circumstances as determined by the Administrator on an

individual basis. Written requests and supporting data should be sent to the Animal and Plant Health Inspection Service, Animal Care, 4700 River Road, Unit 84, Riverdale, Maryland 20737-1234;

(11) Methods of euthanasia used must be in accordance with the definition of the term set forth in 9 CFR part 1 Section 1.1 of Subchapter A, unless a deviation is justified for scientific reasons, in writing, by the investigator and approved by the IACUC.

Emergency Operations for IACUC

WTAMU IACUC is committed to ensuring that vertebrate animals used in research are treated in a humane, ethical manner, with the highest standard of care according to applied federal, state, and institutional regulations and policies. The procedure 15.99.05.W1.06AR WTAMU Emergency Operations for Institutional Animal Care and Use is intended to provide WTAMU's Institutional Animal Care and Use Committee (IACUC), faculty, staff and students, a general plan of action in the event of an emergency or disaster with potential impact to the animals housed in campus laboratories or in WTAMU associated animal care facilities, to include the Nance Ranch, WTAMU Feedlot, WTAMU Horse Center, the Buffalo Mascot facility, WTAMU Gerson Ranch, WTAMU Rat Lab, WTAMU Mouse Lab, and the WTAMU Swine Facility.

Veterinary Care

Veterinary care is an essential part of an animal care and use program. The primary focus of the veterinarian is to oversee the well-being and clinical care of animals used in research, testing, teaching, and production. This responsibility extends to monitoring and promoting animal well-being at all times during animal use and during all phases of the animal's life. Well-being is determined by considering physical, physiologic, and behavioral indicators, which vary by species. The number, species, and use of animals housed in an institution may influence the complexity of the veterinary care program, but a veterinary program that offers a high quality of care and ethical standards must be provided, regardless of the number of animals or species maintained.

An adequate veterinary care program consists of assessment of animal well-being and effective management of:

- animal procurement and transportation
- preventive medicine (including quarantine, animal biosecurity, and surveillance)
- clinical disease, disability, or related health issues
- protocol-associated disease, disability, and other sequelae
- surgery and perioperative care
- pain and distress
- anesthesia and analgesia
- euthanasia.

The veterinary care program is the responsibility of the attending veterinarian (AV), who is certified or has training or experience in laboratory animal science and medicine or is otherwise qualified in the care of the species being used. Some aspects of the veterinary care program can be conducted by persons other than a veterinarian, but a mechanism for direct and frequent communication should be established to ensure that timely and accurate information is conveyed to the responsible veterinarian about issues associated with animal health, behavior, and well-being,

and that appropriate treatment or euthanasia is administered. The AV should provide guidance to investigators and all personnel involved in the care and use of animals to ensure appropriate husbandry, handling, medical treatment, immobilization, sedation, analgesia, anesthesia, and euthanasia. In addition, the AV should provide guidance and oversight to surgery programs and perioperative care involving animals.

Medical Management

There should be a timely and accurate method for communication of any abnormalities in or concerns about animal health, behavior, and well-being to the veterinarian or the veterinarian's designee. The responsibility for communicating these concerns rests with all those involved with animal care and use. Reports should be triaged to ensure that animals most in need receive priority attention, and the veterinarian or veterinarian's designee should perform an objective assessment of the animal(s) to determine an appropriate course of action.

Well-planned experiments with clearly delineated scientific and humane endpoints will help to ensure that a contingency plan is in place for problems that may arise during the study. For animals on research protocols, the veterinarian or veterinarian's designee should make every effort to discuss any problems with the PI or project director to jointly determine the most appropriate course of treatment or action. Standard operating procedures (SOPs) may be developed for recurrent health conditions to expedite treatment. Recurrent or significant problems involving experimental animal health should be communicated to the IACUC, and all treatments and outcomes should be documented (USDA 1997).

Surgery

Successful surgical outcomes require appropriate attention to pre-surgical planning, personnel training, anesthesia, aseptic and surgical technique, assessment of animal well-being, appropriate use of analgesics, and animal physiologic status during all phases of a protocol involving surgery and postoperative care (see Appendix A, Potential Pain and Distress and Surgery sections). The individual impact of those factors will vary according to the complexity of procedures involved and the species of animal used. A team approach to a surgical project often increases the likelihood of a successful outcome by providing input from persons with different expertise (Brown and Schofield 1994; Brown et al. 1993).

Surgical outcomes should be continually and thoroughly assessed to ensure that appropriate procedures are followed and timely corrective changes are instituted. Modification of standard techniques may be required (for instance, in aquatic or field surgery), but should not compromise the well-being of the animals. In the event of modification, close assessment of outcomes may have to incorporate criteria other than clinical morbidity and mortality. Such assessments rely on continuing communication among technical staff, investigators, veterinarians, and the IACUC.

Anesthesia and Analgesia

The selection of appropriate analgesics and anesthetics should reflect professional veterinary judgment as to which best meets clinical and humane requirements as well as the needs of the research protocol. The selection depends on many factors, such as the species, age, and strain or stock of the animal, the type and degree of pain, the likely effects of particular agents on specific organ systems, the nature and length of the surgical or pain-inducing procedure, and the safety of

the agent, particularly if a physiologic deficit is induced by a surgical or other experimental procedure (Kona-Boun et al. 2005).

Preemptive analgesia (the administration of preoperative and intraoperative analgesia) enhances intraoperative patient stability and optimizes postoperative care and well-being by reducing postoperative pain (Coderre et al. 1993; Hedenqvist et al. 2000). Analgesia may be achieved through timely enteral or parenteral administration of analgesic agents as well as by blocking nociceptive signaling via local anesthetics (e.g., bupivacaine).

Alleviation of chronic pain may be more challenging than postprocedural pain; commercially available opiate slow-release transdermal patches or implantable analgesic-containing osmotic mini pumps may be useful for such relief. Because of wide individual variation in response to analgesics, regardless of the initial plan for pain relief, animals should be closely monitored during and after painful procedures and should receive additional drugs, as needed, to ensure appropriate analgesic management (Karas et al.2008; Paul-Murphy et al. 2004). Nonpharmacologic control of pain may be effective and should not be overlooked as an element of postprocedural or perioperative care for research animals (NRC 2009a; Spinelli 1990). Appropriate nursing support may include a quiet, darkened recovery or resting place, timely wound or bandage maintenance, increased ambient warmth and a soft resting surface, rehydration with oral or parenteral fluids, and a return to normal feeding through the use of highly palatable foods or treats.

Most anesthetics cause a dose-dependent depression of physiologic homeostasis and the changes can vary considerably with different agents. The level of consciousness, degree of antinociception (lack of response to noxious stimuli), and status of the cardiovascular, respiratory, musculoskeletal, and thermoregulatory systems should all be used to assess the adequacy of the anesthetic regimen. Interpretation and appropriate response to the various parameters measured require training and experience with the anesthetic regimen and the species. Loss of consciousness occurs at a light plane of anesthesia, before antinociception, and is sufficient for purposes of restraint or minor, less invasive procedures, but painful stimuli can induce a return to consciousness. Antinociception occurs at a surgical plane of anesthesia and must be ascertained before surgery. Individual animal responses vary widely and a single physiologic or nociceptive reflex response may not be adequate for assessing the surgical plane or level of analgesia (Mason and Brown 1997).

For anesthesia delivery, precision vaporizers and monitoring equipment (e.g., pulse oximeter for determining arterial blood oxygen saturation levels) increase the safety and choices of anesthetic agents for use in rodents and other small species. For injectable anesthestic protocols, specific reversal agents can minimize the incidence of some side effects related to prolonged recovery and recumbency. Guidelines for the selection and proper use of analgesic and anesthetic drugs should be developed and periodically reviewed and updated as standards and techniques are refined. Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use recorded, and disposed of legally and safely.

Some classes of drugs such as sedatives, anxiolytics, and neuromuscular blocking agents may not provide analgesia but may be useful when used in combination with appropriate analgesics and anesthetics to provide balanced anesthesia and to minimize stress associated with perioperative procedures. Neuromuscular blocking agents (e.g., pancuronium) are sometimes used to paralyze skeletal muscles during surgery in which general anesthetics have been administered (Klein 1987); because this paralysis eliminates many signs and reflexes used to assess anesthetic depth,

autonomic nervous system changes (e.g., sudden changes in heart rate and blood pressure) can be indicators of pain related to an inadequate depth of anesthesia. It is imperative that any proposed use of neuromuscular blocking drugs be carefully evaluated by the veterinarian and IACUC to ensure the well-being of the animal. Acute stress is believed to be a consequence of paralysis in a conscious state and it is known that humans, if conscious, can experience distress when paralyzed with these drugs (NRC 2008; Van Sluyters and Oberdorfer 1991). If paralyzing agents are to be used, the appropriate amount of anesthetic should first be defined on the basis of results of a similar procedure using the anesthetic without a blocking agent (NRC 2003, 2008, 2009a).

Euthanasia

Euthanasia is the act of humanely killing animals by methods that induce rapid unconsciousness and death without pain or distress. Unless a deviation is justified for scientific or medical reasons, methods should be consistent with the *AVMA Guidelines on Euthanasia* (AVMA 2007 or later editions). In evaluating the appropriateness of methods, some of the criteria that should be considered are ability to induce loss of consciousness and death with no or only momentary pain, distress, or anxiety; reliability; irreversibility; time required to induce unconsciousness; appropriateness for the species and age of the animal; compatibility with research objectives; and the safety of and emotional effect on personnel.

Euthanasia may be planned and necessary at the end of a protocol or as a means to relieve pain or distress that cannot be alleviated by analgesics, sedatives, or other treatments. Criteria for euthanasia include protocol-specific endpoints (such as degree of a physical or behavioral deficit or tumor size) that will enable a prompt decision by the veterinarian and the investigator to ensure that the endpoint is humane and, whenever possible, the scientific objective of the protocol is achieved.

Standardized methods of euthanasia that are predictable and controllable should be developed and approved by the AV and IACUC. Euthanasia should be carried out in a manner that avoids animal distress. Automated systems for controlled and staged delivery of inhalants may offer advantages for species killed frequently or in large numbers, such as rodents (McIntyre et al. 2007). Special consideration should be given to euthanasia of fetuses and larval life forms depending on species and gestational age (Artwohl et al. 2006).

The selection of specific agents and methods for euthanasia will depend on the species involved, the animal's age, and the objectives of the protocol. Generally, chemical agents (e.g., barbiturates and nonexplosive inhalant anesthetics) are preferable to physical methods (e.g., cervical dislocation, decapitation, use of a penetrating captive bolt); however, scientific considerations may preclude the use of chemical agents for some protocols. Although carbon dioxide (CO2) is a commonly used method for rodent euthanasia, there is ongoing controversy about its aversive characteristics as an inhalant euthanasia agent. This is an area of active research (Conlee et al. 2005; Danneman et al.1997; Hackbarth et al. 2000; Kirkden et al. 2008; Leach et al. 2002; Niel et al. 2008) and further study is needed to optimize the methods for CO2 euthanasia in rodents (Hawkins et al. 2006). The acceptability of CO2 as a euthanasia agent for small rodents should be evaluated as new data become available. Furthermore, because neonatal rodents are resistant to the hypoxia-inducing effects of CO2 and require longer exposure times to the agent (Artwohl et al. 2006), alternative methods should be considered (e.g., injection with chemical agents, cervical dislocation, or decapitation) (Klaunberg et al. 2004; Pritchett-Corning 2009).

It is essential that euthanasia be performed by personnel skilled in methods for the species in question and in a professional and compassionate manner. Special attention is required to ensure proficiency when a physical method of euthanasia is used. Death must be confirmed by personnel trained to recognize cessation of vital signs in the species being euthanized. A secondary method of euthanasia (e.g., thoracotomy or exsanguination) can also be used to ensure death. All methods of euthanasia should be reviewed and approved by the AV and IACUC.

Euthanizing animals is psychologically difficult for some animal care, veterinary, and research personnel, particularly if they perform euthanasia repetitively or are emotionally attached to the animals being euthanized (Arluke 1990; NRC 2008; Rollin 1986; Wolfle 1985). When delegating euthanasia responsibilities, supervisors should be sensitive to this issue.

Training

Researchers conducting surgical procedures must have appropriate training to ensure that good surgical technique is practiced—that is, asepsis, gentle tissue handling, minimal dissection of tissue, appropriate use of instruments, effective hemostasis, and correct use of suture materials and patterns (Brown et al. 1993; Heon et al. 2006). Training may have to be tailored to accommodate the wide range of educational backgrounds frequently encountered in research settings. For example, persons trained in human surgery may need training in interspecies variations in anatomy, physiology, the effects of anesthetic and analgesic drugs, and/or postoperative care requirements. Technical staff performing rodent surgery may have had little formal training in surgical techniques and asepsis and may require general surgical training as well as training for the specific techniques they are expected to perform (Stevens and Dey 2007).

Training guidelines for research surgery commensurate with an individual's background are available (ASR 2009) to assist institutions in developing appropriate training programs. The IACUC, together with the AV, is responsible for determining that personnel performing surgical procedures are appropriately qualified and trained in the procedures (Anderson 2007).

Emergency Care

Procedures must be in place to provide for emergency veterinary care both during and outside of regularly scheduled hours. Such procedures must enable animal care and research staff to make timely reports of animal injury, illness, or death. A veterinarian or the veterinarian's designee must be available to expeditiously assess the animal's condition, treat the animal, investigate an unexpected death, or advise on euthanasia. In the case of a pressing health problem, if the responsible person (e.g., investigator) is not available or if the investigator and veterinary staff cannot reach consensus on treatment, the veterinarian must have the authority, delegated by senior administration and the IACUC, to treat the animal, remove it from the experiment, institute appropriate measures to relieve severe pain or distress, or perform euthanasia if necessary.

Animal Procurement

All animals must be acquired lawfully, and WTAMU should ensure that all procedures involving animal procurement are conducted in a lawful manner. Before procuring animals, the principal investigator should confirm that there are sufficient facilities and expertise to house and manage the species being acquired. Procurement of animals should be linked to the prior approval of animal use and number by the IACUC. Attention should also be given to the population status of the

species under consideration; the threatened or endangered status of species is updated annually by the Fish and Wildlife Service (DOI 2007). Appropriate records and other forms of documentation should be maintained for animals acquired by an institution for its investigators.

Transportation of Animals

Transportation of animals is governed by a number of US regulatory agencies and international bodies. The Animal Welfare Regulations (USDA 1985) set standards for interstate and export/import transportation of regulated species; the International Air Transport Association (IATA) updates the Live Animals Regulations annually and IATA member airlines and many countries agree to comply with these regulations to ensure the safe and humane transport of animals by air (IATA 2009). The Centers for Disease Control and Prevention (CDCP) and USDA enforce regulations to prevent the introduction, transmission, or spread of communicable diseases and regulate the importation of any animal or animal product capable of carrying a zoonotic disease. The US Fish and Wildlife Service regulates importation/exportation of wild vertebrate and invertebrate animals and their tissues. As the national authority arm of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), the US Fish and Wildlife Service also regulates movement of CITES-listed species that are captive bred, including nonhuman primates (DOI 2007). Institutions should contact appropriate authorities to ensure compliance with any relevant statutes and other animal transportation requirements that must be met for animals to cross international boundaries, including those not of the country of final destination. The National Research Council (NRC) publication *Guidelines for the Humane Transportation of Research Animals* provides a comprehensive review of this topic.

Post Approval Monitoring

Monitoring of animal care and use is required by the PHS Policy. The *Guide* (p. 33) describes methods for continuing review to include "continuing protocol review; laboratory inspections (conducted either during regular facilities inspections or separately); veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary, and IACUC staff and members; and external regulatory inspections and assessments."

Continuing protocol review may consist of an annual update. The PHS Policy determines the maximum interval between IACUC review and approval as 3 years, i.e., a complete *de novo* review is required at least every 3 years. The review must encompass all of the criteria in the Policy at IV.C.1.a.-g. Animal work may not be administratively extended beyond the 3-year expiration date.

IACUC Authorization to Suspend and to Re-approve Activities

WTAMU has developed methods for reporting and investigating animal welfare concerns by creating a compliance helpline. The IACUC also has a procedure to evaluate concerns regarding the care and use of animals. (SOP No. 15.99.05.W1.07AR WTAMU Potential Non-Compliance in the Course of Vertebrate Animal Care and Use Research). Concerns may be raised by staff or employees of the institution, individuals in the community, or even members of the IACUC. The IACUC prohibits discrimination against or reprisal for reporting violations of regulations or standards under the Animal Welfare Act (AWA).

The IACUC is empowered to suspend a project if it finds noncompliance with the WTAMU

procedures, PHS Policy, *Guide*, Assurance, or violations of the Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with the suspension vote of a majority of the quorum present. Further, the IACUC must consult with the IO regarding the reasons for the suspension. The IO is required to take appropriate corrective action and report the action and the circumstances surrounding the suspension to the CEO and regulatory authorities.

Training

It is WTAMU's responsibility to ensure that IACUC members are provided with training opportunities to understand their work and role. Such training should include formal orientation to introduce new members to the institution's Program; relevant legislation, regulations, guidelines, and policies; animal facilities and laboratories where animal use occurs; and the processes of animal protocol and program review (Greene et al. 2007). Ongoing opportunities to enhance their understanding of animal care and use in science should also be provided. For example, IACUC members may meet with animal care personnel and research teams; be provided access to relevant journals, materials, and web-based training; and be given opportunities to attend meetings or workshops.

All personnel involved with the care and use of animals must be adequately educated, trained, and/or qualified in basic principles of laboratory animal science to help ensure high-quality science and animal well-being. The federal Animal Welfare Law (administered by the USDA) and regulations of the Department of Health and Human Services (including PHS) require training and continuing education of all scientists, research technicians, animal care technicians and others involved with animal care and use. These laws and regulations require that the Institutional Animal Care and Use Committee (IACUC), as an agent of West Texas A&M University, determine that personnel wishing to conduct procedures on animals are qualified and trained to do so on the animal species proposed. To fulfill this responsibility, the IACUC requires all personnel involved with animal care and use to complete the appropriate training modules in the Collaborative Institutional Training Initiative (CITI) training program. West Texas A & M University Environmental Health and Safety will follow the Texas A & M University System Policy 33.05.02 Required Employee Training. Staff and faculty whose required training is delinquent more than 90 days will have their access to the Ɨinternet terminated until all trainings are completed. Only Blackboard and Single Sign-on will be accessible. Internet access will be restored once training has been completed. Student workers whose required training is delinquent more than 90 days will need to be terminated by their manager through Student Employment.

Occupational Health and Safety

WTAMU has an occupational health and safety program (OHP) (SOP No 24.01.01.W1.43AR WTAMU Occupational Health Program which must be completed by all personnel that have contact with animals. Confidentiality and other medical and legal factors must be considered in the context of appropriate federal, state, and local regulations. Depending on the facility, research activities, hazards, and animal species involved, the program may not affect all personnel equally. The Occupational Health Program includes:

- pre-placement medical evaluation;
- identification of hazards to personnel and safeguards appropriate to the risks associated with

the hazards;
- appropriate testing and vaccinations including pre-employment or pre-exposure serum collection if needed;
- training of personnel regarding their duties, any hazards, and necessary safeguards;
- provisions for treating and documenting job-related injuries and illnesses;
- facilities, equipment, and procedures designed, selected, and developed to reduce the possibility of physical injury or health risk to personnel;
- good personal hygiene practices, prohibiting eating and drinking, use of tobacco products, and application of cosmetics and/or contact lenses in animal rooms and laboratories; and
- personal protective equipment (PPE).

Occupational Health and Safety in the Care and Use of Research Animals, published in 1997 by the National Research Council (NRC), includes helpful guidelines and references for establishing and maintaining an effective and comprehensive program.

Record Keeping Requirements

WTAMU EHSP will maintain the following IACUC records:

A. Minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations.
B. Records of proposed activities involving animals, proposed significant changes in activities involving animals, and whether IACUC approval was given or withheld.
C. Records of semi-annual IACUC reports and recommendations (including minority views), prepared in accordance with the requirements of Sec. 2.31(c)(3) of this subpart, and forwarded to the Institutional Official.

No official state records may be destroyed without permission from the Texas State Library as outlined in Texas Government Code, Section 441.187 and 13 Texas Administrative Code, Title 13, Part 1, Chapter 6, Subchapter A, Rule 6.7. The Texas State Library certifies Agency retention schedules as a means of granting permission to destroy official state records.

West Texas A & M University Records Retention Schedule is certified by the Texas State Library and Archives Commission (TSLAC). West Texas A & M University Environmental Health and Safety will follow Texas A & M University Records Retention Schedule as stated in the Standard Operating Procedure 61.99.01.W0.01 Records Management. All official state records (paper, microform, electronic, or any other media) must be retained for the minimum period designated.

Annual Report

WTAMU IACUC will submit an annual report documenting activities and animal usage to the United States Department of Agriculture Animal Plant Health Inspection Service (USDA-APHIS) on or before December 1 of each calendar year. The report shall be signed and certified by the Institutional Official, and shall cover the previous Federal fiscal year.

Semi-Annual Evaluation

The IACUC's task of performing the semi-annual evaluation is important and is a requirement of the USDA Animal Welfare Act Regulations.

This review has three main goals:

- Monitor the facilities and program of animal care and use to determine if they meet the standards in the USDA Animal Welfare Act Regulations.
- Identify deficiencies, create a plan and schedule for correcting any found, and make sure corrections are made.
- Communicate the results of the review to the IO, along with any suggestions for improving the facilities or program.

The evaluation consists of:

I. An inspection of areas that house animals or that support animal use procedures (Appendix J – Implemented Spring 2015), and
II. A review of the animal care and use program (Appendix I – Implemented Spring 2015). As opposed to the "bricks and mortar" animal facility inspection, the review of the animal care and use program refers to activities such as training, occupational health and safety, IACUC functions, and adherence to institutional policies that ensure compliance with the USDA Animal Welfare Act Regulations.

It is important for IACUC members to understand that the USDA expects the animal facilities will be inspected **AND** the program of animal care and use will be evaluated during these semi-annual evaluations.

The design of animal facilities combined with appropriate animal housing and management are essential contributors to animal well-being, the quality of animal research and production, teaching or testing programs involving animals, and the health and safety of personnel. An appropriate Program (see Chapter 2) provides environments, housing, and management that are well suited for the species or strains of animals maintained and takes into account their physical, physiologic, and behavioral needs, allowing them to grow, mature, and reproduce normally while providing for their health and well-being.

Fish, amphibians, and reptiles are *poikilothermic* animals: their core temperature varies with environmental conditions and they have limited ability (compared with birds and mammals) to metabolically maintain core temperature. The majority of poikilothermic laboratory animals are aquatic species—for example, fish and most amphibians—although some, such as reptiles and certain amphibian species, are terrestrial. Personnel working with aquatic animals should be familiar with management implications, e.g., the importance of providing appropriate temperature ranges for basic
physiologic function.

The Basis for the Evaluation

The IACUC bases its semi-annual review on the USDA Animal Welfare Act Regulations. The USDA Animal Welfare Regulations require that **at least two IACUC members** perform the semi-annual evaluation. The IACUC may invite consultants to assist. **Regardless, the entire IACUC remains responsible for the review.**

By law, **no IACUC member who wishes to participate may be excluded.**

Once the evaluation is complete, a report must be written summarizing the findings. This report will include:

I. A description of the nature and extent of the research facility's adherence to the provisions of the USDA Animal Welfare Act Regulations.
II. Specific identification of departures from the provisions and the reason(s) for each departure.
III. Any minority views expressed by any IACUC member.

According to the Animal Welfare Act Regulations (AWAR), once the evaluation report is written, it must be "reviewed and signed" by a majority of IACUC members. Note that a majority of **all IACUC members** must review and sign the report--**not just the members who conducted the evaluation or a majority of a convened quorum**.

Next the report **must be submitted to the IO**. By reviewing the report, the IO can gain an understanding of how effective the animal care and use program is and what resources may need to be committed to improve the program or correct deficiencies.

Adoption of OLAW

OLAW requires Assured Institutions to base their programs of animal care and use on the 8th Edition of the *Guide* as of January 1, 2012. Assured Institutions must complete at least one semi-annual program review and facility evaluation using the 8th Edition of the *Guide* as the basis for evaluation by December 31, 2012.

West Texas A & M University formally adopts the animal welfare law as specified in the AWA and implementing the AWARs. In the event that WTAMU receives National Institute of Health (NIH) or National Park Service (NPS) funding this Standard Operating Procedure (SOP) meets the intent of the 8th Edition of the *Guide* and the summary of requirements stated in the *Guide.* http://grants.nih.gov/grants/olaw/2011positionstatement.htm. Any additional requirements outlined in the *Guide* will be implemented for the specific NIH and PHS grants as applicable and as required by the NIH and NPS.

[54 FR 36147, Aug. 31, 1989, as amended at 58 FR 39129, July 22, 1993; 59 FR 67612, Dec. 30, 1994; 60 FR 13895, Mar. 15, 1995; 63 FR 62926, Nov. 10, 1998]

Related Statutes, Policies, or Requirements

General References on Animal Care and Use

Regulations and guidelines addressing the proper handling of vertebrates can be found at Resources | WTAMU and are summarized below:

Animal Welfare Act, 7 U.S.C. 2131-2159; 9CFR 2.22,2.80, and 37102(g).

Guide for the Care and Use of Laboratory Animals. 8th Edition, Institute for Laboratory Animal Research, Division on Earth and Life Studies, National Research Council, of the National Academies The National Academies Press, Washington, D.C. 2011. http://grants.nih.gov/grants/olaw/2011positionstatement.htm

Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. Federation of Animal Science Societies, Savoy, IL, 1999.

1993 Report of the AVMA Panel on Euthanasia. J Amer Vet Med Assoc, 202(2): 230-249. Jan 15, 1993.

Public Health Service Policy on Humane Care and Use of Laboratory Animals. Office of Laboratory Animal Welfare, National Institutes of Health, Office of the Director, Rockville, MD, 1996.

Contact Office

WTAMU Environmental Health and Safety Program
(806) 651-2270

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

Application for Vertebrate Animal Use (AVAU) APPLICATION INSTRUCTIONS

IACUC Guidelines

The following are specific, section-by-section instructions for completing the Application for Vertebrate Animal Use (AVAU). Numbers refer to the numbered items on the AVAU. The form opens as a fillable pdf on the IACUC webpage. If you have issues with the document, please contact AR-EHS for assistance. (806.651.2270 or ar-ehs@wtamu.edu)

Cover Page:

ID#: *Do not write in this space*. A research compliance administrator will assign a specific number, unique to each protocol.

This application applies to: (choose teaching or research)

If requesting a teaching authorization, then indicate the course number with section(s) and include a syllabus with the proposal.

Title of Project: This can be grant title, course title, a pilot project, etc.

Submitted to: If applicable, give the name of the funding agency to which the proposed study will be submitted. Also provide the deadline for submitting proposals to the specific agency.

Renewal: For renewals, provide previous IACUC protocol number and expiration date. Leave blank if not applicable.

The AVAU has two major sections: the Confidential Section and the Non-Confidential Section. Both sections must be completed. The Confidential Section contains information which will not be disclosed during a public information request.

Confidential Section:

1) Provide all required information about PI; verify that all personnel have completed the online CITI training (Contact AR-EHS for specifics); verify that all personnel have completed the initial risk assessment survey (linked in the application); verify animals are free of disease associated to health risk to workers; choose the type(s) of animal(s) used.

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

Provide a one-Paragraph summary of project or activity.

Describe briefly what you will be doing with the animals.

List species chosen and the justification for the species chosen.

1a. Will animals be housed? Check location(s).
There are occasions in which the PI will not require animals to remain in a research setting such as those animals used in field studies and client-owned animals that will remain with their owners throughout the study. Locations of field studies must be specific.

1b. For animals that will remain at the research facility, provide the name of the facility and the physical address.

1c. List locations where procedures will be performed. Location of surgery areas should also be included here. This should include a physical address, as well as a building name and room number, if applicable. (Examples: 1. Rat ovariectomy, NSB room 216. 2. Oral dosing of cats, KRC, room 186G.)

1d. Provide the location of the investigator's lab or the off-campus site and the duration of the animal's stay. Facilities must be inspected prior to animal use by at least two IACUC members.

1e. Transportation of animals must conform to all federal regulations and guidelines. Transporting animals from their domiciliary area requires proper containment of the animal in a secure cage, pen, etc. with appropriate supplies, as necessary, for trip. Method of transport (hand-carry, car, airplane, etc.) must be listed.

2) All PIs and other individuals listed on the AVAU who work with and care for animals must undergo WTAMU IACUC training. For each person; please list name, contact email, role in the project, and detailed animal related experience and training for procedures being performed. Provide specific information for those performing euthanasia, anesthesia and surgery FOR SECTION A.

3) Complete #3 if individuals have been consulted in regards to the proposed animal activity. This will avoid releasing information in non-confidential sections of the form, such as Section G.

Assurance: Several assurances are required of the PI as set forth by federal regulations and guidelines. Review carefully to be sure that these assurances are being met. Contact the IACUC Office (phone: 806-651-2270, e-mail: ar-ehs@wtamu.edu) or the IACUC Chair if you have questions. Contact Academic Research and Environmental Health and Safety (phone 806-651-2270) for more information regarding Occupational Health & Safety issues.

Your **signature** indicates that you have read and agree to comply with the assurances. The AVAU will not be processed if it is not signed.

There must be a **page break** before the Non-Confidential Section. The Non-Confidential Section must be started at the top of a new page.

Non-Confidential Section:

Section A: Animal Care and Use

1. The purpose and importance of the animal use activity should be written in language that can be understood by laypersons and non-scientists. The purpose and importance should demonstrate a correlation to the procedures and/or manipulations. For those teaching a class, summarize the class and expected goals for the students. Do not use abbreviations.

2. Procedures and manipulations that are being performed on the animals must be described in detail from the time the animals enter the study until they are euthanized or otherwise terminated from the study. Again, language must be used that can be understood by laypersons or non-scientists. Surgery should be described in Section E.

3. Consideration of Alternatives - If there are procedures that could cause more than momentary pain or stress, explain why live vertebrate animals must be used in the proposed activity. Address why computer models, visual aids, or other non-animal techniques cannot be used.

> 3a. Literature search should include key words that are likely to address the issue of alternatives. In many databases, a literature search with keywords such as “in vitro models,” “alternative,” “animal models,” etc. will provide information on the use of non-animal alternatives in research. List any other service used for information concerning alternatives to the proposed animal use procedures. Although the literature search is recommended, other methods may serve as a basis for obtaining information on alternatives.)
>
> 3b. This area can include awareness of the literature due to attendance at various seminars, etc. It also can include one’s own expertise in the field of the proposed animal use activity.
>
> 3c. Indicate any other methods or sources used to identify possible alternatives.
>
> 3d. Explain how the methods have assisted you in identifying alternatives or conclude alternatives are not efficient.

4. Fill out the table using the guide above. No animal should be listed more than once.

Species and strain: Latin name is not necessary, but the common name must be provided. In field studies be sure to indicate non-target species as such.
Age and/or weight: Give either, or both if known. Alternately, ranges may be used.
Source: Self-explanatory. Do not give specific vendor names!
Categories of use: Based on the proposed activities that may cause pain or distress
Total number of animals: Include the maximum number of animals that are needed for the three-year life cycle of this specific protocol. Do not use ranges of numbers such as 10 to 15. (Field studies using observations and trapping for population counts may use expected ranges of captures and should be discussed in the application.

4a. through 4c.:
Check the appropriate answer applicable to your study. (NOTE: 4c. If you check other, you must specify in the field below.)

4d. Explain how it was determined to use the number of animals shown in Table 4, above. The numbers should be based on experimental design. Tables or flow charts can be used to show treatment groups and number of animals. Example: 10 animals in each group, 3 treatments (treatment A, treatment B, and control), and two replicates of each treatment. 10x3x2=60 (should be same number as “total” in 4). Explanation should include, when appropriate, a statistical justification for group size.

Section B: Invasive sample collection from live animals

Only include those sample collections that are invasive. Fill out provided table, as applicable. Example: Fecal collection from floor dropping does not need to be listed here. Fecal collection by fecal loop needs to be described here.

Section C: Substance Administration

This section should be used to address substance administration. Complete Sections D and F for anesthetics, analgesics, tranquilizers and euthanasia agents.

1. List all substances given to animals with dosage information. Contact AR-EHS (806-651-2270) for additional information. Contact the IACUC Chairman for information on mouse antibody production testing, rat antibody production testing, and hamster antibody production testing.

2. Describe in detail the precautions taken to protect people and animals for each substance checked in C1.

3. Describe effects of agents on animal.

4. Verify you have a safety plan approved by AR-EHS.

5. Indicate if you think radiological approval will be needed.

6. Indicate whether or not the safety plan reflects the location and experimental protocol.

6a. If not, explain why not.

Section D: Potential Pain and Distress

Proper use of animals including the avoidance of discomfort, distress, and pain when consistent with sound scientific practices is imperative. Unless the contrary is established, PIs should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

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. The plan for checking the animal's condition must be thoroughly outlined.

3. Describe how pain will be minimized. If animals cannot be euthanized, explain how the information derived from allowing the animals to die without intervention contributes to the proposed animal use purpose and importance.

4. Scientific justification must be provided on why pain-relieving drugs or therapies are not acceptable in the proposed activity for animal use.

5. Scientific justification must be provided when death is to serve as the experimental endpoint.

6. All drugs including anesthetics, analgesics, antibiotics, paralytics, etc. that will be given to animals should be listed here. Painful procedures in which paralytics are used also must include anesthetics. Refer to the IACUC Guidelines on Intra- and Post- Operative Monitoring and Record Keeping.

a. On the table provided, list species, procedure/condition, agent used, dosage/route, frequency, and duration.

b. Describe monitoring procedures to ensure safety of agents.

c. Describe monitoring procedures for recovery from agents.

d. Describe how it will be determined that analgesics are working.

7. Restraint for more than one hour: It is important that any restraint device be suitable in size and design for the animal being held. Prolonged restraint should be avoided unless essential to the study's objectives. The restraint device must be correctly operated to minimize stress and avoid injury to the animals. Any drugs used to facilitate restraint should be listed in Section D. Whenever possible, the animals should be conditioned to the restraint device.

8. Field studies only. Describe trapping or capture methods used. Explain how pain and distress 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. Contact AR-EHS (phone: 806-651-2270, e-mail: ar-ehs@wtamu.edu) or the IACUC Chairman for questions. Federal regulations, guidelines, and standards for laboratory animals can be found in the *Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act Regulations, the Public Health Service Policy on the Humane Care and Use of Laboratory Animals and the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching.*

Section E: Surgery

1. Check the appropriate box. In non-survival surgery the animal is not allowed to recover from anesthesia, but is instead euthanized.

2. Describe surgical procedure.

3. Explain how long the animals are maintained for the proposed animal use after surgery.

4. Appropriate procedures for post-operative care of the animals, in accordance with established veterinary medicine and nursing practices, must be provided. Refer to the IACUC Guidelines on Intra- and Post-Operative Monitoring and Record Keeping.

5. This section should be used to address multiple survival surgeries. A second surgery that is terminal does not require justification. Major surgery means surgical intervention that penetrates and exposes a body cavity or any procedure that produces permanent impairment of physical or physiological functions.

Section F: Euthanasia/Disposition

1. Provide species, method/agent and dosage/route for all euthanasia of animals in the table provided.

2. Scientific justification must be given if using methods that vary from those recommended by the most recent report of the American Veterinary Medical Association (AVMA) Panel on Euthanasia. The AVMA has set forth guidelines on euthanasia; the panel has determined that cervical dislocation and decapitation should be used only “when scientifically justified by the user.” The WTAMU IACUC has determined that exceptions to the AVMA guidelines will be considered by the IACUC on a case-by-case basis.

3. If animals will not be euthanized, information on final disposition must be provided (i.e., transferred to another protocol, adopted, sold for slaughter, etc.). For animals entering the food chain, be sure to adhere to established drug withdrawal periods.

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

APPLICATION FOR VERTEBRATE ANIMAL USE (AVAU)
Institutional Animal Care and Use Committee (IACUC)
(REVISED 9.7.2023)

NOTE: BEFORE COMPLETING THIS FORM, READ INSTRUCTIONS HERE.

This application applies to ☐ Research ☐ Teaching

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 this project has been approved previously by the IACUC 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.

ID#:_____ Date Sent to IACUC:_____

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

Approval Date:_____ Expiration Date:_____

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

IACUC Chair_____

This page intentionally left blank.

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 – 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.

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.

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.

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 or violations of pertinent policies, guidelines or laws could result in immediate suspension of this project.

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

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: last page of application lists definitions of categories.)

- **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 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. The 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 in Section 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?
- Have all employees been trained on the plan and documented that they have received training?
- 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 (AV) (see committee information for additional information.) 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 F. 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.

Appendix C

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

Animal Care and Use Protocol Amendment

West Texas A&M University/Cooperative Research, Educational and Extension Team
Institutional Animal Care and Use Committee

Use this form to make a change to an animal care and use protocol. Return completed form to Killgore Research

Center-IACUC, WTAMU Box 60217, Canyon, TX 79016, fax 806-651-2733, phone 806-651-2270, e-mail

ar-ehs@wtamu.edu. Only typed forms will be accepted. For assistance see the IACUC website.

Principal Investigator: _____**Protocol number**:_____

Phone: _____ **Box:**_____ **E-mail:** _____

Protocol title:

_____

Which type(s) of change(s) are being proposed? Check all that apply.

Change in personnel	___	Change in number of animals	___
Change in animal species	___	Addition/deletion of procedure	___
Change in surgical procedure	___	Change in anesthesia or analgesia	___
Change in animal housing	___	Change in euthanasia method	___
Change in funding source	___	Change in project title	___
Change in veterinary care	___		
Change in hazardous substance use	___		
Change in category of animal use	___		

Transfer of Principle Investigator (Complete the Information directly Below) ____

I, **PI Name**, am requesting the above referenced study to be transferred to **New PI Name**. This amendment reflects the change of a new PI and I understand I am still responsible for this study until approval of this amendment.

PI Signature:_____

I, **New PI Name,** accept the role as PI on the above referenced study. I understand I will assume the responsibility of this

study going forward. I also understand this change will be effective on the date this amendment requesting this change is approved. Furthermore, I understand any changes I make in the future to this study will require an amendment to be approved by the IACUC Committee Chair prior to implementation of the change.

New PI Signature:_____

Other

(Describe):_____

_____

Describe all proposed change(s) in detail. If change(s) proposed add any procedures that have the potential to cause animal pain or distress, then you must describe the methods and sources by which alternatives to these procedures have been sought. Please review the original protocol and confirm that all principal investigator assurances apply to proposed change(s). (Attach additional sheets if necessary.)

Justify the need for these proposed changes. (Attach additional sheets if necessary.)

_____ _____

Signature of Principal Investigator Date

IACUC Chair's Action:

___ The changes proposed are not significant and do not require IACUC review. The changes may be implemented and this form is included in the record for this protocol for information only.

___ The changes proposed are considered significant and do require IACUC review. This form and the original protocol review form along with any attachments and comments are forwarded to the primary reviewer. A copy of this form is sent to each IACUC member to permit an opportunity to request additional information or convened IACUC review. In all other respects, the IACUC review of changes is the same as review of an original protocol.

_____ _____

IACUC Chair Signature Date Approved

Appendix D

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

WTAMU/CREET IACUC Committee Review Checklist IACUC REVIEW

FOR VERTEBRATE ANIMAL USE

(Revised 11.18.2022)

The committee will review the following conditions for each IACUC submitted for review:

PROTOCOL # DATE:
PI NAME:

1. Procedures involving animals will avoid or minimize discomfort, distress, and pain to animals:

   Meets condition?
   Comments:

2. The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal, and has provided a written narrative description of the methods and sources, e.g., the Animal Welfare Information Center, used to determine that alternatives were not available:

   Meets condition?
   Comments:

3. The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments:

   Meets condition?
   Comments:

4. Procedures that may cause more than momentary or slight pain or distress to the animals will:

A. Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time:

Meets condition?
Comments:

B. Involve, in their planning, consultation with the attending veterinarian or his/her designee:
Meets condition?
Comments:

C. No use of paralytics without anesthesia:

Meets condition?
Comments:

5. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure. Methods of euthanasia used must be in accordance with the definition of the term set forth in 9CFR part 1 Section 1.1 of Subchapter A, unless a deviation is justified for scientific reasons, in writing, by the investigator:

Meets condition?
Comments:

6. The animals' living conditions will be appropriate for their species in accordance with part 3 of subchapter A 9CFR2.31.(vi) and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by the attending veterinarian or other scientist trained and experienced in the proper care, handling and use of the species being maintained or studied:

Meets condition?
Comments:

7. Medical care for animals will be available and provided as necessary by a qualified veterinarian:

Meets condition?
Comments:

8. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures:

Meets condition?
Comments:

9. Activities that involve surgery include appropriate provision for preoperative and post- operative care

of the animals in accordance with established veterinary medicine and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Non-major operative procedures and all surgery on rodents do not require a dedicated facility, but must be performed using aseptic procedures. Operative procedures conducted at field sites need not be performed in dedicated facilities, but must be performed using aseptic procedures:

Meets condition?
Comments:

10. No animal will be used in more than one major operative procedure from which it is allowed to recover, unless:

A. Justified for scientific reasons by the principal investigator, in writing:
Meets condition?
Comments:

B. Required as routine veterinary procedure or to protect the health or well- being of the animal as determined by the attending veterinarian:

Meets condition?
Comments:

C. In other special circumstances as determined by the Administrator on an individual basis. Written requests and supporting data should be sent to the Animal and Plant Health Inspection Service, Animal Care, 4700 River road, Unit 84, Riverdale, Maryland 20737-1234:

Meets condition?
Comments:

11. Animals used in the study are of the appropriate species and quantity:

Meets condition?
Comments:

12. The PI has demonstrated this research has relevance to the human or animal health, supports the advancement of knowledge, or benefits society:

Meets condition?
Comments:

13. Transportation is provided by qualified and experienced personnel:

Meets condition?
Comments:

Results of Review:
Will a site visit be conducted?
If no, please justify.

Reviewer Signature_____

IACUC Chairman Signature_____

Appendix E

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

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
Letter of Approval

DATE

PI:

We are pleased to inform you that your proposal # ####-##-## submitted to the West Texas A&M University/Cooperative Research, Educational and Extension Team Institutional Animal Care and Use Committee (IACUC) for your study titled, "**Title of Protocol**," has been reviewed and found to meet the requirements found Animal Welfare Act and the Health Research Extension Act of 1985 and WTAMU Standard Operating Procedure 15.99.05.W1.02AR Institutional Animal Care and Use and approved by the WTAMU/CREET IACUC. This approval is extended to you for the remainder of the research project or until **DATE 3 years from date of letter**.

1. **Annual Review:** Within 30 days of the annual due date or the next scheduled IACUC meeting, you will receive notification that an annual report is due. The WTAMU IACUC will conduct a compliance review based on the annual report to evaluate your compliance with the approved plan and requirements under the referenced laws, regulations and policies. Failure to complete an annual report may result in processing delays, study termination, and/or loss of funding.
2. **Completion Report:** Upon completion of the research project (including data analysis and final written papers), a Completion Report must be submitted to the IACUC.
3. **Inspections:** Inspection of the facility where animals are housed will be inspected on a biannual basis by the IACUC and an attending veterinarian.
4. **Unanticipated Problems and Adverse Events:** Unanticipated problems and adverse events must be reported to the IACUC immediately.
5. **Reports of Potential Non-compliance:** Potential non-compliance, including deviations from protocol and violations, must be reported to the IACUC office immediately.
6. **Amendments:** Changes in methodology or personnel as it affects animal subjects, must be requested by submitting an Amendment to the IACUC for review. The Amendment must be approved by the IACUC before being implemented.
7. **Audit:** Your protocol may be subject to audit by the IACUC Administrator during the life of the study. Investigators are responsible for maintaining complete and accurate study records and making them

available for inspection.

Thank you for your cooperation with the IACUC and we wish you well with your research project.

Sincerely,

Chair, WTAMU IACUC

Dr. Angela Spaulding,
Vice President of Research and Compliance

Appendix F

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

Memorandum to IO

TO: Dr. Angela Spaulding, WTAMU VP Research and Compliance/IO;
Dr. Steve Evett, USDA/IO;
Dr. Brent Auvermann, AgriLife/IO

From: WTAMU Institutional Animal Care and Use Committee

Subject: IACUC Semi-Annual Meeting

Date:

This report summarizes the results of the IACUC committee's AWA required bi-annual program review and facility inspection, as required by the applicable Animal Welfare Act (AWA) regulations 9CFR2.31.

This report also meets the requirements of submission of semiannual reports to the Institutional Official as a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW). **This form may also be used by the IACUC committee for any requested inspections by the IO, and, as needed, to address any public and/or employee's complaints.**

Pre-evaluation Checklist:

☐ All committee members have been provided access to the approved WTAMU/CREET IACUC proposals and supporting information for review well as the IACUC Committee evaluation checklist. (Note: The IACUC Committee Review Checklist is used as the basis of the bi-annual review and was designed to meet the bi-annual review requirements outlined under 9CFR2.31(d)i-xi.).

☐

All committee members have been notified of the program review and facility inspections.

☐ No committee member wishing to participate in any part of this evaluation has been excluded.

Since the last review, the following changes have occurred in the institution's program for animal care and use:

I. Description of the Nature and Extent of the Institution's Adherence to the AWA (If a PHS or NIH Grant include PHS Policy, the OLAW *Guide*, 8th edition).

Departures from the AWA and PHS and OLAW if appropriate.

Select one:

☐ There were no departures during this reporting period.

☐ The following departures have been reviewed and approved by the IACUC:

II. Deficiencies in the Institution's Animal Care and Use Program

Animal Care and Use Program Review Date(s):

Select one:

☐ There were no deficiencies in the program during this reporting period.

☐ The following deficiencies have been identified: [describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of this Semiannual Program Review form and Facility Inspection Checklist.

III. Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Date(s):

Select one:

☐ There were no deficiencies in the animal facility during this reporting period.

☐ The following deficiencies have been identified: [describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of this Semiannual Program Review form and Facility Inspection Checklist. The IACUC committee has the authority to require Principal Investigators and research programs to meet the requirements outlined in the AWA and implementing regulations 9CFR 2.31et. seq. as specified in Appendix A.

IV. Minority Views

Select one:

☐ No minority views were submitted or expressed.

☐ The following minority views were expressed: [insert minority views here or attach]

V. Status of AAALAC Accreditation [*identify accredited facilities, if applicable*]

NA

Appendix G

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

Institutional Animal Care and Use
APPLICATION FOR THE STUDY OF WILD ANIMALS IN OR FROM NATURAL SETTINGS

(Revised 11-21-22) ID#_____(Committee Use Only)

ONLY TYPED FORMS WILL BE ACCEPTED.

This application applies to: Research Teaching

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 the course.

Title of project or activity:

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

If this project has been approved previously by the Committee, please indicate the IACUC 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.

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

Date of review:

Approved Approved with Modifications (Attached) Not Approved

Expiration Date:

CONFIDENTIAL

INFORMATION ON PAGES 2-4 IS CONSIDERED PRIVATE AND NOT SUBJECT TO RELEASE UNDER THE PUBLIC RECORDS ACT. PLEASE PROVIDE THE APPROPRIATE INFORMATION IN THE SPACES PROVIDED BELOW, BUT 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

Department

Mailing Address

Email Address

Lab Contact (Technician) and phone number

After-hours emergency contact name and phone number

Duration of project to (IACUC approval is for 3 years max.)

Have all personnel completed the online CITI training? (An RCR refresher course is required annually - contact AR-EHS for additional requirements?

Yes No – Please explain.

Have all personnel completed the initial risk assessment survey?

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 – Describe safety precautions that will be used to protect personnel.

1. ANIMALS

1A. What types of animals are involved in this project or activity?

Livestock	Companion Animals	Laboratory (mice, rats, etc.)
Wildlife	Exotic Animals	Other

1B. Provide a one-paragraph summary of the project or activity. Describe briefly what you will be doing with the animals.

2. HOUSING

2A. Will animals be housed? Yes No

If no, explain why not. (I.e. field studies, client owned)

For field studies, give location. Be specific.

Cage Indoor Pen Metabolism Crate Tie Stall

Outdoor Pen Free Range Other – Please Specify

2B. What is the **physical address** of where the animals will be housed?

2C. Where will procedures (including surgeries) be performed? (Physical address, including building and room number.)

2D. 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.

2E. 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 and method of transport.

3. QUALIFICATIONS

3A. List all personnel in your group; including the PI, who will care for and work with the animals. For each person, please include the following information:

- Name
- Email
- Indicate their role in the project.
- 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 D, SURGERY.

3B. Will this project involve additional individuals beyond the PI and previously identified lead personnel?

No – Proceed to Item #4. Yes – PI agrees to the following:

- No individual will be involved in project activities without receiving training from the PI or lead personnel specific to the scenario
- No individual not listed as the PI or lead personnel will be involved in any activity involving Pain Category B or Pain Category C. (See bottom of page 6 for definitions.)

4. FUNDING SOURCE (if applicable)

If project is funded, please provide details of funding agency and grant details below.

5. PROTOCOL CLASSIFICATION

Please check one:

New project

3rd Year renewal replacing previously approved IACUC protocol #

Please provide a brief summary (a few sentences) describing work accomplished during the last approval period and how the work proposed in this renewal extends the previous studies.

6. ACKNOWLEDGEMENT OF RESPONSIBILITY FOR UNCERTAINTY IN FIELD RESEARCH

The IACUC recognizes that field sampling is inherently unpredictable and unexpected scenarios will be encountered in the field. When such conditions occur, the PI and all personnel involved in the project are expected to handle such situations in accordance with the relevant society guidelines for the taxa involved, including the *Guidelines of the American Society of Mammologists for the Use of Wild Mammals in Research*, the *Guidelines for Use of Fishes in Research* (American Fisheries Society and American Society of Ichthyologists and Herpetologists), the *Guidelines for the Use of Live Amphibians and Reptiles in Field and Laboratory Research* (American Fisheries Society and American Society of Ichthyologists and Herpetologists), and the *Guidelines to the Use of Wild Birds in Research*.

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

Signature of P.I Date

THIS PAGE INTENTIONALLY LEFT BLANK.

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.

7. CHARACTERISTICS OF WILD ANIMALS AND PAIN CATEGORY OF RESEARCH

Is this project a baseline inventory or monitoring project in which taxa and numbers captured will be unknown, but all activities fall within Pain Category A? (Pain categories are listed at the bottom of the page.)

Yes Indicate which are the primary taxa targeted and proceed to Item # 8.

Fishes Reptiles Birds

Amphibians Mammals

No List and describe the animals to be studied. Indicate the anticipated number of animals to be used in each Pain Category of Research and the total number of animals involved during the 3-year approval period of this protocol. If exact numbers are not known, indicate approximately (~) or not to exceed (NTE). (Note: The IACUC recognizes that pain perception by many species of vertebrate animals may not be uniform over the various portions of their bodies, and that broad extrapolation of pain perception across taxonomic lines may not be appropriate. The IACUC also recognizes that it is possible to capture non-target taxa and the PI assumes the responsibility to ensure such captures are dealt with in an ethical way. A single addendum page of response is permissible if it is identified as a response to which item # and page #.)

Taxa or species	**Characteristics (age, sex, weight)**	**# Used in Pain Category A Procedures**	**# Used in Pain Category B Procedures**	**# Used in Pain Category C Procedures**	**Total Number Anticipated**

Pain Categories:

Pain Category A: Anticipated to produce momentary, slight, or no pain, discomfort or distress.

Pain Category B: Anticipated to produce more than momentary or slight pain, discomfort or distress which is alleviated by the use of appropriate anesthetics and/or analgesics.

Pain Category C: Anticipated to produce pain, discomfort, or distress, which cannot, or is not alleviated by the administration of appropriate anesthetics and/or analgesics.

8. OFF-CAMPUS STUDY LOCATION

8A. Is this project a baseline inventory or monitoring project in which specific field locations are variable and unpredictable, but all activities fall within Pain Category A? (Pain categories are listed on page 6 above.)

Yes - Proceed to Item #9

No - Describe below the anticipated off campus location(s) where the specific project will be performed. If this protocol is to be conducted at another academic institution, or a zoological garden, aquarium, or oceanarium please name that institution and attach a letter with official letterhead from that institution that indicates that they are anticipating the presence of this research protocol, and whether they have an assurance on file. If collaborating institutions will supply live animals collected by their staff, or will perform portions of this protocol, or University faculty or staff will conduct this protocol at another institution, those institutions must be declared here.

9. PERMITS

9A. Do you have knowledge of all regulations pertaining to the animals under study, including whether they are considered endangered or threatened, and will obtain all applicable permits before initiating the study? (Note: The IACUC recognizes that state and federal wildlife agencies review applications for permits for their scientific merit and their potential impact on native populations, and issue permits that authorize the taking of specified numbers of individuals, the taxa and methods allowed, the period of study, and often other restrictions designed to minimize the likelihood that an investigation will have deleterious effects.)

Yes – Proceed to Item#10 No – Please explain below:

10. JUSTIFICATION FOR THE USE OF ANIMALS

10A. Briefly state in lay terms the purpose and scope of work (i.e., research hypothesis or teaching objectives) of this request, and the procedures (general sequence of events) in which animals will be involved.

10B. Briefly describe why the requested animals are the subject of study, or are well suited to answer the research questions posed.

10C. Briefly describe the rationale, prior experience, statistical analysis, or other methods used to understand the population status of the taxa or species to be studied, and used to determine the anticipated total number of animals that will be encountered or involved during the 3-year approval period of this protocol. (Note: The total number of animals requested in item # 7 above must be justified here. The IACUC recognizes that it is not always possible to accurately predict at the initiation of field studies the number of animals to be encountered. The minimum number of animals necessary for accomplishing the goals of the study should be used.)

10D. Will this study only consist of the direct, unobtrusive observation of free-ranging animals under natural conditions, and not require that animals be contacted, captured or restrained at any time?

No – Proceed to Item 10E

Yes – STOP. This application is complete.

10E. Will the captured animals ever be transported to the University?

No – Proceed to Item 10F

Yes – Below, name the University building and room number the animals will be taken to.

10F. Will there be scheduled substances controlled by the Drug Enforcement Administration be used in the protocol?

No – Proceed to Item #11

Yes –Below, list the controlled substances to be used.

11. CAPTURE AND RESTRAINT

11A. Briefly describe the technique(s) of wild animal capture, and the method(s) and duration of animal restraint that will be used. If drug-induced immobilization will be used, indicate the dose and route of administration. (Note: Techniques that have minimal impact on the animal, require the shortest period of time to accomplish, reduce hazards to research personnel, and are environmentally benevolent should be used whenever possible. Refer to 15.99.05.W1.02AR WTAMU Institutional Animal Care and Use Procedure.)

11B. Will the method of wild animal capture or restraint cause more than momentary discomfort, pain, or distress to the animals?

No – Proceed to Item 11C Yes - Briefly describe the methods to be used that will assist in avoiding or alleviating the potential for animal distress, pain, or discomfort. If drug-induced sedation, analgesia, or anesthesia will be used, list the drugs, dose, and the route of administration.

11C. Are animals euthanized **immediately at the moment** of capture for preparation as museum specimens, for post mortem tissue collection, or for other purposes? (Note: If animals are euthanized later at the conclusion of study, and not immediately following their first capture, respond "No" here.)

No – Proceed to Item 12 Yes - Does the method of euthanasia immediately upon capture, and means of assuring death following euthanasia comply with 15.99.05.W1.02AR WTAMU Institutional Animal Care and Use Procedure?

No - Within the space below indicate why a deviation is necessary. Yes - Within the space below describe the method of euthanasia used for each taxa or species. If a chemical agent will be used, indicate the dose and route of administration. If tissues are to be collected post mortem, list the tissues to be collected.
Note: If animals are euthanized immediately following capture, STOP here with this response. This application is complete.

12. MARKING

12A. After capture, will animals need to be identified or marked in some manner?

No – Proceed to Item 12B

Yes - Does the marking technique cause more than momentary distress? Briefly describe the marking technique that will be used, the nature and duration of restraint required during marking, the amount of tissue affected by the technique. (Note: If drug-induced sedation, analgesia, or anesthesia will be used during the marking of animals, list the drugs, and the dose and route of administration.)

12B. After marking, is it anticipated that animals will be at greater than normal risk of infection, predation, or survival, or have reduced reproductive fitness?

No – Proceed to Item 12C

Yes - Justify why this marking technique must be used, and why other techniques that have less impact on the animal may conflict with the purposes of this research activity.

12C. Are specimens (e.g., tissues, blood, lymph, body fluids, etc.) collected from the captured animals prior to their release?

No – Proceed to Item 12D Yes – Attach **Appendix A, "Specimen Collection, Ante Mortem".**

12D. Are test substances, other than those used for marking, or for sedation, analgesia, or anesthesia administered to the captured animals prior to their release?

No – Proceed to Item 12E Yes - Attach **Appendix B, "Test Substances".**

12E. Does this animal use end with the release of the animals (with no planned recapture) at the site of capture within twenty-four hours of their restraint, without impairment of their ability to survive, while environmental conditions are conducive to their survival, and while their release is not likely to spread pathogens?

Yes – **STOP here**. This application is complete. No - Proceed to Item 12F.

12F. Does this animal use end after the same marked animals are recaptured again one or more times, with or without the collection of tissue specimens, or the administration of test substances, using methods identical to those described in items #11A, #11B, #12C, & #12D, above, with their release at the original site of capture within twenty-four hours of each episode of restraint, without impairment of their ability to survive, while environmental conditions are conducive to their survival, and while their release is not likely to spread pathogens?

Yes – Indicate below the anticipated number of times that the same wild animal will need to be re-captured, the time interval between each re-capture, and whether tissue specimens will be collected, or test substances will be administered during each episode of restraint, then **STOP here**. This application is complete.

No – Proceed to 12G

12G. Will animals be confined or restricted to an enclosure in their natural setting for longer than 24 hours, or transported to, and housed within an enclosure in a University animal facility, laboratory, or other area on campus?

No – Proceed to Item 12H Yes – Attach **Appendix C – "Animal Maintenance and Care"**

12H. Will surgery be performed on animals as part of this protocol?

No – Proceed to Item 12I Yes – Attach **Appendix D – "Surgery"**

12I. Will animals be subject to experimental procedures other than those described above (e.g., behavioral manipulations, noxious stimuli, or forced exercise)?

No – Proceed to Item 12J Yes – Attach **Appendix E, "Other Experimental Procedures"**

12J. Will animals be involved in Pain Category C research activities where more than momentary or slight painful or stressful outcomes are anticipated or possible, which cannot, or will not be alleviated by the administration of appropriate anesthetics and/or analgesics?

No – Proceed to Item 12K Yes – Within the space below, describe the methods and/or clinical criteria that will be used to ensure timely intervention and removal of the animals from the study in advance of the anticipated discomfort, or why avoidance or alleviation of animal pain or discomfort adversely affects the protocol. The earliest possible clinical end point, which will contribute to the resolution of the hypothesis, must be identified and utilized. (Note: The IACUC recognizes that pain perception by many species of vertebrate animals may not be uniform over the various portions of their bodies, and that broad extrapolation of pain perception across taxonomic lines may not be appropriate.)

12K. Do the consequences of these procedures introduce the possibility of earlier animal death (excluding death from euthanasia) as an endpoint to this protocol (e.g., survival analysis)?

No – Within the space below, indicate the final disposition of the involved animals.

Yes - Does the method of euthanasia and means of assuring death following euthanasia comply with SOP Number 15.99.05.W1.02AR WTAMU Institutional Animal Care and Use Procedure on animal euthanasia within these laboratories?

No - Within the space below indicate why a deviation is necessary. Yes - Within the space below describe the method of euthanasia used for each species. If a chemical agent will be used, indicate dose and route of administration.

STOP here. Complete and attach any required appendixes as indicated above. This application is complete.

APPENDIX A: SPECIMEN COLLECTION, ANTE MORTEM

(Complete & Submit for Review Only if Response to Item 12C was "Yes")

1. Within the space provided, list the tissues or specimens (e.g., blood, spleen, liver, lymph node, body fluid) that will be collected ante mortem from animal(s), and indicate the amount of tissue to be collected, the frequency of collection, and the method that will be used to collect the tissue sample (e.g., needle aspiration, punch biopsy, or surgical excision).

2. Will the procedure used in collecting tissues cause more than momentary pain or discomfort?
(Note: Invasive procedures that are performed while animals are anesthetized which open the integument, enter a body cavity, orifice, or hollow visceral organ are considered to cause more than momentary, slight pain or distress, respond "Yes" below; noninvasive procedures such as needle aspiration, respond "No" below).

   No - Within the space provided, describe the method of restraint, and whether tranquilizers, sedatives, or anesthetics will be used, and their dose and route.

   Yes - Within the space below, describe how anesthesia will be induced and maintained, including the dose and route of agents used, whether post-operative/procedural analgesics will be used, their dose and frequency of administration, and a description of the post-procedural methods of minimizing and/or alleviating pain and discomfort.

Appendix A Complete

APPENDIX B: TEST SUBSTANCES

(Complete & Submit for Review Only if Response to Item 12D was "Yes")

1. Complete the table below. Name the test substance(s) that will be administered to animals. Indicate the class of each substance as either an: (A) infectious agent, (B) primary explant, uncharacterized human blood, lymph or tissue specimen, (C) recombinant DNA, (D) radioisotope, (E) carcinogen, (F) hazardous or toxic chemical, (G) biological toxin, (H) Cell line, (I) Adjuvant, (J) Antigenic Substance, (K) Pharmacologic Agent, or (L) Other class of substance by using the appropriate capital letter. Indicate to which species each substance will be administered. Indicate the dose (e.g., µg/gm bwt), volume per administration, route (e.g., i.v., i.p., s.c.), interval (e.g., 1x, daily, eod, every 3rd day), and duration of administrations (e.g., 5 wks).

Substance (list all substances including vehicle/control)	**Class (above)**	**Species (administered to)**	**Dose/Volume/Route (3.0mg/kg bw / 0.1ml / i.p.)**	**Interval (1x. Eod, ev 3rd day)**	**Duration (5 weeks)**
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

2. In the same order in which substances to be administered are listed in the previous table, very briefly indicate below the purpose of substance administration in the relation to the hypothesis, and the expected effect to the animal(s). If none, so state.

Purpose and Expected Effect of Substance Administration to the Animal		
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

APPENDIX B: TEST SUBSTANCES (cont.)

3. Is there a possibility that any of the test substance(s) could cause more than momentary or slight pain, discomfort, or distress to the animals, either immediately following substance administration, or as a consequence long after administering the test substance(s)?

   No – Proceed to Item #4 Yes - List those substances in the space below. For each such substance describe the consequences of administration that have a potential to cause animal discomfort, pain, or distress, and how discomfort, pain or distress will be anticipated, minimized or alleviated (e.g., nude mice administered tumor cells will be humanely euthanatized if induced tumors become >1.0 cm in diameter, or if tumors ulcerate, or if tumors interfere with posture, locomotion or feeding). If discomfort, pain, or distress will not be alleviated, then justify how treatments interfere with the procedures or the interpretation of results.

(Note: Log entries describing health concerns or complications that develop as a consequence of substance administration to non-rodent mammals, and their treatment and resolution, or when animals are euthanatized must be kept by the PI in the animal facility on forms provided by Comparative Medicine.)

4. Are any of the test substances listed above in response to Appendix B Item 1, included in any of the classes A through G, and considered a regulated or potentially hazardous material to research or animal care personnel?

   No – STOP here. This appendix is complete. Yes - List those substances in the space below and describe procedures to ensure these substances and/or animals to which these substances have been administered will be handled safely (e.g., BSL-2, WTAMU Chemical Hygiene Plan, Universal Precautions, etc.)

Test substance(s) of any of the classes A-G listed above under Appendix B Item 1 are either regulated or potentially hazardous and require prior authorization of use by the appropriate Safety Committee. Signature of the Radiation Safety, Biohazard/Recombinant DNA Safety, or Chemical Safety Compliance Officer below indicates that the applicant has consulted with the appropriate Safety Committee, and that that committee has approved the use of the test substance(s). Signature of the applicant PI on page 1 ensures that research personnel will abide by all relevant, universal precautions regarding blood-borne pathogens, appropriate biosafety level precautions, radiation safety procedures, and the chemical hygiene plan.
(Note: Approval of an application involving hazardous materials is often contingent on a pre-performance meeting involving staff that represents the applicant's laboratory, the IACUC, and the appropriate Safety Committee(s). This meeting is required in order to ensure that all involved personnel are aware of the precautions, containment practices, facilities, protective devices, disposal and decontamination procedures, and other necessary safety procedures that must be followed to protect personnel, and prevent accidental animal exposure to the hazardous material.)

Signature of Safety Officer Date

Appendix B complete

APPENDIX C: ANIMAL MAINTENANCE & CARE

(Complete & Submit for Review Only if Response to Item 12G was "Yes")

1. Will the captured animals be maintained in an enclosure in their natural setting at the site of capture for longer than twenty-four hours?

   No – Proceed to Item #3 Yes - Within the space below, indicate the period of time that animals will be cared for in the field, describe the enclosure(s) that will be used, the methods for maintaining appropriate living conditions that contribute to the animal's health and well-being, including their diet and frequency of feeding if applicable, and how environmental conditions will be controlled. Note: Methods must accommodate salient features of the animal's ecology, morphology, physiology, and/or behavior, and contribute to their health and well-being.

2. Describe the factors that will be monitored to ensure that these methods of animal maintenance in the field contribute to the health and well-being of the confined animals (e.g., appearance, behavior, activity, growth).

3. Will the captured animals be transported to the University or another location and maintained there for longer than twenty-four hours?

   No – Proceed to Item #6 Yes - Within the space below, indicate to where the captured animals will be transported, including the University building and room number if applicable, and the period of time that the animals will be cared for at this new location.

4. While animals are housed on campus, describe the enclosure(s) that will be used, the methods for maintaining appropriate living conditions that contribute to the animal's health and well-being, including their diet and frequency of feeding, and how environmental conditions will be controlled. Note: Methods must accommodate salient features of the animal's ecology, morphology, physiology, and/or behavior, and contribute to their health and well-being.

APPENDIX C: ANIMAL MAINTENANCE & CARE (cont.)

5. Describe the factors that will be monitored to ensure that these methods of animal maintenance in the laboratory contribute to the health and well-being of the confined animals (e.g., appearance, behavior, activity, growth).

6. Will any of these methods of animal maintenance and care in the field or in the laboratory cause more than momentary or slight pain, distress, or discomfort to the animals?

   No – Proceed to Item #7

   Yes – Within the space below, describe the methods that will be used to minimize pain, distress, or discomfort.

7. After the period of animal maintenance in the field or laboratory, will the animals be released at the original site of capture, without impairment of their ability to survive, while environmental conditions are conducive to their survival, and while their release is not likely to spread pathogens?

   No – Proceed to Item #8

   Yes – **STOP here.** Appendix C is complete

8. After the period of animal maintenance in the field or laboratory, will the animals be humanely euthanized as described in response to item 12K, above?

   Yes – STOP here Appendix C is complete.

   No - Within the space, describe the final disposition of the animals.

Appendix C complete

APPENDIX D: SURGERY

(Complete & Submit for Review Only if Response to Item 12H was "Yes")

1. Within the space provided, describe the pre-operative medications, including tranquilizers, sedatives, pre-anesthetics, and general anesthetics, their dose and route.

2. Within the space provided, describe all pre-operative procedures, including whether food or water are withheld, (for what period of time), the shaving of hair, surgical scrub, draping, and placement of leads, probes, or catheters.

3. Will paralyzing agents be used?

   No – Proceed to Item #4 Yes - Within the space provided, justify why it is necessary to use them.

4. Within the spaces provided, describe the surgical procedures in chronological order and in sufficient detail so that the IACUC will be able to determine what is being performed on the animal.
   (Note: Intra-operative monitoring, medications and support are to be described below under item # 5).

5. Within the space provided, describe the methods used for monitoring intra-operative anesthesia, and all intra-operative

medications and/or support.
(Note: Log entries describing surgical events involving non-rodent mammals must be kept by the PI. Log entries must at least include a pre-operative assessment, an anesthetic plan, records of the induction and monitoring of general anesthesia, a brief description of the surgical procedures performed, a record of the recovery from anesthesia (or method of euthanasia of the anesthetized animal), a post-operative assessment, and any complications, treatments, and/or plans.)

APPENDIX D: SURGERY (cont.)

6. Will the animal(s) regain consciousness from anesthesia following surgery?

   No – Stop here this description is complete. Yes – Proceed to Item #7

7. Indicate below where the surgery will be performed, whether in the field at the location(s) described in response to item #8 on page 7 above, or on campus in a laboratory. If on campus, name the building and room number.

8. Will aseptic techniques be used (as a minimum including working in an uncluttered area, the wearing of surgical gloves & mask, preparation of the surgical site with disinfectant, cleaning of instruments with a disinfectant, and appropriate wound closures)?

   No – Within the space provided, please justify. Yes – Proceed to Item #9

9. Animals recovering from general anesthesia must be monitored at least until they are sternal recumbent and capable of purposeful movement. Prior to that point, describe the interval and manner of immediate post-operative monitoring, and clinical reassessment. How frequently will the animals be evaluated, and in what manner will the animal(s) be monitored post-operatively?
   (Note: Log entries of all post-operative events involving non-rodent mammals must be kept by the PI in the animal facility.)

10. Will more than one major surgical procedure be performed on a single animal?
(Note: If a survival surgical procedure is followed by a non-survival surgical procedure, respond "No".)

   No – Proceed to Item #11 Yes – Within the space provided, please justify.

11. Within the space provided, describe post-operative patient care after the animals have been returned to long-term housing, including the administration of analgesics, medications, fluids, and any other support methods (dose, route and frequency of post-operative analgesics and medications must be described), and indicate that skin sutures or staples will be removed at approximately 10 - 14 days post-operatively.

Appendix D complete

APPENDIX E: OTHER EXPERIMENTAL PROCEDURES

(Complete & Submit for Review Only if Response to Item 12I was "Yes")

1. Within the space provided, describe other experimental procedure(s) that have not been described in detail above (e.g., behavioral manipulation, forced exercise, noxious stimuli, physical restraint) and the expected outcome.

2. How long will each procedure last?

3. Will the procedure(s) cause more than momentary, slight pain or discomfort to the animals?

   No – Proceed to Item #4 Yes – Below, describe the methods that will be used to minimize pain and discomfort.

4. Within the space provided, describe the methods for monitoring the condition of the animal during the procedure and during the post-procedural period, and whether a log of observations will be kept.

Appendix E complete

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

Semi-annual Program Review Checklist

Institutional Policies and Responsibilities

Date:

1. Animal Care and Use Program NEW	A*	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program (*Guide*, p 1) [must]					
• IO has authority to allocate needed resources (*Guide*, p 13)					
• Resources necessary to manage program of veterinary care are provided (*Guide*, p 14) [must]					
• Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the *Guide* (*Guide*, pp 11, 15)					
• Program needs are regularly communicated to IO by AV and/or IACUC (*Guide,* p 13)					
• Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (*Guide*, p 14) [must]					
• Inter-institutional collaborations are described in formal written agreements (*Guide*, p 15)					
• Written agreements address responsibilities, animal ownership, and IACUC oversight (*Guide*, p 15)					

2. Disaster Planning and Emergency Preparedness	A*	M	S	C	NA
• Disaster plans for each facility to include satellite locations are in place (*Guide*, p 35, p 75) [must]					
• Plans include provisions for euthanasia (*Guide*, p 35) [must]					
• Plans include triage plans to meet institutional and investigators' needs (*Guide*, p 35)					
• Plans define actions to prevent animal injury or death due to HVAC or other failures (*Guide*, p 35)					
• Plans describe preservation of critical or irreplaceable animals (*Guide*, p 35)					
• Plans include essential personnel and their training (*Guide*, p 35)					
• Animal facility plans are approved by the institution and incorporated into overall response plan (*Guide*, p 35)					
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (*Guide*, p 35)					

3. IACUC	A*	M	S	C	NA

• Meets as necessary to fulfill responsibilities (*Guide*, p 25) [must]					
• IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (*Guide*, p 26) [must]					
• Continuing IACUC oversight after initial protocol approval is in place (*Guide*, p 33)					
• IACUC evaluates the effectiveness of training programs (*Guide*, p 15)					

4. IACUC Protocol Review – Special Considerations	**A***	**M**	**S**	**C**	**NA**
• Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicology effects, organ or system failure, and models of cardiovascular shock (Guide, p 27)					
• For pilot studies, a system to communicate with the IACUC is in place (Guide, p 28)					
• For genetically modified animals, enhanced monitoring and reporting is in place (*Guide*, p 28)					
• Restraint devices are justified in the animal use protocols (*Guide*, p 29) [must]					
• Alternatives to physical restraint are considered (*Guide*, p 29)					
• Period of restraint is the minimum to meet scientific objectives (*Guide*, p 29)					
• Training of animals to adapt to restraint is provided (*Guide*, p 29)					
• Animals that fail to adapt are removed from study (*Guide*, p 29)					
• Appropriate observation intervals of restrained animals are provided (*Guide*, p 29)					
• Veterinary care is provided if lesions or illness result from restraint (*Guide*, p 30) [must]					
• Explanations of purpose and duration of restraint are provided to study personnel (*Guide*, p 30)					
• Multiple surgical procedures on a single animal are justified and outcomes evaluated (*Guide*, p 30)					
• Major versus minor surgical procedures are evaluated on a case-by-case basis (*Guide*, p 30)					
• Multiple survival procedure justifications in non-regulated species conform to regulated species standards (*Guide*, p 30)					
• Animals on food/fluid restriction are monitored to ensure nutritional needs are met (*Guide*, p 31)					
• Body weights for food/fluid restricted animals are recorded at least weekly (*Guide*, p 31)					
• Daily written records are maintained for food/fluid restricted animals (*Guide*, p 31)					
• Pharmaceutical grade chemicals are used , when available, for animal-related procedures (*Guide*, p 31)					
• Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (*Guide*, p 31)					
• Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (*Guide*, p 32)					
• Disposition plans are considered for species removed from the wild (*Guide*, p 32)					
• Toe-clipping only used when no alternative, performed aseptically and with pain relief (*Guide*, p 75)					

5. IACUC Membership and Functions	**A***	**M**	**S**	**C**	**NA**
• IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, IV.A.3.)					
• Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (*Guide*, p 24)[ii]					

• IACUC authority and resources for oversight and evaluation of institution's program are provided (*Guide*, p 14)					
• IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, IV.B.)					
• Conducts semiannual inspections of institutional animal facilities (PHS Policy, IV.B.)					
• IACUC organizationally reports to the Institutional Official (PHS Policy, IV.A.1.b.)					
• Methods for reporting and investigating animal welfare concerns are in place (*Guide*, p 23) [must]					

6. IACUC Training	**A***	**M**	**S**	**C**	**NA**
• All IACUC members should receive:					
○ Formal orientation to institution's program (*Guide*, p 17)					
○ Training on legislation, regulations, guidelines, and policies (*Guide*, p 17)					
○ Training on how to inspect facilities and labs where animal use or housing occurs (*Guide*, p 17)					
○ Training on how to review protocols as well as evaluate the program (*Guide*, p 17)					
○ Ongoing training/education (*Guide*, p 17)					

7. IACUC Records and Reporting Requirements[vi]	**A***	**M**	**S**	**C**	**NA**
• Semiannual report to the IO (PHS Policy, IV.B.)					
○ Submitted to IO every 6 months					
○ Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)					
○ Includes minority IACUC views					
○ Describes IACUC-approved departures from the *Guide* or PHS Policy and the reasons for each departure[vii]					
○ Distinguishes significant from minor deficiencies					
○ Includes a plan and schedule for correction for each deficiency identified[viii]					
• Reports to OLAW (PHS Policy, IV.F.)					
○ Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views					

○ Promptly advises OLAW of serious/ongoing *Guide* deviations or PHS Policy noncompliance (NOT-OD-05-034)					
○ Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034)					
• Reports to U.S. Department of Agriculture (USDA) or Federal funding agency[ix]					
○ Annual report to USDA contains required information including all exceptions/exemptions					
○ Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards					
○ Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies					
○ Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency					

• Records (PHS Policy, IV.E.)					
○ IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years					
○ Records of IACUC reviews of animal activities include all required information[x]					
○ Records of IACUC reviews are maintained for 3 years after the completion of the study					

8. Veterinary Care (See also next section - Veterinary Care)	**A***	**M**	**S**	**C**	**NA**
• An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care[xi]					
• Veterinary access to all animals is provided (*Guide*, p 14) [must]					
• Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (*Guide*, p 14) [must]					
• Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (*Guide*, p 5) [must]					
• Veterinarian provides consultation when interventional control is not possible (*Guide*, p 5) [must]					
• If part time /consulting veterinarian, visits meet programmatic needs (*Guide*, p 14)					
• Regular communication occurs between veterinarian and IACUC (*Guide*, p 14)					
• Veterinarian(s) have experience and training in species used (*Guide*, p 15) [must]					
• Veterinarian(s) have experience in facility administration/management (*Guide*, p 15)					

9. Personnel Qualifications and Training	**A***	**M**	**S**	**C**	**NA**
• All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]					
○ Veterinary/other professional staff (*Guide*, p 15-16)					
○ IACUC members (*Guide*, p 17)					
○ Animal care personnel (*Guide*, p 16)					
○ Research investigators, instructors, technicians, trainees, and students (*Guide*, pp 16-17)					
• Continuing education for program and research staff provided to ensure high quality care and reinforce training (*Guide*, pp 16-17)					
• Training is available prior to starting animal activity (*Guide*, p 17)					
• Training is documented (*Guide*, p 15)					
• Training program content includes: (*Guide*, p 17)					
○ Methods for reporting concerns (*Guide*, p 17)					
○ Humane practices of animal care (e.g., housing, husbandry, handling) [xii]					
○ Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (*Guide*, p 17)[xiii]					
○ Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.g.)					
○ Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.)					
○ Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (*Guide*, p 20)					
○ Animal care and use legislation (*Guide*, p 17)					
○ IACUC function (*Guide*, p 17)					

	○ Ethics of animal use and Three R's (*Guide*, p 17)					

10. Occupational Health and Safety of Personnel	**A***	**M**	**S**	**C**	**NA**
• Program is in place and is consistent with federal, state, and local regulations (*Guide*, p 17) [must]					
• Program covers *all* personnel who work in laboratory animal facilities (*Guide*, p 18)					
• Changing, washing, and showering facilities are available as appropriate (*Guide*, p 19)					
• Hazardous facilities are separated from other areas and identified as limited access (*Guide*, p 19)					
• Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (*Guide*, p 20)					
• Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (*Guide*, p 20)					
• Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (*Guide*, p 21)					
• Personal Protective Equipment for the work area is appropriate and available (*Guide*, p 21)					
• Program for medical evaluation and preventive medicine for personnel includes:					
○ Pre-employment evaluation including health history (*Guide*, p 22)					
○ Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (*Guide*, p 22)					
○ Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (*Guide*, p 23)					
○ Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (*Guide*, p 23)					
○ Promotes early diagnosis of allergies including preexisting conditions (*Guide*, p 22)					
○ Considers confidentiality and other legal factors as required by federal, state and local regulations (*Guide*, p 22) [must]					
○ If serum samples are collected, the purpose is consistent with federal and state laws (*Guide*, p 22) [must]					
• Waste anesthetic gases are scavenged (*Guide*, p 21)					
• Hearing protection is provided in high noise areas (*Guide*, p 22)					
• Respiratory protection is available when performing airborne particulate work (*Guide*, p 22)					
• Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:					
○ Tuberculosis screening provided for all exposed personnel (*Guide*, p 23)					
○ Training and implementation of procedures for bites, scratches, or injuries associated with macaques (*Guide*, p 23)					
○ PPE is provided including gloves, arm protection, face masks, face shields, or goggles (*Guide*, p 21)					
○ Injuries associated with macaques are carefully evaluated and treatment implemented (*Guide*, p 23)					
• Occupational safety and health of field studies is reviewed by OSH committee or office (*Guide*, p 32)					

11. Personnel Security	A*	M	S	C	NA
• Preventive measures in place include pre-employment screening, and physical and IT security (*Guide*, p 23)					

12. Investigating & Reporting Animal Welfare Concerns	A*	M	S	C	NA
• Methods for investigating and reporting animal welfare concerns are established (*Guide*, p 23) [must]					
• Reported concerns and corrective actions are documented (*Guide*, p 24)					
• Mechanisms for reporting concerns are posted in facility and at applicable website with instructions (*Guide*, p 24)					
○ Includes multiple contacts (*Guide*, p 24)					
○ Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (*Guide*, p 24)					

* **A** = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)
NA = not applicable

NOTES:

[1] The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

[1] Part 2 Subpart C - Research Facilities

-2.31(b)(2) - "The Committee shall be composed of a Chairman and at least two additional members; at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]

[1] 2.32(c)(4) - "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]

[1] 2.31(d)(5) - "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]

[1] 2.31(d)(1)(x) - "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]

[1] 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

[1] 2.36(b)(3) - "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]

[1] 2.31(c)(3) - "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]

[1] 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

[1] In addition to PHS requirements for IACUC review/application for funding, USDA regulations require: sources...used to determine that alternatives were not available."

[1] 2.33(a)(1) - "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]

[1] 2.32(c) - "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."

[1] 2.32(c) - additional specifications include:
-"proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"
-"methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."
-"utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research, that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act." [USDA training specifications are more detailed than PHS Policy].

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

Semi-annual Facility Inspection Checklist

About the checklist

The Facility Inspection Checklist is provided to assist institutions in conducting their semiannual reviews facilities for the care and use of animals. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), section IV.B.1.-2., requires the Institutional Animal Care and Use Committee (IACUC) to inspect all of the institution's animal facilities at least once every 6 months using the *Guide for the Care and Use of Laboratory Animals: Eighth Edition (Guide)* as a basis for evaluation.

How to use the checklist

This checklist is a tool to assist IACUCs in conducting thorough semi-annual reviews. The checklist covers the major topics of the *Guide* and the requirements of the PHS Policy. The checklist does not replace the *Guide*, but should be utilized in conjunction with the *Guide.* The *Guide* provides the standards, recommendations, and descriptions of desired outcomes necessary to evaluate and inspect an animal care and use program. Relevant references for the *Guide* and the PHS Policy are noted. Endnotes are included to reference specific U.S. Department of Agriculture (USDA) regulatory requirements that differ from the PHS Policy. Topics that are new to this version of the checklist or identified as a "must" in the *Guide* are highlighted. A column to identify changes that have occurred in the institution's program for animal care and use (PHS Policy IV.A.1.a.-i.) since the last review is also a new feature.

The checklist consists of the following sections:

- Semiannual Facility Inspection Checklist
    - Terrestrial Animal Housing and Support Areas
    - Aquatic Animal Housing and Support Areas
    - Cagewash
    - Special Facilities: Aseptic Surgery
    - Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies
- Endnotes

It is recommended that the physical aspects of a program require visual observation to evaluate, it is recommended that the Facility Inspection section be completed during an inspection of the facilities, including satellite facilities.

A table is provided, "Semiannual Facility Inspection Report," as a format for the IACUC to organize and track information regarding deficiencies, and plans and schedules for correction. IACUCs may choose to attach the table to the Semiannual Report to the Institutional Official.

Questions or comments?
Suggestions or comments about this checklist should be e-mailed to: ar-ehs@wtamu.edu

I. Semiannual Facility Inspection Checklist

Terrestrial Animal Housing and Support Areas
Date
Location

	A*	M	S	C	NA
• **Location:**					
○ animal areas separate from personnel areas (*Guide*, p 134)					
○ separation of species (*Guide*, p 111)					
○ separation by disease status (*Guide*, p 111)					
○ security and access control (*Guide*, p 151)					
• **Construction:**					
○ corridors (*Guide*, p 136)					
○ animal room doors (*Guide*, p 137)					
○ exterior windows (*Guide*, p 137)					
○ floors (*Guide*, p 137)					
○ drainage (*Guide*, p 138)					
○ walls and ceilings (*Guide*, p 138)					
○ heating ventilation and air conditioning (*Guide*, p 139)					
○ power and lighting (*Guide*, p 141)					
○ noise control (*Guide*, p 142)					
○ vibration control (*Guide*, p 142)					
○ environmental monitoring (*Guide*, p 143)					
• **Room/Cage:**					
○ temperature and humidity (*Guide*, p 43)					
○ ventilation and air quality (*Guide*, p 45)					
○ illumination (*Guide*, p 47)					
○ noise and vibration (*Guide*, p 49)					
I. Primary Enclosure:					
○ space meets physiologic, behavioral [xiv], and social[xv] needs (*Guide*, pp 51, 55-63)					
○ secure environment provided (*Guide*, p 51)					
○ durable, nontoxic materials in good repair and no risk of injury (*Guide*, p 51)					
○ flooring is safe and appropriate for species (*Guide*, p 51)					
○ adequate bedding and structures for resting, sleeping, breeding (*Guide*, p 52)					
○ objective assessments of housing and management are made (*Guide*, p 52)					
○ procedures for routine husbandry are documented (*Guide*, p 52)					
○ socially housed animals can escape or hide to avoid aggression (*Guide*, p 55)					
○ cage height provides adequate clearance (*Guide*, p 56)					
○ animals express natural postures, can turn around, access food and water, and rest away from urine and feces (*Guide*, p 56) [must]					
○ rationale[xvi] for *Guide*/USDA space exceptions approved by IACUC and based on performance indices (*Guide*, p 56)					
○ dogs and cats allowed to exercise and provided human interaction (*Guide*, p 58)					
○ nonhuman primates are socially housed except for scientific, veterinary or behavior reasons (*Guide*, pp 58-59)					
○ single housing of nonhuman primates is for shortest duration possible (*Guide*, p 60)					
o opportunities for release into larger enclosures is considered for single caged nonhuman primates (*Guide*, p 60)					
o agricultural animals are housed socially (*Guide*, p 60)					

	o food troughs and water devices for agricultural animals allow access for all animals (*Guide*, p 60)					
•	**Environmental Enrichment, Behavioral and Social Management:**					
	o structures and resources promote species typical behavior (*Guide*, pp 52-54)					
	o novelty of enrichment is considered (*Guide*, p 53)					
	o species specific plans for housing including enrichment, behavior and activity are developed and reviewed regularly by IACUC, researchers and veterinarian (*Guide*, pp 53, 58, 60, 63)					
	o animal care personnel receive training to identify abnormal animal behaviors (*Guide*, p 53)					
	o stability of pairs or groups is monitored for incompatibility (*Guide*, p 64)					
	o single housing is justified for social species (*Guide*, p 64)					
	o single housing is limited to the minimum period necessary (*Guide*, p 64)					
	o additional enrichment for single housed animals is provided (*Guide*, p 64)					
	o single housing is reviewed regularly by IACUC and veterinarian (*Guide*, p 64)					
	o habituation to routine procedures is part of enrichment program (*Guide*, p 64)					
•	**Sheltered or Outdoor Housing:** (e.g., barns, corrals, pastures, islands)					
	o weather protection and opportunity for retreat (*Guide*, p 54) [must]					
	o appropriate size (*Guide*, p 54)					
	o ventilation and sanitation of shelter (no waste/moisture build-up) (*Guide*, p 54)					
	o animal acclimation (*Guide*, p 55)					
	o social compatibility (*Guide*, p 55)					
	o roundup/restraint procedures (*Guide*, p 55)					
	o appropriate security (*Guide*, p 55)					
•	**Naturalistic Environments:**					
	o animals added /removed with consideration of effect on group (*Guide*, p 55)					
	o adequate food, fresh water, and shelter ensured (*Guide*, p 55)					
•	**Food:**					
	○ feeding schedule and procedures including caloric intake management (*Guide*, pp 65-67)					
	○ contamination prevention (*Guide*, p 65)					
	○ vendor quality control (*Guide*, p 66)					
	○ storage in sealed containers (*Guide*, p 66)					
	○ expiration date labeling (*Guide*, p 66)					
	○ vermin control (*Guide*, p 66)					
	○ rotation of stocks (*Guide*, p 66)					
•	**Water:**					
	○ ad libitum unless justified (*Guide*, pp 67-68)					
	○ QC procedures (*Guide*, pp 67-68)					
•	**Bedding and Nesting Materials:**					
	○ species appropriate (*Guide*, pp 68-69)					
	○ keeps animals dry (*Guide*, pp 68-69)					
	○ QC procedures (*Guide*, pp 68-69)					
	o hazardous wastes are rendered safe before removal from facility (*Guide*, pp 73-74) [must]					
	o animal carcasses (*Guide*, pp 73-74)					
•	**Pest Control:**					
	o regularly scheduled (*Guide*, p 74)					
	o documented program including control of rodent pests and insecticide use (*Guide*, p 74)					
•	**Emergency, Weekend, and Holiday Animal Care:**					
	o care provided by qualified personnel every day (*Guide*, p 74)					

o	provision for accessible contact information (*Guide*, p 74)					
o	monitoring of backup systems (*Guide*, p 143)					
o	veterinary care available after hours, weekends, and holidays (*Guide*, pp 74, 114) [must]					
o	a disaster plan that takes into account both personnel and animals (*Guide*, p 75)					
•	**Identification:**					
o	cage/rack cards contain required information (*Guide*, p 75)					
o	genotype information included and standardized nomenclature used when applicable (*Guide*, p 75)					
•	**Recordkeeping:**					
o	clinical records accessible and contain appropriate information (*Guide*, pp 75-76)					
o	records are provided when animals are transferred between institutions (*Guide*, p 75)					
•	**Breeding Genetics and Nomenclature:**					
o	appropriate genetic records, management and monitoring procedures (*Guide*, p 76)					
o	phenotypes that affect wellbeing are reported to IACUC and effectively managed (*Guide*, p 77)					
•	**Storage:**					
o	adequate space for equipment, supplies, food, bedding and refuse (*Guide*, p 141)					
o	bedding in vermin-free area and protected from contamination (*Guide*, p 141)					
o	food in vermin-free, temperature and humidity-controlled area and protected from contamination (*Guide*, p 141)					
o	refuse storage is separate (*Guide*, p 141)					
o	carcass and animal tissue storage is separate, refrigerated below 7ºC and cleanable (*Guide*, p 141)					
•	**Personnel:**					
o	adequate space for locker rooms, administration and training (*Guide*, p 135)					

***A** = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)
NA = not applicable

NOTES:

[xiv] Part 3 Subpart A 3.8 - "...research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. In addition the plan must be approved by the attending veterinarian. The plan must provide written standard procedures..."

[xv] Part 3 Subpart D 3.81 - "...research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates."

[xvi] Part 3 Subpart A 3.6(c)(1) - "Each dog housed in a primary enclosure must be provided with a minimum amount of floor space, calculated as follows:
(length of dog in inches + 6)^2 /144 = required floor space in square feet)."

- Part 3 Subpart D 3.80 (b) - "Primary enclosures [for nonhuman primates] must meet the minimum space requirements provided in this subpart."

- In situations where the USDA regulations and the *Guide* differ with respect to space requirements, the larger of the two must be followed.