



ENVIRONMENTAL HEALTH AND SAFETY STANDARD OPERATING PROCEDURES

SOP No. 15.99.05.W1.02AR WTAMU Institutional Animal Care and Use Procedure

Approved: August 15, 2010

Last Revised: December 6, 2018

Next Scheduled Review: December 6, 2023

Environmental Health and Safety at WTAMU is composed of two distinct but integrated environmental safety departments that 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 all fire detection and suppression systems. General Safety (GHS-EHS) promotes safe work and health practices, to all faculty, staff, students, and visitors. Examples of General Health and Safety components include: office safety, proper lifting techniques, trip and fall prevention.

Supplements [TAMUS Regulation 15.99.05](#)

Contents

| | |
|---|----|
| Purpose | 2 |
| Roles and Responsibilities | 3 |
| The IO and Animal Research Protocols | 4 |
| Attending Veterinarian (AV) | 4 |
| The Committee Chair | 5 |
| Committee Members | 5 |
| Environmental Health and Safety Program (EHSP) | 6 |
| Procedure on Use of Animals and Lab Animal Care Facilities | 7 |
| Special Considerations for IACUC Review | 9 |
| <i>Experimental and Humane Endpoints</i> | 9 |
| <i>Unexpected Outcomes</i> | 9 |
| <i>Physical Restraint</i> | 10 |
| <i>Multiple Survival Surgical Procedures</i> | 11 |
| <i>Food and Fluid Regulation</i> | 11 |
| <i>Use of Non-Pharmaceutical-Grade Chemicals and Other Substances</i> | 12 |
| <i>Use of Activated or Inactivated Pathogenic Microorganisms and Extracted genomic material</i> | 12 |
| <i>Field Investigations</i> | 12 |
| <i>Agricultural Animals</i> | 13 |
| <i>Population Management Identification</i> | 14 |
| Application Processing | 14 |
| Application for Multiple Projects, Co-submission and Re-review | 14 |
| Overseas and Field Research and IACUCs from Other Institutions | 15 |
| Preparation and Review of Blanket Protocols | 15 |
| AVAU Duration, Annual Reports and Renewal | 16 |

| | |
|---|----|
| Tracking of IACUC Approval and Approved Animal Numbers | 16 |
| IACUC Meetings..... | 16 |
| IACUC Inspections..... | 16 |
| IACUC Meetings and Inspection Reports..... | 17 |
| IACUC Proposed Activity Reviews..... | 18 |
| IACUC Committee Review Checklist | 18 |
| Emergency Operations for IACUC..... | 19 |
| Veterinary Care | 19 |
| Medical Management..... | 20 |
| Surgery..... | 20 |
| Anesthesia and Analgesia..... | 21 |
| Euthanasia | 22 |
| Training..... | 23 |
| Emergency Care..... | 24 |
| Animal Procurement | 24 |
| Transportation of Animals..... | 24 |
| Post Approval Monitoring..... | 24 |
| IACUC Authorization to Suspend and to Re-approve Activities..... | 25 |
| Training..... | 25 |
| Occupational Health and Safety | 26 |
| Record Keeping Requirements..... | 26 |
| Annual Report | 27 |
| Semi-Annual Evaluation | 27 |
| The Basis for the Evaluation..... | 28 |
| Adoption of OLAW | 28 |
| General References on Animal Care and Use..... | 29 |
| Appendix A..... | 30 |
| Application for Vertebrate Animal Use (AVAU) APPLICATION INSTRUCTIONS | 30 |
| Appendix B | 34 |
| APPLICATION FOR VERTEBRATE ANIMAL USE | 34 |
| Categories..... | 46 |
| Appendix C | 48 |
| Animal Care and Use Protocol Amendment..... | 48 |
| Appendix D..... | 49 |
| WTAMU IACUC Committee Review Checklist..... | 49 |
| Appendix E | 51 |
| IACUC Letter of Approval | 51 |
| Appendix F..... | 53 |
| Memorandum to IO | 53 |
| APPENDIX G | 55 |
| IACUC BI-ANNUAL INSPECTIONS REMEDIAL ACTIONS | 55 |
| Appendix H..... | 60 |
| APPLICATION FOR THE STUDY OF WILD ANIMALS | 60 |
| Appendix I..... | 82 |
| Semiannual Program Review Checklist..... | 82 |
| Appendix J..... | 90 |
| Semiannual Facility Inspection Checklist..... | 90 |

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) Policy (PHS 2002) 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 Use 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 Application 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 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 wellbeing 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 wellbeing 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 Vice President for Research and Compliance (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 Chair

The Committee Chair is appointed by the IO/VPRC and the chair'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 chair shall submit the biannual inspection and programmatic review using the "Memorandum to the IO" (Appendix F) to the Institutional Official for review and approval.

Committee Members

The Panhandle oriented "Cooperative Research, Educational and Extension Team (CREET)" is an interinstitutional collaboration between West Texas A & M University, Texas AgriLife Extension Service, Texas Veterinary Medical Diagnostic Laboratory 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.

- A. Chair: Dr. Gary Bigham, Education (2014-2017)
- B. One veterinarian: Dr. Robert Ballinger, Palo Duro Animal Hospital for small animal (2014-2017) and Dr. Chris Morrow, Mobile Veterinary Practice (2015 – 2018)
- C. Three representatives unaffiliated with University:
 - 1. Pablo Pinedo, Texas AgriLife (2014-2017) (CREET)
 - 2. Andy Cole, US Dept. of Agriculture, Agricultural Research Service (USDA-ARS) (2014-2017) (CREET)
 - 3. Melanie Hartman, U. S. Fish and Wildlife Service, Buffalo Lake National Wildlife Refuge (2014-2017)
- D. One representative from non-science discipline: Lisa Davis, Nursing (2014-2017)
- E. Five representatives from science disciplines with experience in animal research
 - 1. Dr. John Richeson, Agriculture (2013-2016)
 - 2. Dr. Gary Barbee, Environmental Science (2014-2017)
 - 3. Dr. Lance Baker, Agriculture (2013-2016)
 - 4. Dr. Richard Kazmaier, Biology (2013-2016)
 - 5. Dr. Maxine DeButte, Psychology (2013-2016)
- F. Non-voting members:
 - 1. Vice President for Research and Compliance
 - 2. The Director of Sponsored Research
 - 3. Director of Academic and Research Environmental Health and Safety

Environmental Health and Safety Program (EHSP)

The Supervisor of Environmental Health and Safety Program (EHSP) who serves as a support role to the IO, IACUC chairperson 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 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. Application for Vertebrate Animal Use The application form can be found at www.wtamu.edu/iacucapplication 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 chair person shall assign each approved AVAU a specific number indicating the sequential AVAU approved and the month and year approved using the following format.

01-01-10 (Indicating approved AVAU #1 in January, 2010).

Based on the IACUC committee’s recommendations for approval, the IACUC chair person 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 nonanimal 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 toxicologic 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, 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; Saucedo 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 wellbeing. 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 postprocedural 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 Investigations may involve the observation or use of nondomesticated 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 concern 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 (Castelhana-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, AVAU, 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 rapid turnaround time on review of an Application for Vertebrate Animal Use (AVAU), s/he should contact EHSP.

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 Chair 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 Supervisor of EHSP 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 significant changes are anticipated in an on-going project, a Protocol Amendment Form (Appendix C) must be submitted to EHSP prior to initiation of these changes. However, total approval time for a single Application for Vertebrate Animal Use may not exceed three years. Consult the EHSP (phone 806-651-2270, e-mail AR-EHS@wtamu.edu for information).

Applications can be obtained from the IACUC website: www.wtamu.edu/iacuc. 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, e-mail AR-EHS@wtamu.edu). After review and approval, the Chair of the IACUC will send the approval information to the principal investigator 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 human care and use of animals, using title 9, chapter 1, subchapter A-Animal Welfare, as a basis for evaluation (9CFR2.31(c)(1)). The IACUC meetings will be called by the IACUC chairperson 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 (9CFR2.31(c)(2)). In addition, the WTAMU committee will utilize the above guidance in the conduct of the biannual 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)(9CFR2.31(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 result 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 Institutional Office 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 9CFR2.31 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 9CFR2.31 (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 is attached at Appendix D and addresses the following requirements of 9CFR2.31(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 9CFR2.31 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 9CFR part 1 Section 1.1 of Subchapter A, unless a deviation is justified for scientific reasons, in writing, by the investigator.

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, and the Buffalo Mascot 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 wellbeing 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 principal investigator 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 presurgical 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, Anesthesia, Pain, and Surgery). 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 anesthetic 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, 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 be also used to ensure death. All methods of euthanasia should be reviewed and approved by the veterinarian 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 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 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 Internet 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, 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 semiannual 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. 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 bi-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 Institutional Official.** 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 semiannual 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 the implementing AWARs. In the event that WTAMU receives National Institute of Health

(NIH) or National Park Service (NPS) funding this 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 outline 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 <http://www.wtamu.edu/academics/iacuc-federal-regulations.aspx> 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

Application for Vertebrate Animal Use (AVAU) APPLICATION INSTRUCTIONS

**West Texas A&M
University IACUC Guideline
12/12/12**

Specific Instructions by AVAU Sections

The following are specific, page-by-page instructions on completing the AVAU form. Numbers refer to the numbered items of the AVAU form. The form can be downloaded into MS Word, WordPerfect, or PDF. Handwritten forms will be returned.

Cover Page:

ID#: The IACUC committee will assign a specific number, unique to each protocol. Do not write in this space.

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

Submitted to: 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.

New, Renewal: Check appropriate box. Renewal applications should provide previous IACUC protocol number.

The AVAU form has two major sections: the Confidential Section and the Non-Confidential Section. Both sections must be completed. The Confidential Section is not subject to release under the Freedom of Information Act.

Confidential Section:

1)

- a. 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.
- b. For animals that will remain at the research facility, provide the name of the facility and the room number.
- c. List locations where procedures will be performed. Location of surgery areas should also be included here. (Examples: 1. Rat ovariectomy, ANNS room 216. 2. Oral dosing of cats, KRC, room 186G.) Procedures performed in investigator's laboratory or at an off-campus site should be listed in 1d.
- d. 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 two IACUC members.
- e. 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 form who work with animals unsupervised must undergo WTAMU IACUC training. For individuals involved in animal care and use, years of experience with the animal listed and years of experience performing the procedures described must be included.

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 Chairperson if you have questions. Contact 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** after the 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

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. Abbreviations and acronyms must be defined.

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.

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.

Explain why the species selected is a good choice for the proposed activity.

5a. **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

Category A: Experiments involving either no living materials or use of plants, bacteria, protozoa, unhatched eggs, cell culture or invertebrate animal species. **NO REVIEW REQUIRED**

Category B: Animal use activities which involve only breeding, conditioning, or holding.

Category C: Animal use activities which involve no pain, distress greater than an injection, or use of pain relieving drugs. Routine procedures (e.g. injections, blood sampling, physical examinations, food/water deprivations for a few hours) fall into this category.

Category D: Animal use activities which involve accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs are used. Procedures, which would generally call for the use of anesthetics, analgesics or tranquilizers in human beings, fall into this category.

Category E: Animal use activities which involve accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs are not used. An explanation of the procedures producing pain or distress in the animals and reasons such drugs were not used shall be included in Section A of the AVAU.

Total number of animals: Include the maximum number of animals that are needed for the three-year life 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.)

Check the appropriate answer

Check the appropriate answer

Check the appropriate answer

Explain how it was determined to use the number of animals shown in 5a. 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. $10 \times 3 \times 2 = 60$ (should be same number as "total" in 5a). Explanation should include, when appropriate, a statistical justification for group size.

Section B: Invasive Sample Collection

Only include those sample collections that are invasive. 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. Contact EHSP (806-651-2270) for additional information. Contact the IACUC Chairperson for information on mouse antibody production testing, rat antibody production testing, and hamster antibody production testing.

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

b. The plan for checking the animal's condition must be thoroughly outlined, including specific information on the provisions for euthanasia should it become necessary.

c. 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.

2. a. 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*.

b. Describe how it will be determined that animals are sufficiently anesthetized and how vital signs are being monitored.

c. Describe how the animal's recovery from anesthesia will be monitored.

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

3. Restraint: 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.

4. Exceptions to standards: Contact EHSP (phone: 806-651-2270, e-mail: AR-EHS@wtamu.edu) or the IACUC chairperson 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

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

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

Aseptic technique must be used for all survival surgeries. Major surgical procedures on non-rodent species must be conducted in facilities intended for that purpose unless otherwise approved by the IACUC.

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*.

This section should be used to address multiple survival surgery. 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. Complete this information in D.

Section F: Euthanasia/Disposition

Self-explanatory.

The American Veterinary Medical Association (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.

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.

Section G: Alternatives

A 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.

This 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.

Provide a written narrative of how it was determined that alternatives to the proposed animal use activity do not exist. Use the information obtained from 1-3 in Section G to assist in writing this summary.

APPLICATION FOR VERTEBRATE ANIMAL USE

WEST TEXAS A&M UNIVERSITY
(revised 12/12/12)

ID# _____ (Committee Use Only)

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 the course.

Only typed forms will be accepted.

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 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.

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

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.

Date of Review: _____

___ Approved ___ Approved with modification (Attached) ___ Not Approved

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

Chairman, Institutional Animal Care and Use Committee

EXPIRATION DATE: _____

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, 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) _____ Phone Number _____
Department _____
Mailing Address _____
E-mail address: _____ Fax Number _____
Lab Contact (Technician) and phone number: _____.

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? (A refresher course is required every two years.) (a.) Yes (b.) No - Please explain why not.

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?

a. Yes

b. 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

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

1) a. 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

b. Where will animals be housed?

Nance Ranch, WTAMU Feedlot, Old Main (OM room number ____),

Agricultural Natural Sciences (ANS room number ____), WTAMU Horse Center,

WTAMU Meat Lab, Agricultural Education Learning Center, USDA Agricultural Research Services

Other – please specify

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

Nance Ranch, WTAMU Feedlot, Old Main (OM room number ____),

Agricultural Natural Sciences (ANS room number ____), WTAMU Horse Center,

WTAMU Meat Lab, Agricultural Education Learning Center, USDA Agricultural Research Services

Other – please specify

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

2

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 and method of transport.

List all personnel in your group who will care for and work with the animals without direct (in-lab) supervision; include the PI. For each person:

Indicate their role in the project.

List 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

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

PRINCIPAL INVESTIGATOR ASSURES:

That she/he will abide 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 he/she 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 (Completion of this section is required for all applications)

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.)

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.

1. 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.

2. Other information services utilized (list):

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

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

5. a. Provide the following information for all animals. No animal should be listed more than once; count each in highest proposed category of use.

Category B – Animals being bred or held but not yet used in research

Category C - No stress, pain, or use of pain-relieving drugs

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**** | 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.

- b. Is this a laboratory exercise for purposes of teaching students? _____ Yes _____ No
- c. Do you have data from prior studies that is sufficient to calculate the sample size? _____ Yes _____ No
- d. 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:

e. 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.5.a) 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]/Hamster 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 Environmental Health and Safety?

___ Yes # _____ No ___

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 Environmental Health and Safety, phone 806-651-2134.

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, and 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 action 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.1.

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 experimental 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. Provide 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 ensured?

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

8. 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 an 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. Surgery

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

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 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. Breeding colony includes parents and offspring.
- Newly acquired animals that are handled in accordance with IACUC approval and applicable regulations.
- Animals held under proper captive conditions or wild animals that are being observed.

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

Examples:

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

Classification D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.

Examples:

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

Classification E: Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

Examples:

- Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain.
- Surgical and postsurgical sequella from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.
- Negative conditioning via electric shocks that would cause pain in humans.
- Chairing of nonhuman primates not conditioned to the procedure for the time period used.

**Animal Care and Use Protocol Amendment
West Texas A&M University
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: _____ Address: _____
 E-mail: _____
 Protocol title: _____

Which type(s) of changes in protocol 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 | _____ | | |
| 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

WTAMU IACUC Committee Review Checklist
IACUC REVIEW FOR VERTEBRATE ANIMAL USE
(Revised 02/23/12)

ID# _____ (Committee Use Only)

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

- (i) Procedures involving animals will avoid or minimize discomfort, distress, and pain to animals; (YES, NO, N/A) Comment:

- (ii) 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; (YES, NO, N/A) Comment:

- (iii) The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments; (YES, NO, N/A) Comment:

- (iv) 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; (YES, NO, N/A) Comment:

 - B. Involve, in their planning, consultation with the attending veterinarian or his or his designee; (YES, NO, N/A) Comment:

 - C. Not include the use of paralytics without anesthesia. (YES, NO, N/A) Comment:

- (v) 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; (YES, NO, N/A) Comment:

- (vi) The animals' living conditions will be appropriate for their species in accordance with part 3 of subchapter A 9CFR2.31. 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; (YES, NO, N/A)
Comment:
- (vii) Medical care for animals will be available and provided as necessary by a qualified veterinarian; (YES, NO, N/A) Comment:
- (viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures; (YES, NO, N/A) Comment:
- (ix) 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; (YES, NO, N/A)
Comment:
- (x) 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; (YES, NO, N/A) Comment:
- B. Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; (YES, NO, N/A) Comment:

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; (YES, NO, N/A) Comment:

(xi) 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. (YES, NO, N/A) Comment:

IACUC COMMITTEE MEMBER: _____

_____ Approved _____ Approved with modification (Attached) _____ Not Approved

Will site visit be conducted? (YES, NO, N/A)

Appendix E

IACUC Letter of Approval

MMDDYYYY

P.I
Address
Canyon, TX 79016

We are pleased to inform you that your proposal # XX-XX-XX 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**", 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 IACUC. This approval is extended to you for the remainder of the research project or until (3 years - enter date). You will submit an annual report in May/October of each year notifying the committee the status of this research project. Should you make changes in the methodology as it affects animal subjects, you must submit an amendment to the IACUC. The WTAMU IACUC will conduct a compliance review in May to evaluate your compliance with the approved plan and requirements under the referenced laws, regulations and policies.

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

Sincerely,

Dr. Gary Bigham, Chair WTAMU IACUC
Assistant Professor, Educational Leadership

Memorandum to IO

Memorandum to: Angela Spaulding, West Texas A&M University Research Compliance Officer

From: Institutional Animal Care and Use Committee

Subject: Semiannual Report of the Program Review and Facility Inspection/Requested Inspection

Date: [insert 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 for any by the IACUC committee for any requested inspections by the IO, and, as needed, to address any public and/or employees complaints.**

Pre-evaluation Checklist:

_____All committee members have been provided access to the approved WTAMU 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.

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 A or B:

- A. There were no departures during this reporting period.
- B. The following departures have been reviewed and approved by the IACUC:
[include reason for each departure]

I. Deficiencies in the Institution’s Animal Care and Use Program

Animal Care and Use Program Review Date(s):

Select A or B:

- A. There were no deficiencies in the program during this reporting period.
- B. 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.]*

II. Deficiencies in the Institution’s Animal Facility

Animal Facility Inspection Date(s):

Select A or B:

- A. There were no deficiencies in the animal facility during this reporting period.
- B. 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.]*

III. Minority Views

Select A or B:

- A. No minority views were submitted or expressed.
- B. The following minority views were expressed: *[insert minority views here or attach]*

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

| |
|--|
| |
|--|

V. Signatures [*signatures of a majority of the IACUC members*]

| Names of IACUC Members | Signatures |
|------------------------|------------|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

APPENDIX G

IACUC BI-ANNUAL INSPECTIONS REMEDIAL ACTIONS

IACUC Programmatic Improvement Recommendations to the IO.

The IACUC committee shall not less than bi-annually review the IACUC program as specified under the AWA and implementing regulations conformance of the program to any new and applicable requirements and the Programs success in meeting the objectives of the AWA and other applicable requirements. If the IACUC committee identified program deficiencies the committee will prepare recommendations for submittal to the I.O. regarding any aspect of the research facility's animal program, facilities, or personnel training (9CFR2.31(c)(5).

The IO also, in consultation with the IACUC, reviews IACUC bi-annual recommendations and takes the appropriate action as specified in 9CFR2.31(d)(xi)(7).

(7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity; and....

In addition,

If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. 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; [(9CFR2.31(c)(3)]

IACUC Committee Remedial Actions Process and Authorities

The IACUC committee has the authority to require investigators address minor and significant deficiencies as specified in the AWA and implementing regulations 9CFR2.31(d)(xi)(2-7) as follows:.

(2) Prior to IACUC review, each member of the Committee shall be provided with a list of proposed activities to be reviewed. Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, 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 of the IACUC, and with the 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;

(3) The IACUC may invite consultants to assist in the review of complex issues arising out of its review of proposed activities. Consultants may not approve or withhold approval of an activity, and may not vote with the IACUC unless they are also members of the IACUC;

(4) The IACUC shall notify principal investigators and the research facility in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the principal investigator an opportunity to respond in person or in writing. The IACUC may reconsider its decision, with documentation in Committee minutes, in light of the information provided by the principal investigator;

(5) The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually;

(6) The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. The IACUC may suspend an activity 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;

(7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity; ...

REFERENCES

9CFR231 Institutional Animal Care and Use Committee (IACUC) § 2.31 Institutional Animal Care and Use Committee (IACUC).

(a) The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility's animal program, facilities, and procedures. Except as specifically authorized by law or these regulations, nothing in this part shall be deemed to permit the Committee or IACUC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility.

(b) *IACUC membership.* (1) The members of each Committee shall be appointed by the Chief Executive Officer of the research facility;

(2) The Committee shall be composed of a Chairman and at least two additional members;

(3) Of the members of the Committee:

(i) At least one shall be a Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the research facility;

(ii) At least one shall not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals;

(4) If the Committee consists of more than three members, not more than three members shall be from the same administrative unit of the facility.

(c) *IACUC functions.* With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

(1) Review, at least once every six months, the research facility's program for humane care and use of animals, using title 9, chapter I, subchapter A—Animal Welfare, as a basis for evaluation;

(2) Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter I, 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 inspection;

(3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; *Provided, however,* That the IACUC may determine the best means of conducting evaluations of the research facility's programs and facilities; and *Provided, further,* That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite *ad hoc* consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion of the required semiannual 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. The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A—Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. 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. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. 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;

(4) 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;

(5) Make recommendations to the Institutional Official regarding any aspect of the research facility's animal program, facilities, or personnel training;

(6) 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 paragraph (d) of this section;

(7) 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; and

(8) Be authorized to suspend an activity involving animals in accordance with the specifications set forth in paragraph (d)(6) of this section.

(d) IACUC review of activities involving animals.

(1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; *Provided, however,* That field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:

(i) Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals;

(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, 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;

(iii) The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments;

(iv) 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;

(v) 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;

(vi) The animals' living conditions will be appropriate for their species in accordance with part 3 of this subchapter, 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;

(vii) Medical care for animals will be available and provided as necessary by a qualified veterinarian;

(viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;

(ix) Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical 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;

(x) 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; or

(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;

(xi) Methods of euthanasia used must be in accordance with the definition of the term set forth in 9 CFR part 1, §1.1 of this subchapter, unless a deviation is justified for scientific reasons, in writing, by the investigator.

(2) Prior to IACUC review, each member of the Committee shall be provided with a list of proposed activities to be reviewed. Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, 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 of the IACUC, and with the 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;

(3) The IACUC may invite consultants to assist in the review of complex issues arising out of its review of proposed activities. Consultants may not approve or withhold approval of an activity, and may not vote with the IACUC unless they are also members of the IACUC;

(4) The IACUC shall notify principal investigators and the research facility in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the principal investigator an opportunity to respond in person or in writing. The IACUC may reconsider its decision, with documentation in Committee minutes, in light of the information provided by the principal investigator;

(5) The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually;

(6) The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. The IACUC may suspend an activity 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;

(7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity; and

(8) Proposed activities and proposed significant changes in ongoing activities that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the research facility. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:

(1) Identification of the species and the approximate number of animals to be used;

(2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used;

(3) A complete description of the proposed use of the animals;

(4) A description of 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; and

(5) A description of any euthanasia method to be used.

[54 FR 36147, August 31, 1989, as amended by 59 FR 67611, Dec. 30, 1994; 63 FR 62926, Nov. 10, 1998]

West Texas A & M University
Institutional Animal Care and Use

APPLICATION FOR THE STUDY OF WILD ANIMALS

IN OR FROM NATURAL SETTINGS

Submit an electronic version to AR-EHS@wtamu.edu

ID# _____ (Committee Use Only)

This application applies to

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

Only typed forms will be accepted.

Title of project or activity: _____

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

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

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

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.

Date of Review: _____

Approved Approved with modification (Attached) Not Approved

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

Chairman, Institutional Animal Care and Use Committee

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) _____ Phone Number _____

Department _____.

Mailing Address _____.

E-mail address: _____ Fax Number _____

Lab Contact (Technician) and phone number: _____.

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? (A refresher course is required every two years.) (a.) Yes (b.) No - Please explain why not.

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?

a. Yes

b. No - Please describe safety precautions that will be used to protect personnel.

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

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

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

2) A.) 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

B.) Where will animals be housed?

Not Applicable

Nance Ranch, WTAMU Feedlot, Old Main (OM room number _____),

Agricultural Natural Sciences (ANS room number _____), WTAMU Horse Center,

- WTAMU Meat Lab, Agricultural Education Learning Center, USDA Agricultural Research Services
- Other – please specify

C.) Where will procedures (including surgeries) be performed? Include building and room number.

- Not Applicable
- Nance Ranch, WTAMU Feedlot, Old Main (OM room number____),
- Agricultural Natural Sciences (ANS room number____), WTAMU Horse Center,
- WTAMU Meat Lab, Agricultural Education Learning Center, USDA Agricultural Research Services
- Other – please specify

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 and method of transport.

3.) QUALIFICATIONS

List all personnel in your group who will care for and work with the animals without direct (in-lab) supervision; include the PI. For each person:

Indicate their role in the project.

List 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

| Name & Degree | Role | Years Experience/Species | Cert# |
|---------------|------|--------------------------|-------|
| | | | |
| | | | |
| | | | |
| | | | |

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

(Note: Indicate role of involved personnel as either Principal (PI), or Secondary (SI) Investigators, or technicians/assistants (T). Indicate each individual's years of experience with animals described herein (e.g., 6 yrs/snakes, 4 yrs/turtles). Certification of orientation, training, and experience regarding the regulatory, occupational health and safety, and care and use aspects of the animals requested herein is required prior to IACUC review of this protocol, and is available from the IACUC c/o Environmental Health and Safety, 806-651-2270. Certification numbers if applicable for each involved individual must be listed.)

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 #7 below for definitions)

4. FUNDING SOURCE

Is project funded?

No: Proceed to Item # 5. Yes: Provide details of funding agency and grant #:

| | |
|---------|-----------|
| Agency: | Grant # : |
|---------|-----------|

5. PROTOCOL CLASSIFICATION

Please check one.

a. New Project; Proceed to Item # 6.

3rd Yr renewal replacing previous approved IACUC Protocol #

b. 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.

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 Mammalogists for the Use of Wild Mammals in Research (<http://www.mammalsociety.org/uploads/Sikes%20et%20al%202011.pdf>), the Guidelines for Use of Fishes in Research (American Fisheries Society and American Society of Ichthyologists and Herpetologists: <http://www.asih.org/sites/default/files/documents/Resources/guidelinesfishresearch2003-draft.pdf>), the Guidelines for

Use of Live Amphibians and Reptiles in Field and Laboratory Research (American Society of Ichthyologists and Herpetologists: <http://www.asih.org/sites/default/files/documents/Resources/guidelinesherpsresearch2004.pdf>), and the Guidelines to the Use of Wild Birds in Research (The Ornithological Council: http://www.nmnh.si.edu/BIRDNET/documents/guidlines/Guidelines_August2010.pdf).

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

Signature of P.I.

Date .

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?

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). Indicate whether the planned procedures are anticipated to produce momentary, slight, or no pain, discomfort or distress (Pain Category A), more than momentary or slight pain, discomfort or distress which is alleviated by the use of appropriate anesthetics and/or analgesics (Pain Category B), or pain, discomfort, or distress, which cannot, or is not alleviated by the administration of appropriate anesthetics and/or analgesics (Pain Category C). (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 |
|-----------------|------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

8. OFF CAMPUS STUDY LOCATION.

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?

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.

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: Explain within the space below.

JUSTIFICATION FOR THE USE OF ANIMALS.

10. 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.

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

12. 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.)

No: . Proceed to Item # 14. Yes: . STOP here. This application is complete.

14. Will the captured animals ever be transported to the University?

No: . Proceed to Item # 15. Yes: . Within the space below, name the University building and room number where animals will be taken.

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

No: . Proceed to item # 16 Yes: Within the space, list the controlled substances to be used.

CAPTURE & RESTRAINT.

16. 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.)

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

No: Proceed to item # 18 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, and the dose and route of administration.

18. 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 # 19. 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.

MARKING

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

No: Proceed to item # 21. 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.)

20. 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 # 21 Yes: Justify below 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.

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

No: . Proceed to Item # 22. Yes: . Attach Appendix A, "Specimen Collection, Ante Mortem".

22. 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 # 23. Yes: . Attach Appendix B, "Test Substances".

23. 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 # 24.

24. 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 # 16, # 17, # 21, & # 22, 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 recaptured, 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 item # 25.

25. 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 # 26. Yes: . Attach Appendix C, "Animal Maintenance and Care".

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

No: . Proceed to Item # 27. Yes: . Attach Appendix D, "Surgery".

27. 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 # 28. Yes: . Attach Appendix E, "Other Experimental Procedures".

28. 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 # 29. 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.)

No: . Proceed to Item # 30. Yes: . Within the space, explain why an earlier endpoint is not possible.

30. Are animals euthanized at the completion of this study?

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 # 21 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.

Description of Appendix A is complete.

APPENDIX B: TEST SUBSTANCES

(Complete & Submit for Review Only If Response to Item # 22 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 bw), volume per administration, route (e.g., i.v., i.p., s.c.), and 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 3 rd 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 table above, 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 nonrodent 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 item 1, page 8, 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 item 1, page 8 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(s)

Date

Description of Appendix B is complete.

APPENDIX C: ANIMAL MAINTENANCE & CARE

(Complete & Submit for Review Only If Response to Item # 25 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.

APPENDIX C: ANIMAL MAINTENANCE & CARE (cont.)

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.

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 # 30, page # 6, above?

Yes: STOP here. Appendix C is complete. No: . Within the space below, describe the final disposition of the animals, below.

Description of Appendix C is complete.

APPENDIX D: SURGERY

(Complete & Submit for Review Only If Response to Item # 26 was "Yes")

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

APPENDIX D: SURGERY (cont.)

4 (cont.). Within the space provided, describe the surgical procedures in enough 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 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 nonrodent 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.)

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 2 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, justify why not. 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 nonrodent 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 nonsurvival surgical procedure, respond "No".)

No: . Proceed to item # 11. Yes: . Within the space provided, 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.

Description of Appendix D is complete.

APPENDIX E: OTHER EXPERIMENTAL PROCEDURES
(Complete & Submit for Review Only If Response to Item # 27 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: . Within the space provided, 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.

Description of Appendix E is complete.

Semiannual Program Review Checklist

About the checklist

The Semiannual Program Review Checklist is provided to assist institutions in conducting their semiannual reviews of programs 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 review the institution's program for humane care and use of animals and 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 semiannual 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:

- I. Semiannual Program Review Checklist
 - Institutional Policies and Responsibilities
 - Veterinary Care
- II. Endnotes

It is recommended that the Program Review section be completed during an IACUC meeting.

A table is provided, "Semiannual Program Review" 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 Program Review Checklist ⁱ

Institutional Policies and Responsibilities

Date:

| 1. Animal Care and Use Program NEW | | A* | M | S | C | NA |
|---|--|----|---|---|---|----|
| <ul style="list-style-type: none"> Responsibility for animal well-being is assumed by all members of the program (<i>Guide, p 1</i>) [must] | | | | | | |
| <ul style="list-style-type: none"> IO has authority to allocate needed resources (<i>Guide, p 13</i>) | | | | | | |
| <ul style="list-style-type: none"> Resources necessary to manage program of veterinary care are provided (<i>Guide, p 14</i>) [must] | | | | | | |
| <ul style="list-style-type: none"> Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the <i>Guide</i> (<i>Guide, pp 11, 15</i>) | | | | | | |
| <ul style="list-style-type: none"> Program needs are regularly communicated to IO by AV and/or IACUC (<i>Guide, p 13</i>) | | | | | | |
| <ul style="list-style-type: none"> Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (<i>Guide, p 14</i>) [must] | | | | | | |
| <ul style="list-style-type: none"> Inter-institutional collaborations are described in formal written agreements (<i>Guide, p 15</i>) | | | | | | |
| <ul style="list-style-type: none"> Written agreements address responsibilities, animal ownership, and IACUC oversight (<i>Guide, p 15</i>) | | | | | | |
| 2. Disaster Planning and Emergency Preparedness | | A* | M | S | C | NA |
| <ul style="list-style-type: none"> Disaster plans for each facility to include satellite locations are in place (<i>Guide, p 35, p 75</i>) [must] | | | | | | |
| <ul style="list-style-type: none"> Plans include provisions for euthanasia (<i>Guide, p 35</i>) [must] | | | | | | |
| <ul style="list-style-type: none"> Plans include triage plans to meet institutional and investigators' needs (<i>Guide, p 35</i>) | | | | | | |
| <ul style="list-style-type: none"> Plans define actions to prevent animal injury or death due to HVAC or other failures (<i>Guide, p 35</i>) | | | | | | |
| <ul style="list-style-type: none"> Plans describe preservation of critical or irreplaceable animals (<i>Guide, p 35</i>) | | | | | | |
| <ul style="list-style-type: none"> Plans include essential personnel and their training (<i>Guide, p 35</i>) | | | | | | |
| <ul style="list-style-type: none"> Animal facility plans are approved by the institution and incorporated into overall response plan (<i>Guide, p 35</i>) | | | | | | |
| <ul style="list-style-type: none"> Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (<i>Guide, p 35</i>) | | | | | | |
| 3. IACUC | | A* | M | S | C | NA |
| <ul style="list-style-type: none"> Meets as necessary to fulfill responsibilities (<i>Guide, p 25</i>) [must] | | | | | | |
| <ul style="list-style-type: none"> IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (<i>Guide, p 26</i>) [must] | | | | | | |
| <ul style="list-style-type: none"> Continuing IACUC oversight after initial protocol approval is in place (<i>Guide, p 33</i>) | | | | | | |
| <ul style="list-style-type: none"> IACUC evaluates the effectiveness of training programs (<i>Guide, p 15</i>) | | | | | | |
| 4. IACUC Protocol Review - Special Considerations | | A* | M | S | C | NA |
| <ul style="list-style-type: none"> Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (<i>Guide, p 27</i>) | | | | | | |
| <ul style="list-style-type: none"> For pilot studies, a system to communicate with the IACUC is in place (<i>Guide, p 28</i>) | | | | | | |

| | | | | | |
|--|--|--|--|--|--|
| <ul style="list-style-type: none"> For genetically modified animals, enhanced monitoring and reporting is in place (<i>Guide, p 28</i>) | | | | | |
| <ul style="list-style-type: none"> Restraint devices are justified in the animal use protocols (<i>Guide, p 29</i>) [must] | | | | | |
| <ul style="list-style-type: none"> Alternatives to physical restraint are considered (<i>Guide, p 29</i>) | | | | | |
| <ul style="list-style-type: none"> Period of restraint is the minimum to meet scientific objectives (<i>Guide, p 29</i>) | | | | | |
| <ul style="list-style-type: none"> Training of animals to adapt to restraint is provided (<i>Guide, p 29</i>) | | | | | |
| <ul style="list-style-type: none"> Animals that fail to adapt are removed from study (<i>Guide, p 29</i>) | | | | | |
| <ul style="list-style-type: none"> Appropriate observation intervals of restrained animals are provided (<i>Guide, p 29</i>) | | | | | |
| <ul style="list-style-type: none"> Veterinary care is provided if lesions or illness result from restraint (<i>Guide, p 30</i>) [must] | | | | | |
| <ul style="list-style-type: none"> Explanations of purpose and duration of restraint are provided to study personnel (<i>Guide, p 30</i>) | | | | | |
| <ul style="list-style-type: none"> Multiple surgical procedures on a single animal are justified and outcomes evaluated (<i>Guide, p 30</i>) | | | | | |
| <ul style="list-style-type: none"> Major versus minor surgical procedures are evaluated on a case-by-case basis (<i>Guide, p 30</i>) | | | | | |
| <ul style="list-style-type: none"> Multiple survival procedure justifications in non-regulated species conform to regulated species standards (<i>Guide, p 30</i>) | | | | | |
| <ul style="list-style-type: none"> Animals on food/fluid restriction are monitored to ensure nutritional needs are met (<i>Guide, p 31</i>) | | | | | |
| <ul style="list-style-type: none"> Body weights for food/fluid restricted animals are recorded at least weekly (<i>Guide, p 31</i>) | | | | | |
| <ul style="list-style-type: none"> Daily written records are maintained for food/fluid restricted animals (<i>Guide, p 31</i>) | | | | | |
| <ul style="list-style-type: none"> Pharmaceutical grade chemicals are used , when available, for animal-related procedures (<i>Guide, p 31</i>) | | | | | |
| <ul style="list-style-type: none"> Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (<i>Guide, p 31</i>) | | | | | |
| <ul style="list-style-type: none"> Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (<i>Guide, p 32</i>) | | | | | |
| <ul style="list-style-type: none"> Disposition plans are considered for species removed from the wild (<i>Guide, p 32</i>) | | | | | |
| <ul style="list-style-type: none"> Toe-clipping only used when no alternative, performed aseptically and with pain relief (<i>Guide, p 75</i>) | | | | | |

5. IACUC Membership and Functions

| | A* | M | S | C | NA |
|--|----|---|---|---|----|
| <ul style="list-style-type: none"> IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, IV.A.3.) | | | | | |
| <ul style="list-style-type: none"> Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (<i>Guide, p 24</i>)ⁱⁱ | | | | | |
| <ul style="list-style-type: none"> IACUC authority and resources for oversight and evaluation of institution's program are provided (<i>Guide, p 14</i>) | | | | | |
| <ul style="list-style-type: none"> IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, IV.B.) | | | | | |
| <ul style="list-style-type: none"> Conducts semiannual inspections of institutional animal facilities (PHS Policy, IV.B.) | | | | | |
| <ul style="list-style-type: none"> IACUC organizationally reports to the Institutional Official (PHS Policy, IV.A.1.b.) | | | | | |
| <ul style="list-style-type: none"> Methods for reporting and investigating animal welfare concerns are in place (<i>Guide, p 23</i>) [must] | | | | | |

| | | | | | |
|--|--|--|--|--|--|
| <ul style="list-style-type: none"> Reviews and investigates concerns about animal care and use at institutionⁱⁱⁱ (PHS Policy, IV.B.) | | | | | |
| <ul style="list-style-type: none"> Procedures are in place for review, approval, and suspension of animal activities^{iv} (PHS Policy, IV.B.) | | | | | |
| <ul style="list-style-type: none"> Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, IV.B.) | | | | | |
| <ul style="list-style-type: none"> Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) (<i>Guide</i>, p 27-32) | | | | | |
| <ul style="list-style-type: none"> Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS^v (<i>Guide</i>, p 30) [must] | | | | | |

6. IACUC Training

A* M S C NA

| | | | | | |
|---|--|--|--|--|--|
| <ul style="list-style-type: none"> All IACUC members should receive: <ul style="list-style-type: none"> Formal orientation to institution’s program (<i>Guide</i>, p 17) Training on legislation, regulations, guidelines, and policies (<i>Guide</i>, p 17) Training on how to inspect facilities and labs where animal use or housing occurs (<i>Guide</i>, p 17) Training on how to review protocols as well as evaluate the program (<i>Guide</i>, p 17) Ongoing training/education (<i>Guide</i>, p 17) | | | | | |
|---|--|--|--|--|--|

7. IACUC Records and Reporting Requirements^{vi}

A* M S C NA

| | | | | | |
|--|--|--|--|--|--|
| <ul style="list-style-type: none"> Semiannual report to the IO (PHS Policy, IV.B.) <ul style="list-style-type: none"> 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 <i>Guide</i> 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.E.) <ul style="list-style-type: none"> 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 <i>Guide</i> 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} <ul style="list-style-type: none"> 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 | | | | | |
|--|--|--|--|--|--|

| | | | | | |
|--|--|--|--|--|--|
| <ul style="list-style-type: none"> Records (PHS Policy, IV.E.) <ul style="list-style-type: none"> 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* 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**

| | | | | | |
|---|--|--|--|--|--|
| <ul style="list-style-type: none"> 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**

| | | | | | |
|--|--|--|--|--|--|
| <ul style="list-style-type: none"> All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must] <ul style="list-style-type: none"> 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) <ul style="list-style-type: none"> 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 (<i>Guide</i> , p 20) | | | | | |
| ○ Animal care and use legislation (<i>Guide</i> , p 17) | | | | | |
| ○ IACUC function (<i>Guide</i> , p 17) | | | | | |
| ○ Ethics of animal use and Three R's (<i>Guide</i> , 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 (<i>Guide</i> , p 17) [must] | | | | | |
| • Program covers <i>all</i> personnel who work in laboratory animal facilities (<i>Guide</i> , p 18) | | | | | |
| • Changing, washing, and showering facilities are available as appropriate (<i>Guide</i> , p 19) | | | | | |
| • Hazardous facilities are separated from other areas and identified as limited access (<i>Guide</i> , p 19) | | | | | |
| • Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (<i>Guide</i> , p 20) | | | | | |
| • Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (<i>Guide</i> , p 20) | | | | | |
| • Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (<i>Guide</i> , p 21) | | | | | |
| • Personal Protective Equipment for the work area is appropriate and available (<i>Guide</i> , p 21) | | | | | |
| • Program for medical evaluation and preventive medicine for personnel includes: | | | | | |
| ○ Pre-employment evaluation including health history (<i>Guide</i> , p 22) | | | | | |
| ○ Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (<i>Guide</i> , p 22) | | | | | |
| ○ Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (<i>Guide</i> , p 23) | | | | | |
| ○ Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (<i>Guide</i> , p 23) | | | | | |
| ○ Promotes early diagnosis of allergies including preexisting conditions (<i>Guide</i> , p 22) | | | | | |
| ○ Considers confidentiality and other legal factors as required by federal, state and local regulations (<i>Guide</i> , p 22) [must] | | | | | |
| ○ If serum samples are collected, the purpose is consistent with federal and state laws (<i>Guide</i> , p 22) [must] | | | | | |
| • Waste anesthetic gases are scavenged (<i>Guide</i> , p 21) | | | | | |
| • Hearing protection is provided in high noise areas (<i>Guide</i> , p 22) | | | | | |
| • Respiratory protection is available when performing airborne particulate work (<i>Guide</i> , p 22) | | | | | |
| • Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include: | | | | | |

| | | | | | |
|---|-----------|----------|----------|----------|-----------|
| o Tuberculosis screening provided for all exposed personnel (<i>Guide, p 23</i>) | | | | | |
| o Training and implementation of procedures for bites, scratches, or injuries associated with macaques (<i>Guide, p 23</i>) | | | | | |
| o PPE is provided including gloves, arm protection, face masks, face shields, or goggles (<i>Guide, p 21</i>) | | | | | |
| o Injuries associated with macaques are carefully evaluated and treatment implemented (<i>Guide, p 23</i>) | | | | | |
| • Occupational safety and health of field studies is reviewed by OSH committee or office (<i>Guide, p 32</i>) | | | | | |
| 11. Personnel Security | A* | M | S | C | NA |
| • Preventive measures in place include pre-employment screening, and physical and IT security (<i>Guide, p 23</i>) | | | | | |
| 12. Investigating & Reporting Animal Welfare Concerns | A* | M | S | C | NA |
| • Methods for investigating and reporting animal welfare concerns are established (<i>Guide, p 23</i>) [must] | | | | | |
| • Reported concerns and corrective actions are documented (<i>Guide, p 24</i>) | | | | | |
| • Mechanisms for reporting concerns are posted in facility and at applicable website with instructions (<i>Guide, p 24</i>) | | | | | |
| o Includes multiple contacts (<i>Guide, p 24</i>) | | | | | |
| o Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (<i>Guide, p 24</i>) | | | | | |

- * **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].

Semiannual 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 semiannual 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:

I. 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

II. 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 |
|---|----|---|---|---|----|
| <ul style="list-style-type: none"> Location: | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> animal areas separate from personnel areas (<i>Guide, p 134</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> separation of species (<i>Guide, p 111</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> separation by disease status (<i>Guide, p 111</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> security and access control (<i>Guide, p 151</i>) | | | | | |
| <ul style="list-style-type: none"> Construction: | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> corridors (<i>Guide, p 136</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> animal room doors (<i>Guide, p 137</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> exterior windows (<i>Guide, p 137</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> floors (<i>Guide, p 137</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> drainage (<i>Guide, p 138</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> walls and ceilings (<i>Guide, p 138</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> heating ventilation and air conditioning (<i>Guide, p 139</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> power and lighting (<i>Guide, p 141</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> noise control (<i>Guide, p 142</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> vibration control (<i>Guide, p 142</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> environmental monitoring (<i>Guide, p 143</i>) | | | | | |
| <ul style="list-style-type: none"> Room/Cage: | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> temperature and humidity (<i>Guide, p 43</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> ventilation and air quality (<i>Guide, p 45</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> illumination (<i>Guide, p 47</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> noise and vibration (<i>Guide, p 49</i>) | | | | | |
| <ul style="list-style-type: none"> Primary Enclosure: | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> space meets physiologic, behavioral^{xiv}, and social^{xv} needs (<i>Guide, pp 51, 55-63</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> secure environment provided (<i>Guide, p 51</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> durable, nontoxic materials in good repair and no risk of injury (<i>Guide, p 51</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> flooring is safe and appropriate for species (<i>Guide, p 51</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> adequate bedding and structures for resting, sleeping, breeding (<i>Guide, p 52</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> objective assessments of housing and management are made (<i>Guide, p 52</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> procedures for routine husbandry are documented (<i>Guide, p 52</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> socially housed animals can escape or hide to avoid aggression (<i>Guide, p 55</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> cage height provides adequate clearance (<i>Guide, p 56</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> animals express natural postures, can turn around, access food and water, and rest away from urine and feces (<i>Guide, p 56</i>) [must] | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> rationale^{xvi} for <i>Guide</i>/USDA space exceptions approved by IACUC and based on performance indices (<i>Guide, p 56</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> dogs and cats allowed to exercise and provided human interaction (<i>Guide, p 58</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> nonhuman primates are socially housed except for scientific, veterinary or behavior reasons (<i>Guide, pp 58-59</i>) | | | | | |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> single housing of nonhuman primates is for shortest duration possible (<i>Guide, p 60</i>) | | | | | |

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

| | | | | | |
|---|--|--|--|--|--|
| ○ minimizes scientific variables (<i>Guide</i> , pp 68-69) | | | | | |
| • Sanitation: | | | | | |
| ○ frequency of bedding/substrate change (<i>Guide</i> , p 70) | | | | | |
| ○ cleaning and disinfection of microenvironment (<i>Guide</i> , pp 70-71) | | | | | |
| ○ cleaning and disinfection of macroenvironment (<i>Guide</i> , p 72) | | | | | |
| ○ assessing effectiveness (<i>Guide</i> , p 73) | | | | | |
| • Waste Disposal: | | | | | |
| ○ procedures for collection (<i>Guide</i> , pp 73-74) | | | | | |
| ○ procedures for storage and disposal (<i>Guide</i> , pp 73-74) | | | | | |
| ○ hazardous wastes are rendered safe before removal from facility (<i>Guide</i> , pp 73-74) [must] | | | | | |
| ○ animal carcasses (<i>Guide</i> , pp 73-74) | | | | | |
| • Pest Control: | | | | | |
| ○ regularly scheduled (<i>Guide</i> , p 74) | | | | | |
| ○ documented program including control of rodent pests and insecticide use (<i>Guide</i> , p 74) | | | | | |
| • Emergency, Weekend, and Holiday Animal Care: | | | | | |
| ○ care provided by qualified personnel every day (<i>Guide</i> , p 74) | | | | | |
| ○ provision for accessible contact information (<i>Guide</i> , p 74) | | | | | |
| ○ monitoring of backup systems (<i>Guide</i> , p 143) | | | | | |
| ○ veterinary care available after hours, weekends, and holidays (<i>Guide</i> , pp 74, 114) [must] | | | | | |
| ○ a disaster plan that takes into account both personnel and animals (<i>Guide</i> , p 75) | | | | | |
| • Identification: | | | | | |
| ○ cage/rack cards contain required information (<i>Guide</i> , p 75) | | | | | |
| ○ genotype information included and standardized nomenclature used when applicable (<i>Guide</i> , p 75) | | | | | |
| • Recordkeeping: | | | | | |
| ○ clinical records accessible and contain appropriate information (<i>Guide</i> , pp 75-76) | | | | | |
| ○ records are provided when animals are transferred between institutions (<i>Guide</i> , p 75) | | | | | |
| • Breeding Genetics and Nomenclature: | | | | | |
| ○ appropriate genetic records, management and monitoring procedures (<i>Guide</i> , p 76) | | | | | |
| ○ phenotypes that affect wellbeing are reported to IACUC and effectively managed (<i>Guide</i> , p 77) | | | | | |
| • Storage: | | | | | |
| ○ adequate space for equipment, supplies, food, bedding and refuse (<i>Guide</i> , p 141) | | | | | |
| ○ bedding in vermin-free area and protected from contamination(<i>Guide</i> , p 141) | | | | | |
| ○ food in vermin-free, temperature and humidity controlled area and protected from contamination (<i>Guide</i> , p 141) | | | | | |
| ○ refuse storage is separate (<i>Guide</i> , p 141) | | | | | |
| ○ carcass and animal tissue storage is separate, refrigerated below 7°C and cleanable (<i>Guide</i> , p 141) | | | | | |

| | | | | | |
|--|--|--|--|--|--|
| <ul style="list-style-type: none"> • Personnel: | | | | | |
| <ul style="list-style-type: none"> ○ adequate space for locker rooms, administration and training (<i>Guide</i>, 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.