I. INTRODUCTION & PURPOSE
   A. Parker University is committed to the humane care and use of the animals in activities related to research, testing, and teaching. The University has an Assurance on file with the Office of Laboratory Animal Welfare #A4580-01. In order to accomplish the objectives inherent in these regulations and principles, the IACUC has been designated to ensure their implementation in the overall animal care and use program.

II. INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE- IACUC
   A. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through experience and expertise of its members to oversee the institution’s animal program, facilities, and procedures.

III. LINES OF AUTHORITY AND CHARGE
   A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are illustrated below:

1) The President is the chief executive officer of the University and responsible to the Board of Trustees for its administration. The Presidents’ authority or responsibility may be delegated to another member of the faculty or staff.

2) Research at the University is carried out under the administrative direction of the Provost who is responsible to the President. The Provost has been designated as
the Institutional Official called for in the Animal Welfare Act and PHS Policy and has complete authority to carry out his/her responsibility in this capacity and to ensure compliance with the PHS policy.

IV. OCCUPATIONAL HEALTH & SAFETY/TRAINING
   A. All persons involved in animal research, care, and handling, shall participate in the University occupational health and safety program. See Occupational Health & Safety Program.

V. VETERINARY CARE
   A. The Institution Veterinarian has authority to ensure implementation campus-wide of all applicable requirements specified in the Guide & Animal Welfare Act Regulations by:
      1) Ensuring that there is, and maintaining the mechanism for, daily observation of every animal in the institution’s animal care program in order to obtain timely information regarding problems in animal health, behavior and well-being.
      2) Establishing appropriate policies and procedures for laboratory animal veterinary care such as: advising on experimental models; reviewing protocols and proposals with respect to veterinary care, animal husbandry and animal welfare; monitoring occupational health, hazard containment and zoonosis control programs; and supervising animal nutrition, husbandry and sanitation.
      3) Ensuring that a program of preventive medicine is maintained that includes the following:
      4) Verification that there is lawful procurement of healthy animals from responsible vendors that the animals are transported appropriately and are quarantined and stabilized upon arrival according to procedures appropriate for the species and circumstances.
      5) Separation of animals by species, source and health status
      6) Ensuring maintenance of procedures for the surveillance, diagnosis, treatment and control of disease and injuries and for ensuring the availability of emergency, weekend and holiday care.
      7) Ensuring that research personnel are provided with guidelines and advice concerning the choice and use of anesthetics, analgesics and tranquilizers. Ensure that muscle relaxants or paralytics are used properly in conjunction with drugs known to produce adequate anesthesia.
      8) Ensuring that aseptic surgery is performed in suitable facilities as outlined in the Guide and that all surgery is performed or directly supervised by trained, experienced personnel, including provision of training in aseptic surgery for those who require it.
      9) Ensuring that techniques for euthanasia are carried out by trained personnel using acceptable techniques in accordance with institutional polices and applicable laws. The techniques used should not interfere with postmortem evaluation and should follow current guidelines established by the American Veterinary Medical Association Panel on Euthanasia. Techniques other than those in accordance with the above mentioned guidelines will be reviewed and approved by the IACUC and University Veterinarian.
      10) Ensuring that necropsies are completed as required.
11) Ensuring that scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment or use are qualified to perform their duties.

12) Temporarily suspending any activity involving animals not being conducted in accordance with the Guide or Animal Welfare Act until such time as the IACUC can be fully convened and the activity be reviewed, and appropriate action be determined by a quorum of the IACUC.

13) Other responsibilities and/or priorities as delegated by the Institutional Official or IACUC or as mandated by changes in the Guide, federal regulations, or other applicable guidelines or standards.

VI. SURGERY - DEFINITIONS, POLICIES AND GUIDELINES

A. Survival Surgery - Multiple Major Survival Surgery Definition and Policy:

1) The Policy Sub-Committee recommends that the IACUC endorse as policy the following excerpt from page 11 of the 1996 National Research Council "Guide for the Care and Use of Laboratory Animals." "Major surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic function. Multiple major survival surgical procedures on a single animal are discouraged but may be permitted if scientifically justified by the user and approved by the IACUC. For example, multiple major survival surgical procedures can be justified if they are related components of a research project, if they will conserve scarce animal resources, or if they are needed for clinical reasons. If multiple major 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 (AWRs)."

2) Multiple Major Survival Surgery - Each protocol is reviewed on a case by case basis by the IACUC and the minimum requirements are as follows:

3) The second surgery must be related to the research protocol

4) The protocol must be justified beyond the standard procedure, with a written justification

5) The protocol must have additional follow-up observation included beyond what is required for the standard survival surgery, with an awareness of the second surgery

6) The "pre-surgical, the surgery and the post-surgical periods," including any special procedures or extra care which may be required during the period between surgeries

7) Surgery - Procedures need to be outlined in the protocol for preparation of the animal, including aseptic preparation of the surgical site including shaving of fur and appropriate disinfecting of the skin, pre-surgical medication(s), and food or fluid restriction.

8) Major Surgery - Major survival surgical procedures in non-rodent mammals must be conducted in a facility specifically intended and used only for that purpose and which is maintained and operated to ensure cleanliness. Additionally, aseptic procedures which include the wearing of sterile surgical gloves, gowns, caps and face masks; and use of sterile surgical instruments and draping must be used.

9) Minor and Rodent Surgery - Non-major survival surgical procedures and all surgery on rodent species do not require a dedicated surgery facility; however, the area of the laboratory or room where surgery is performed should not be used for other functions when surgery is in progress. Additionally, the area should be clean and free of clutter, procedures that minimally include the use of sterile instruments,
surgical masks and gloves, surgical draping as appropriate, and aseptic preparation of the surgery site as described above.

10) Post-Surgical Period - The post-surgical period is generally considered to be the period from the end of surgery to the point when the surgical wound is healed, e.g., at the time of suture removal.

11) Non-Survival Surgery - Non-survival surgery is defined as a surgery in which the animal is euthanized before recovery from anesthesia.

12) Animals must be maintained at a proper anesthetic plane without recovery before euthanasia.

VII. FOOD OR FLUID RESTRICTION

A. Food or Fluid Restriction Definitions

1) Standard for Food Intake: "Animals should be fed palatable, non-contaminated, and nutritionally adequate food daily or according to their particular requirements...." (P. 38, "Guide for the Care and Use of Laboratory Animals," National Research Council, 1996.)

2) Standard for Water Intake: "Ordinarily, animals should have access to potable, uncontaminated drinking water according to their particular requirements." (P. 40, "Guide for the Care and Use of Laboratory Animals," National Research Council, 1996.)

3) Restriction is any deviation from the standards for food and water intake.

4) Deprivation is total withholding of either food or fluid.

5) Fasting for surgical procedures is usually for a period of less than 12 hours, with the exception of farm animals which would have a longer period of fasting. This is not considered deprivation and the following guidelines below do not apply.

B. Food or Fluid Restriction Policy and Guidelines

1) The IACUC endorses as policy the following excerpt from page 12 of the 1996 National Research Council "Guide for the Care and Use of Laboratory Animals." "When experimental situations require food or fluid restriction, at least minimal quantities of food and fluid should be available to provide for development of young animals and to maintain long-term well-being of all animals. Restriction for research purposes should be scientifically justified, and a program should be established to monitor physiologic or behavioral indexes, including criteria (such as weight loss or state of hydration) for temporary or permanent removal of an animal from the experimental protocol. Restriction is typically measured as a percentage of the ad libitum or normal daily intake or as percentage change in an animal's body weight. Precautions that should be used in cases of fluid restriction to avoid acute or chronic dehydration include daily recording of fluid intake and recording of body weight at least once a week or more often, as might be needed for small animals, such as rodents. Special attention should be given to ensuring that animals consume a suitably balanced diet because food consumption might decrease with fluid restriction. The least restriction that will achieve the scientific objective should be used." The plan for appropriate periodic weighing, starting with a pre-experimental weight, and monitoring of animal health must be included in the protocol.

2) When food deprivation is planned:
   a. Additional provisions for close monitoring of weight at time intervals appropriate to the species must be included in the protocol; and
b. It must be specified that when there are weight losses greater than 30% (taking into account the normal anticipated growth for that animal), the deprivation must be terminated or the animal must be euthanized if weight loss continues beyond 30%.

VIII. PHYSICAL RESTRAINT - DEFINITIONS, POLICIES AND GUIDELINES

A. Physical Restraint Definitions

1) "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" (p. 11, "Guide for the Care and Use of Laboratory Animals," National Research Council, 1996). This includes any cage size smaller than required by any federal regulation or guideline.

2) Prolonged restraint includes any procedure involving restraint for a duration of time which could lead to distress.

3) Planned restraint includes any procedure involving restraint that is of short duration but is of such intensity that it could lead to distress.

4) Planned prolonged restraint is considered distressful.

B. Physical Restraint Policy and Guidelines –

1) The IACUC endorses as policy the following based on the recommendations in the "Guide" "Animals can be physically restrained briefly either manually or with restraint devices. Restraint devices should be suitable in size, design, and operation to minimize discomfort or injury to the animal. Many dogs, nonhuman primates (e.g., Reinhardt 1991, 1995), and other animals can be trained, through use of positive reinforcement, to present limbs or remain immobile for brief procedures.

2) Prolonged restraint, including chairing of nonhuman primates, should be avoided unless it is essential for achieving research objectives and is approved by the IACUC. Less-restrictive systems that do not limit an animal's ability to make normal postural adjustments, such as the tether system for nonhuman primates and stanchions for farm animals, should be used when compatible with protocol objectives. 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."

3) The protocol must include a plan for appropriate monitoring of animals throughout the entire period of restraint and a description of how stress and/or distress will be evaluated. If unanticipated distress is encountered with use of any physical restraint, it should be promptly reported to the IACUC.

4) Restraint devices should be suitable in size, design, and operation to minimize discomfort or injury to the animal.

5) Restraint devices are not to be considered normal methods of housing.

6) Restraint devices should not be used simply as a convenience in handling or managing animals.

7) The period of restraint should be the minimum required to accomplish the research objectives.

8) Veterinary care should be provided if lesions or illnesses associated with restraint are observed. The presence of lesions, illness, or severe behavioral change often necessitates temporary or permanent removal of the animal from restraint.
IX. DETERMINATION OF LEVELS OF PAIN & DISTRESS DEFINITIONS, POLICIES AND GUIDELINES
A. USDA Pain Levels:
B. Level B: Breeding or Holding Colony Protocols
C. Level C: No more than momentary or slight pain or distress. For example: euthanatized for tissues; just observed under normal conditions; positive reward projects.
D. Level D: Pain or distress relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress. For example: survival surgery, non-survival surgery, induced infections or antibody production with appropriate anesthesia and post-op/post-procedure analgesia when necessary.
E. Level E: Pain or distress or potential pain or distress that is not relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress.
Note, there is no USDA level A
F. Euthanasia - "The term euthanasia is derived from the Greek terms eu meaning "good" and thanatos meaning "death." A "good death" would be one that occurs without pain and distress. In the context of this report, euthanasia is the act of inducing humane death in an animal. Euthanasia techniques should result in rapid unconsciousness followed by cardiac or respiratory arrest and ultimate loss of brain function. In addition, the technique should minimize any stress and anxiety experienced by the animal prior to unconsciousness. Stress may be minimized by technical proficiency and humane handling of the animals to be euthanatized."
G. Humane is defined as "Characterized by kindness, mercy, or compassion, marked by an emphasis on humanistic values and concerns; Synonyms: humane, compassionate, humanitarian, merciful. The central meaning shared by these adjectives is "marked or motivated by concern with the alleviation of suffering"
H. Non-Survival Surgery would include any surgical procedure where there is the potential for more than momentary or slight pain prior to death, including those due to procedures requiring extended time periods. Any protocol which includes surgical procedures not directly associated with euthanasia, prior to euthanasia should be categorized as non-survival surgery.
I. Guidelines for determining USDA classification in protocols involving tissue collection before/after euthanasia and/or animal perfusion:
   1) If an animal will be euthanatized by an approved physical or chemical method of euthanasia solely for the collection of tissues (after the animal's death), the procedure should be classified as USDA C.
   2) If an animal will be anesthetized so that non-vital tissues can be collected (liver or skin biopsy), and the animal will then be allowed to recover, the procedure should be classified as USDA D (survival surgery).
   3) If an animal will be anesthetized so that non-vital tissues can be collected (liver or skin biopsy, etc.), and the animal will then be euthanatized, the procedure should be classified as USDA D (non-survival surgery). In this scenario, it is necessary to justify why the animal could not be euthanatized (USDA category C) rather than anesthetized.
   4) If an animal will be anesthetized so that vital tissues can be collected (heart, both kidneys or lungs, whole liver, etc.), the animal will obviously succumb to the procedure. To determine whether this will be euthanasia or non-survival surgery, we
must consider the definition of euthanasia. A critical component of this definition is "rapid unconsciousness followed by loss of cardiac, respiratory and brain function". Based on this definition, procedures which require tissue manipulation or other prolonged techniques prior to the animal's death (more than a few minutes) should be classified as non-survival surgery (USDA D). Similarly, if an animal will be anesthetized so that the tissue can be collected in the "freshest" possible state (i.e. heart) and the tissues will be rapidly excised, the procedure should be classified as euthanasia (USDA C). (Note: In this scenario, it is difficult to justify why the animal couldn't be euthanized rather than anesthetized.)

5) If an animal will be anesthetized so that it can be chemically perfused, the same "test of time" applies (i.e. long, technical manipulations should be classified as USDA D, while rapid intravascular injection of the perfusate without other manipulations should be classified as USDA C).

NOTE: Because the USDA classification system is based on the "potential for pain, distress or discomfort," the anesthetic/euthanasia drug dose becomes a critical concern. For example, if a known "euthanasia dose" of pentobarbital will be administered, drug irreversibility is assumed. Thus, once the animal is confirmed to be in an anesthetic plane (toe pinch response, etc.), tissues can be collected/ procedures can be performed without the concern about what the animal will be perceiving. This procedure would then be classified as USDA C. The Committee recommends using an euthanizing dose whenever possible. Other methods may be appropriate with proper scientific justification.

X. CONTROVERSIAL EUTHANASIA METHODS DEFINITIONS, POLICIES AND GUIDELINES
A. Definitions:

1) Euthanasia - The term euthanasia is derived from the Greek terms eu meaning "good" and Thanatos meaning "death." A "good death" would be one that occurs without pain and distress. In the context of this report, euthanasia is the act of inducing humane death in an animal. Euthanasia techniques should result in rapid unconsciousness followed by cardiac or respiratory arrest and ultimate loss of brain function. In addition, the technique should minimize any stress and anxiety experienced by the animal prior to unconsciousness. Technical proficiency and humane handling of the animals to be euthanatized may minimize stress.

2) Humane is defined as “Characterized by kindness, mercy, or compassion, marked by an emphasis on humanistic values and concerns; Synonyms: humane, compassionate, humanitarian, and merciful. The central meaning shared by these adjectives is "marked or motivated by concern with the alleviation of suffering" 2

B. Policies And Guidelines

1) “PHS Policy and USDA Regulations require that an IACUC review and approve the methods of euthanasia which are proposed. These must be consistent with the recommendations of the 2000 Report of the AVMA Panel on Euthanasia, or succeeding revised editions, unless there are scientific justifications for alternative methods.” “… criteria used to evaluate the appropriateness of a given method include compatibility with the requirements of the research, reliability, irreversibility, the minimization of distress to animals and persons performing euthanasia, and safety to the latter. The species of animal being used and the qualifications of the investigators are also important considerations. Three categories of methods exist: inhalation and non-inhalation pharmacologic agents, and physical methods.”
C. Inhalation Agents

1) Ether - Ether is the agent upon to which all other inhalation anesthetic agents are compared, as it was the first inhalation anesthetic agent. Ether is extremely irritating to the mucosal lining of the respiratory tract. It is stressful to the animal. It has high explosive potential and is flammable and therefore it requires an explosion-proof hood. There are also problems with storage and disposal of carcasses when ether is used for euthanasia.

2) Ether usage requires strong scientific justification and must have approval by the IACUC and can only be used in an explosion-proof hood.

3) Carbon Dioxide (CO2) - Prolonged carbon dioxide inhalation is an effective and approved method of euthanatizing small (less than 800 grams) rodents and small birds when it is done in accordance with the following guidelines. In fact, CO2 euthanasia has several advantages over other methods of euthanasia. For example, carbon dioxide is a potent central nervous system depressant and thus causes rapid unconsciousness and anesthesia. Carbon dioxide exposure has also been shown to induce analgesia that begins within a few minutes of exposure and lasts for as long as an hour. Carbon dioxide is a relatively inert, inexpensive and easily procured gas that is not very hazardous for exposed humans. Finally, carbon dioxide does not accumulate in or contaminate tissues and has minimal effects on tissue architecture (with the exception of the lungs). Nonetheless, since inhalation of carbon dioxide is known to cause mucosal irritation and thus may cause short-term stress in animals exposed to this gas, a few precautions are warranted.

4) It is better to prefll the chamber prior to using a 70% CO2:30% oxygen gas mixture prior to introduction of the animals so that unconsciousness will be induced in the shortest amount of time. Rodents will be unconscious in about 30 seconds in precharged chambers vs. 150 seconds in chambers filled slowly by continuous flow.

5) Carbon dioxide concentration in the chamber should be maintained in excess of 70%. At least 50% is required to cause unconsciousness. Some animals can withstand 70% without being anesthetized.

6) Either 100% CO2 or 70% CO2:30% O2 may be used. No differences in stress reactions have been observed between inhalation of 70% or 100% CO2, although it takes significantly longer to induce unconsciousness with the mixture.

7) Leave the animals in the euthanasia chamber for at least 5 minutes to assure death. Regardless of how long the animals are exposed to the CO2, the chest MUST BE opened or a vital organ removed to prevent the animal from reviving.

Note: The above guidelines apply to rodents and small birds. Larger animals such as rabbits are better euthanatized by other methods, although exceptions may be approved with proper justification.

D. Acceptable Inhalation Agents - Halothane and isofluorane are acceptable agents with or without pre-medication. As with carbon dioxide, death of the animal must be ensured with a physical method. It is important to minimize potential hazards to personnel by using fume hoods.

E. Non-Inhalation Agents - Acceptable Non-Inhalation Agents

1) Sodium pentobarbital is the most commonly used non-inhalation agent. A surgical method to ensure death must also be used after surgical anesthesia has been reached.

2) Unacceptable Non-inhalation Agents when used alone, the injectable agents listed in the following: strychnine, nicotine, caffeine, magnesium sulfate, potassium chloride,
cleaning agents, solvents, disinfectants and other toxins or salts, and all neuromuscular blocking agents are unacceptable and are absolutely condemned for use as euthanasia agents.

F. Physical Methods - It is strongly advised that anesthesia be used prior to the use of any physical method.
   1) Exceptions must be approved with proper scientific justification and training. Physical methods of euthanasia include captive bolt, cervical dislocation, exsanguination, and pithing. However, some of these procedures, namely exsanguination, captive bolt, and pithing are not recommended as sole means of euthanasia.

G. Cervical Dislocation - This method is primarily reserved for euthanasia of mice and neonatal rats. "Manual cervical dislocation is a humane technique for euthanasia of poultry, other small birds, mice, rats weighing <200 g, and rabbits weighing <1 kg when performed by individuals with a demonstrated high degree of technical proficiency." It is strongly advised that anesthesia be used prior to use of any physical method. Exceptions must be approved with scientific justification. Training and certification by a University veterinarian in this technique is required.

H. Decapitation - This method requires scientific justification when used without prior anesthesia. Physical hazard to the investigator must be taken into consideration and it is essential that the equipment be properly maintained with appropriate documentation. Training and certification by a University veterinarian in this technique is required.

I. Physical Methods Of Ensuring Euthanasia - Following chemical euthanasia, a physical method is required to ensure death. Physical methods include exsanguination with anesthesia, pithing, thoracotomy, removal of a vital organ, cervical dislocation and decapitation.

XI. DEATH AS AN ENDPOINT - DEFINITIONS, POLICIES AND GUIDELINES
A. Definitions - Death as an endpoint refers to projects in which the animals’ non-experimentally induced death is required as a measured data point. It does not refer to projects in which the animals will be euthanized prior to non-experimentally induced death for tissue collection or project termination. Moribund is defined as "in a dying state". Animals are considered to be moribund if they evidence unconsciousness or show no response to external stimuli such as a toe pinch withdrawal test.

B. Policies And Guidelines - "The routine use of death as an endpoint should be discouraged. Endpoints other than death must always be considered and should be used whenever the research objective makes it possible." Investigators must perform euthanasia on all moribund experimental animals unless there is scientific justification that euthanasia would invalidate experimental data collection. All "death as an endpoint" protocols without relief of pain or distress are identified as USDA Pain Level E. If killing a moribund animal would invalidate the study, the scientific justification for using death as an endpoint must be provided in writing as part of the animal care protocol and must be approved by the University, Institutional Animal Care and Use Committee (IACUC). Investigators who receive approval from the IACUC to use death as an experimental endpoint must also agree to the following:
   1) Written records of all monitoring sessions, indicating the time of the observations, the person observing the animals, and any observations such as the number of animals evidencing clinically abnormal behavior and the number of animals found dead, must be maintained and made available to the IACUC.
2) Animals must be monitored twice daily and any animals evidencing clinically abnormal behavior must be removed from group housing situations and housed individually with easy access to food and water.

3) Use the minimum number of animals necessary to achieve statistical significance and to use alternative endpoints other than death whenever possible.

4) A proposal foregoing the use of anesthetics, analgesics or tranquilizing drugs must be extensively justified to the IACUC. State clearly why alternatives are not appropriate. "Several authors have recommended the use of pilot experiments in determining endpoints, using clinical evaluations of the animal's state is of particular value when dealing with the unknown effects of a compound." It is recommended that consideration be given to alternative endpoints. The following endpoint criteria for the euthanasia of animals are suggested.

C. Reporting Animal Deaths - At the termination of the research study, all animals must be assigned to one of three categories in the Animal Care and Use Protocol:

1) The animals will be euthanatized.

2) The animals will die prior to euthanasia due to the experimental design. This is termed "death as an endpoint" and requires special justification in order to be approved by the IACUC.

3) Occasionally, an animal falls into a third category and dies UNEXPECTEDLY prior to collection of useable data. The cause of death may or may not be known, but from a research standpoint these animals have not been utilized as an experimental subject. Federal regulations require that animal deaths be tracked and reviewed by the Veterinarian and IACUC. This is also important for the animal program at the University because unexpected animal deaths may be an indicator of health problems in a colony.

D. Deaths that must be reported

1) Animals that are found dead by a caretaker, technician, investigator, veterinarian, etc. These deaths must be reported if you expected the animal to die and this was stated in the Animal Care and Use Protocol. If possible, these animals should be preserved for examination by the Veterinarian by bagging, tagging and placing in a designated refrigerator (please do not freeze).

XII. OVERCROWDING

A. Overcrowded mouse cages represent a significant animal welfare concern. Such cages are noncompliant with Public Health Service (PHS) Policy and our Assurance to PHS. The Guide for the Care and Use of Laboratory Animals states the PHS recommendations for housing densities.

XIII. WEANING

A. Investigators who choose to manage their own breeding colonies are responsible for timely weaning. Conventional mice are typically weaned at 21 days of age. All litters must be weaned by 24 days of age unless doing otherwise is justified in the animal protocol and is approved by IACUC. Delayed weaning protocols must be approved by IACUC with specification of actual weaning ages.

XIV. IDENTIFICATION
A. A completed cage card must be present on all mouse cages. The information on the card should include: the animal source and date of birth or arrival at the facility, the animal’s species and strain or stock.

B. Individual animal identification such as ear punches, ear tags, toe clips, tattoos and implantable transponders is encouraged, especially in cases where animals are group housed and/or appear identical. All methods of identification must be described in the animal protocol and approved by IACUC.

XV. STORAGE OF CONTROLLED DRUGS - POLICY & PROCEDURES
A. Controlled substances are often used in research settings for anesthesia, analgesia, sedation or euthanasia. Controlled substances are drugs which are regulated by the Drug Enforcement Administration (DEA) because of potential for abuse. The presence of such drugs on the premises poses a risk of theft or diversion to an unapproved use. The University has a permit from the DEA to obtain and use controlled substances. In order to retain our permit, it is critical that investigators store drugs safely and maintain accurate inventory records.

B. Controlled substances must be stored in a locked cabinet. The key to this drug safe must be kept in a secure place away from the drug storage safe. The key to the drug storage safe should not be on a shelf or in a drawer immediately adjacent to the drug-storage site or left on top of the drug storage safe.

C. It is not necessary to handle drugs for oral administration aseptically, however, drugs which are mixed with food or fluid for oral administration should be refrigerated and used within 30 days. These diluted products must be clearly labeled as specified above.

D. Non-controlled substances used for anesthesia or analgesia, such as xylazine, isoflurane or halothane, should be stored in such a way that the drugs are not visible or accessible to the casual laboratory visitor.

XVI. AUTOCLAVES AND AUTOCLAVE USE
A. General Statement of Policy - This policy shall stand as a guide for personnel in preparing items for sterilization in laboratories with steam autoclaves. To assure that autoclaves are maintained properly for the safety of personnel and good research practices. Autoclaves are safe and highly effective when used properly. They sterilize equipment and supplies, killing biological contamination and denaturing proteins. Autoclaves remove chemical contamination. General Information about Autoclaving and Steam Sterilization:

B. Steam autoclaving is the most desirable method for decontaminating cultures, lab glassware, pipettes, or other small items contaminated with biohazardous material. Autoclaving is a reliable way to sterilize media and lab equipment as well as decontaminate infectious waste.

C. Optimal effectiveness of an autoclave depends on three important parameters: time, temperature, and steam penetration. In addition, here are some general guidelines that should be followed:
   1) Thorough examinations should be done by a qualified person once a year and all users must be trained in proper techniques and practices.

D. Autoclave Guidelines
   1) An autoclave bag/packs should be filled to two-thirds of its capacity.
   2) After the bag/pack is 2/3 full, it should be loosely taped closed.
3) Autoclave tape should be affixed to the exterior of the bag to ensure the contents have received proper autoclave temperature.
4) For multiple surgical instrument sterilization, it is recommended that autoclaves be tested monthly by steri-strips or Bacillus stearothermophilus spores.
5) All instruments that come into direct contact with the surgical area must be sterile.
6) Sterilization of instruments can be achieved in a number of ways:
   a. steam (autoclave)
   b. dry heat (e.g. hot bead sterilizer)
   c. ethylene oxide
7) If surgeries are to be performed on consecutive animals, surgical instruments must be sterilized between animals. Using multiple surgical packs, chemical sterilants with a minimum 10 minutes contact time, or use of a hot bead sterilizer can achieve this.
8) After five animals a new set of autoclave-sterilized instruments should be used.
9) An alternative to chemical sterilants is bead sterilization for one minute. Instruments must be clean and dry before inserting into the glass beads.

XVII. USE OF EXPIRED MEDICAL MATERIALS POLICY AND GUIDELINES
A. Background - According to USDA Animal Care Resource Guide Policy the policy on the use of expired medical materials (Policy #3) is as follows:
   1) “The use of expired medical materials such as drugs, fluids, or sutures on regulated animals is not considered to be acceptable veterinary practice and does not constitute adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act.
B. All expired medical materials found in a licensed or registered facility are to be brought to the attention of the responsible official. The facility must either dispose of all such materials or segregate them in an appropriately labeled, physically separate location from non-expired medical materials.

XVIII. POLICY FOR CARE OF ANIMALS DURING AN EMERGENCY OR DISASTER:
A. In the case of emergency or disaster every effort will be made to secure and protect animals from any harm or distress. The Principal Investigator is responsible for any special handling requirements in the event of an emergency.

XIX. HAZARDOUS AGENTS
A. The Safety Committee oversees policies related to the use of chemical and biological agents at the University to ensure that they are used in a safe and healthful manner and in accordance with all applicable government regulations and with University policy and procedure. The committee recommends policies to the President concerning the use of chemicals and biological agents. The committee is composed of faculty and staff appointed by the Provost. The members are selected based on their knowledge of the health and environmental effects of chemicals and biological agents, and the risks associated with those effects. The Safety Committee has the authority to require the immediate, temporary cessation of any University activity should it determine that such activity represents a substantial and immediate threat to human health or the environment. The President reviews such actions.