POLICY

The use of expired drugs or medical materials (i.e. fluids, disinfectant solutions, catheters, sutures) in animals is considered inadequate veterinary care. These materials may lose potency or degrade to toxic byproducts if stored after their expiration dates, resulting in unpredictable effects that can jeopardize animal welfare.

Euthanasia, anesthetic, analgesic, and emergency drugs cannot be used beyond their expiration dates, even if the procedure is terminal. In rare circumstances a request may be made to the IACUC to utilize expired drugs or medical materials, but it is highly advised that consultation with a veterinarian be made prior to submitting the request. The Principal Investigator (PI) must provide specific justification in the IACUC Application. Otherwise, the use of expired drugs or materials is not authorized.

Each laboratory must establish a procedure to facilitate the identification and removal of expired drugs and other medical materials used for research involving animals. This includes labeling all drug preparations with the date of preparation and the earliest expiration date of the component drugs. All expired supplies must be labeled "Expired - Do Not Use" and stored separately from non-expired drugs or materials if immediate disposal is not possible.

REGULATION

Reference 9CFR Animal Health and Husbandry Standards, 3.110 Veterinary Care, USDA Animal Care Resource Guide Policies, March 25, 2011, Policy #3 Veterinary Care, Expired Medical Materials: Paragraph 2: For acute terminal procedures, where an animal is put under anesthesia, the research is carried out (surgery or testing of a compound) and the animal is euthanized without ever waking up, medical materials may be used beyond their “to be used by” date if such materials use does not adversely affect the animal’s wellbeing or compromise the validity of the scientific study. Anesthesia, analgesia, emergency drugs and euthanasia drugs that are within their expiration dates are required for all such procedures. The attending veterinarian and the Institutional Animal Care and Use committee (IACUC) are responsible for ensuring that proposed animal activities avoid or minimize discomfort, distress, and pain to the animal. The Animal and Plant Health Inspection Service (APHIS) has determined that these responsibilities cannot be met unless the veterinarian and the IACUC maintain control over the use of expired materials.

PHS Policy, U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training:
V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia.
IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

PROCEDURE

1.0 EXPIRED DRUG OR MATERIAL USE IN SURVIVAL STUDIES
   1.1 In general, drugs or materials that have reached their expiration date should not be used on any research animal that is unanesthetized or is to recover from an anesthetic procedure.
   1.2 If there is a need to utilize expired materials or drugs other than anesthetics or analgesics in a survival procedure, the Principal Investigator (PI) must request IACUC approval and provide
specific justification in the IACUC Application. **NOTE:** These materials will only be considered for use if the PI, in consultation with the Attending Veterinarian, determines that use of expired drugs or materials would not be expected to jeopardize research results or have a negative impact on the physiology or well-being of the animal.

2.0 **EXPIRED DRUG OR MATERIAL USE IN NONSURVIVAL STUDIES**

2.1 If there is a need to utilize expired drugs or materials, in non-survival studies, the PI must request IACUC approval and provide specific justification in the IACUC Application. **NOTE:** These materials will only be considered for use if the PI in consultation with the Attending Veterinarian determines that use of expired drugs or materials would not be expected to jeopardize research results or have a negative impact on the physiology or well-being of the animal.

3.0 **STERILITY DATING**

3.1 Medical materials such as catheters, surgical instruments, sterile gloves, suture materials, and pressure transducers are often labeled with an expiration date to assure sterility. In general, after the expiration date these materials should be used only in procedures involving anesthetized animals in non-survival studies.

3.2 If needed for survival studies, outdated items (or any items that may no longer be sterile) should be repackaged and re-sterilized before use. Re-sterilized items should be labeled with a new expiration date that is appropriate for the packaging used.

3.3 If the PI obtains information from the manufacturer that provides documentation that a particular material or instrument has been shown to remain sterile beyond the date on the packaging, a request to use the item in survival studies will be considered by the IACUC.

4.0 **SEGREGATION**

4.1 All expired drugs or materials that are to be kept in inventory by a PI in his or her laboratory and used as described above must be clearly and individually labeled as "Expired--For Conditional Use Only" and be kept together in an area physically separate from all other materials and drugs.

4.2 The area (drawer, cabinet, shelf, etc.) in which they are kept must also be labeled "Expired--For Conditional Use Only." The use of computer-generated preprinted labels and use of color coded labels may make this process easier.

5.0 **INVENTORY**

5.1 In order to assure that expired items are identified in a timely fashion so that they can either be discarded or appropriately labeled for conditional use, each research group is strongly encouraged to inspect its drug storage areas on a regular basis (i.e., every 30 to 60 days).

**A.** Experience at UNMC has shown that those laboratories that assign the responsibility for this task to one specific person have fewer problems with expired drugs or materials. A simple system using color-coded stickers can easily be instituted.