

**Institutional Animal Care and Use Committee  
Policy #24  
Expired Drugs**

In concurrence with  
TTUHSC El Paso Assurance #D19-01056  
and Federal Regulations and Guidelines

**I. BACKGROUND:**

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. Pharmaceutical grade drugs are tested for purity to reduce the possibility that they are contaminated with toxic compounds that may harm an animal.

**II. RESPONSIBILITY**

Each researcher is responsible and accountable for ensuring that expired materials are not used for animal research that s/he conducts. Principal Investigators (PIs) and laboratory staff are responsible for ensuring that expired drugs and medical materials are properly disposed after their expiration date or labelled "Not for Use in Animals".

**III. POLICY**

**Drug:** Any substance or chemical listed in a pharmacopeia intended to be administered by injection, inhalation, topical application, ingestion, electroporation or suppository that is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals.

No expired drugs or fluids are allowed for use on animals in research or instruction, including terminal procedures. All drugs must be discarded within one month of the manufacturer's expiration date or labelled "Not for Use in Animals".

**Expiration Date:** All chemicals used on or in animals must have an expiration date clearly labeled on the container. The expiration date is the date printed on the label/package for materials with a manufacturer's expiration.

**Drugs without expiration dates should be dated when opened:** The investigator should determine the stability of the drug to identify a reasonable shelf-life. This is commonly obtained from the manufacturer. If stability is unknown, the drug should not be used beyond one year.

**Dilutions, Reconstitutions, Compounding:** For drug preparations made by the investigators, the expiration date is no more than thirty (30) days from the date of preparation. Such materials should be prepared using aseptic (sterile) technique, under proper storage conditions, and should be labeled by name, drug concentration, and the new expiration date as soon as they are prepared. The expiration date may vary from the manufacturer's expiration date. If drug or material is transferred to another container, it should be clearly labeled with the name of the drug or material and the expiration date of the original stock. An item is considered expired the day after the month or date indicated on the label (i.e., an item labeled January 2016 would be considered expired on February 1, 2016). When

Reviewed and Approved by the TTUHSC IACUC: 04/12/19

investigators wish to access sterile diluents multiple times (i.e. to obtain small volumes for administration and drug mixing), the investigators can do so only if they do not add any chemical to the fluid, they access the fluid(s) aseptically and they store the fluid(s) as recommended by the manufacturer. Under these conditions, the investigator can use the sterile fluid(s) for up to thirty (30) days after initial opening.

**Medical Material:** A non-bioactive substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or a substance (other than food) intended to affect the structure or any function of the body. Examples include but are not limited to: gauze, sutures, catheters, etc. 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 must be discarded. Expired materials capable of being re-sterilized should be dated with a new expiration date appropriate for the package being used. 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.

**Exceptions:** Under special conditions, an investigator might require use of an expired or non-pharmaceutical grade substance (for example, no pharmaceutical-grade drug is available, or a pharmaceutical-grade drug is available, but is not compatible with the delivery requirements of the protocol). To do so, the investigator must provide scientific justification of the usage in her/his animal protocol and the protocol must be approved by the IACUC.

#### **IV. IACUC Recommendations**

The IACUC recommends that each laboratory establish an inventory procedure to facilitate the identification and discarding of expired drugs.

**All medical materials and supplies used in live animals, including acute procedures, should be individually labeled.** The LARC area supervisor in LARC shared procedures rooms, or the Principal Investigator for all other shared-use laboratories, shall be authorized to discard materials which cannot be clearly identified by owner, whether or not they have reached their expiration date. EH&S will be contacted to arrange for disposal of unidentifiable contents.

The following are general guidelines suggested to help comply with this policy:

- Store all drugs in one location (to make checking easier). Please contact LARC if you would like assistance in obtaining a lockable box for your drugs.
- Consider assigning the inventory responsibilities to one specific individual, with another individual assigned as backup.
- Establish an inventory system which minimizes the amount of drug or medical supplies on hand.
- Perform regular monthly checks of your inventory and discard all expired drugs or medical materials.
- Contact your suppliers to see if they will accept the return of some expired drugs or medical supplies for credit.

- Place all expired drugs and medical materials in a clearly labeled container while they await pickup for disposal or return to manufacturer.

## **V. REGULATIONS**

*Guide for the Care and Use of Laboratory Animals, Eighth Edition*, November, 2013, p. 123. – *Anesthesia and Analgesia* – “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.”

*PHS Policy FAQ F.5* (<http://grants.nih.gov/grants/olaw/faqs.htm#663>) – “The use of expired pharmaceuticals, biologics, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care. Euthanasia, anesthesia and analgesia agents should **not** be used beyond their expiration date...”

According to the USDA Animal Welfare Regulations Animal Care Policy #3: “...the use of expired medical materials (e.g. drugs, fluids, sutures, anesthetics, sedatives, or analgesics) during any survival surgical procedure on a regulated species is not considered acceptable veterinary practice and therefore not consistent with adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act.” The finding of expired drugs and/or materials during a USDA inspection may result in a citation for inadequate veterinary care.