

Institutional Animal Care Program		
Title: Use of Non-Pharmaceutical Grade Compounds and/or Expired Medical Materials		
Policy#: IACP 015	Date in Effect: 11/14/08	
Rev #: 01	Rev Date: 12-11-15	
Rev #: 02	Rev Date: 04/12/19	
In Effect <input type="checkbox"/>	Rescinded <input type="checkbox"/>	Date Rescinded:

A) RESPONSIBILITIES

It is the responsibility of all personnel using animals in research and teaching to ensure that only pharmaceutical grade compounds and non-expired medical materials are used in animals in research at UTSA. It is the responsibility of the IACUC to review for approval properly justified requests for an exception to this policy.

B) APPLICATION

This policy applies to all animal use in research and teaching at UTSA.

C) REFERENCES

- 1) USDA Animal Care Policies, Policy #3, Veterinary Care,
http://www.aphis.usda.gov/animal_welfare/downloads/policy/policy3.pdf.
- 2) Frequently Asked Questions About the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*.
http://grants2.nih.gov/grants/olaw/faqs.htm#useandmgmt_4.

D) PROCEDURES

- 1) **Pharmaceutical grade compounds**. For animal research and teaching, investigators are expected to use pharmaceutical-grade compounds whenever these are available, even in acute procedures. Issues such as sterility, pyrogenicity, stability, pharmacokinetics, and quality control have usually been addressed during the course of producing pharmaceutical-grade compounds, but one cannot say the same for substances formulated in the research laboratory. The use of non-pharmaceutical-grade chemical compounds in experimental animals can be, however, a necessary and acceptable component of biomedical research, providing it meets the below criteria:
 - a) IACUC Approval Requirement:

- (1) Non-pharmaceutical-grade chemical compounds, including expired pharmaceutical drugs, may be used in research/teaching utilizing animals if their use is reviewed and approved by the IACUC before they are used. The following areas must be addressed in the justification submitted to the IACUC for their consideration of an exception to this policy:
 - (a) Scientific necessity must be documented;
 - (b) An acceptable veterinary or human pharmaceutical-grade compound is not available; and,
 - (c) Cost savings alone do not adequately justify the use of non-pharmaceutical-grade compounds in animals.
- (2) In preparing proposals to use non-pharmaceutical-grade chemical compounds, investigators should address the quality of the preparations they propose to use, i.e., issues of **purity, stability and sterility**. Investigators should explain if and to what extent purity and sterility will be maintained in the preparation and administration of the compound, in particular when it is administered parenterally. Information about stability and pharmacokinetics should be given when available.
- 2) **Expired Medical Materials**. The following issues must be taken into consideration when proposing the use of expired medical materials:
 - a) The use of expired medical materials such as drugs, fluids, or sutures on animals is not consistent with acceptable veterinary practice and does not constitute adequate veterinary care as required by the Federal Regulations governing the use of animals in research.
 - b) Euthanasia, anesthesia and analgesia agents should not be used beyond their expiration date, even if a procedure is terminal.
 - c) Expired materials should not be used unless the manufacturer verifies efficacy beyond the expiration date, or the investigator is able to document to the satisfaction of the IACUC that such use would not negatively impact animal welfare or compromise the validity of the study.
 - d) All expired medical materials must either be disposed of or segregated in an appropriately labeled, physically separate location from non-expired medical

materials. For guidance on disposal of expired medical materials (including expired controlled/scheduled substances) contact the EHSRM (x-5250).

- e) For acute terminal procedures, the use of expired medical materials may be permitted if properly justified to and approved by the IACUC, provided their use does not adversely affect the animal's well-being or compromise the validity of the scientific study.
- f) Proper anesthesia, analgesia, and euthanasia are required for all such procedures.
- g) Drugs administered to relieve pain or distress and emergency drugs must not be used beyond their expiration date. The University Veterinarian and the IACUC are responsible for ensuring that proposed animal activities avoid or minimize discomfort, distress, and pain to the animal.

3) Expiration of Mixed Drugs

- a) Dilution or mixing of injected drugs allows more precise or enhanced dosing but may shorten the shelf life of the compound.
- b) UTSA-IACUC's standard is for diluted drugs to be labeled and discarded after 30 days.