

University of California, Merced
Institutional Animal Care and Use Committee Policy

Version No. 1

Policy No. 114

Use of Expired Drugs and Medical Material in Research Animals

- I. **Purpose:** The Animal Welfare Act and Regulations mandate that all animals in research facilities receive adequate veterinary care and treatment to ensure that pain and distress are minimized. Such care includes appropriate use of anesthetic, analgesic, tranquilizing drugs or euthanasia consistent with accepted standards of veterinary care.
- II. **Definitions:**
- a. **Acute/terminal procedure:** A procedure, surgical or non-surgical, for which an animal receives an anesthetic agent and is euthanized without recovering from anesthesia.
 - b. **Chemical grade:** Compounds or agents that may be chemically identical to their pharmaceutical grade counterparts but do not conform to recognized standards for purity and bioavailability.
 - c. **Medical materials:** Items used clinically or for research purposes that may have an expiration date assigned by the vendor for the purpose of guaranteeing sterility.
 - d. **Pharmaceutical grade compound:** Drugs, biologics or reagents approved by the U.S. Food and Drug Administration (FDA) or for which a chemical purity standard has been established by the United States Pharmacopeia-National Formulary or British Pharmacopeia. Pharmaceutical grade agents are intended for use in human or veterinary medicine and meet the highest standards for purity and bioavailability.
 - e. **Survival procedure:** A procedure, surgical or non-surgical, performed on an animal that is subsequently allowed to recover from anesthesia.
- III. **Policy:** The use beyond its published expiration date of any drug administered to relieve pain or distress (anesthetics, analgesics, antibiotics), including euthanasia agents is not consistent with acceptable or adequate veterinary practice and is not allowed under any circumstances. Expired medical materials such as saline solution, sutures, medical devices, etc., may be used in animals undergoing acute/terminal procedures if their use does not adversely affect the animal's well-being or compromise the validity of the study. In addition, the IACUC expects that investigators will use pharmaceutical grade medications whenever they are available, even in acute/terminal procedures. Non-pharmaceutical grade compounds should be used only after specific review and approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical grade product. Cost savings is not sufficient justification for using non-pharmaceutical grade compounds in research animals.
- IV. **Responsibility:** It is the Principal Investigator's responsibility to ensure that drugs and medical materials used in animal subjects are within the vendor's expiration date. In addition, it is recommended that each investigator establish an inventory procedure to facilitate the identification and discarding of expired drugs and medical materials in a timely fashion. Disposal services for expired drugs and/or controlled substances can be arranged by calling UCM EH&S at 209-228-7864.

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V. Related Policies and Guidelines:

- Research and Instruction Using Animal Subjects (Policy 100)

VI. References:

- Animal Welfare Regulations, 9 CFR Chapter 1, Subchapter A, Part 2, Subpart C, Section 2.33(b)1-5
- Guide for the Care and Use of Laboratory Animals, 8th Edition (2011)