

**Expired Drugs, Medical Materials &
Devices**
IACUP Policy
Effective Date: October 2021



I. Purpose

This policy establishes the limitations on usage of expired drugs and medical materials in animal research in order to protect the health and welfare of research animals. This policy has been developed to ensure that UCSF complies with the Guide for the Care and Use of Animals, 8th Edition, and the NIH Guidelines and the PHS Policy on the Humane Care and Use of Laboratory Animals.

II. Regulatory or Accreditation Authority

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

(https://olaw.nih.gov/faqs#/guidance/faqs?anchor=questionuseandmgmt_5) – 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, even if a procedure is terminal. Other 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.

III. Scope

This policy applies to all laboratory animals housed at UCSF, both in and outside of centralized LARC care space.

IV. Definitions (optional)

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. Examples include but are not limited to: Tamoxifen, Meloxicam, anesthesia agents, analgesia agents, etc.

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 Device: An instrument, apparatus, implant or other similar article intended for use in the diagnosis, treatment, or prevention of disease.

V. Policy

A. Expired Drugs and Agents

All drugs and agents to be administered to animals must be discarded on or before the manufacturer's expiration date. Expired drugs, fluids, food, therapeutics, or agents must not be provided to lab animals in research or instruction or stored within the animal use area. Diluting and mixing drugs or agents may change drug chemical composition and shelf life. Therefore, all dilutions and mixtures must be discarded within 30 days of preparation, unless the manufacturer specifies a longer shelf-life for dilutions and the manufacturer specifications are followed for preparation and storage.

All drugs, agents or dilutions awaiting proper disposal (e.g., controlled substances) must be labeled (e.g., Expired) and stored separately.

B. Expired Medical Materials

The use of expired medical materials for survival procedures is not permitted. Medical materials may be used beyond their expiration date for **acute terminal procedures only** where an animal is anesthetized during the study and euthanized without recovery, if such use does not adversely affect the animal's well-being or compromise the validity of the scientific study. They must be clearly labelled (e.g., "EXPIRED, for terminal procedure use only") and stored separately from other in-date drugs and materials. Non-expired medical materials outside of their sterility date can be used for non-sterile purposes or can be-sterilized and re-labeled with a new expiration date.

C. Expired Medical Devices

Medical devices may be used beyond their expiration date for **terminal** procedures. The use of expired medical devices during terminal procedures does not require separate request or IACUC approval.

Under specific circumstances, expired medical devices may be re-sterilized and used for survival procedures. The IACUC form, "[Request to Use Expired & Resterilized Medical Devices](#)," must be submitted to and approved by the IACUC. **A separate request form must be completed for each protocol.** If approved, LARC must inspect all medical devices, perform the resterilization and packaging procedures, and determine if each device is appropriate for subsequent use. Only devices that maintain their integrity and functionality can be used in

animals. An individual device may be resterilized no more than once, unless otherwise allowed per manufacturer.

D. IACUC Storage Recommendations

The IACUC recommends that each laboratory establish an inventory procedure to identify and discard expired items. Items not intended for live animal use should be labeled (e.g., “In Vitro Use Only”) if stored within the animal use area.

All medical materials and supplies used in live animals, including acute procedures, should be individually labeled. If items are not individually labeled, they must be kept in a drawer, bin, cabinet or other container clearly labeled with the PI’s name. 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. EH&S will be contacted to arrange for disposal of unidentifiable contents.

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

1. Store all drugs in one location to facilitate regular oversight. Please contact LARC if you would like assistance in obtaining a lockable box or cabinet for your drugs.
2. Consider assigning inventory responsibilities to one lab member and identify another lab member as backup.
3. Establish an inventory system which minimizes the amount of drug or medical supplies on hand.
4. Consider use of a color-coded labeling system that overtly identifies year and month of expiration. Contact the IACUC office if you would like guidance.
5. Perform regular (e.g., monthly) checks of your inventory and discard all expired items.
6. Contact suppliers to see if they will accept return of expired drugs or medical supplies for credit or replacement.
7. Place all expired drugs and medical materials intended for disposal in a clearly labeled container while they await pickup for disposal or return to the supplier/manufacturer.

E. Disposal

Disposal services for expired drugs and/or controlled substances are available at no cost to the investigator by calling EH&S at 415-476-0544.

References:

Kapoor A., et. al. Guidance on reuse of cardio-vascular catheters and devices in India: A consensus document. *Indian Heart Journal* 69 (2017) 357–363.