

Drexel University Animal Care and Use Committee

Policy on Expired Drugs and Medical Materials

1. Purpose

The purpose of this policy is to provide guidance to principal investigators and their staff regarding the expiration and disposal of expired drugs and medical materials. This policy has been developed to ensure compliance 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.

2. Scope

The principal investigator is responsible for ensuring that everyone working on an applicable protocol adheres to this policy.

3. Regulatory Authority

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, 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.

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.

4. Definitions

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, injectable fluids, anesthesia agents, analgesia agents, euthanasia agents, etc. This also includes experimental compounds approved by the IACUC.

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: sutures, catheters, gauze, etc.

5. Policy

A. Expired Drugs

All drugs must be discarded on or before the manufacturer's expiration date. No expired drugs or fluids are allowed for use on animals for research or instruction.

All dilutions and mixtures of drugs are to be discarded after one month from the date of preparation unless a shorter shelf-life is specified by the manufacturer. Dilutions and mixtures of drugs may change the chemical composition of a drug and could alter its shelf life. For this reason, even if it is earlier than the manufacturer's drug expiration date, all dilutions or mixtures made from a drug must be discarded after one month. Containers must be clearly labeled with compound names, concentrations, and date of preparation and expiration.

Bags of fluids are considered expired one month after the bag is opened or pierced with a needle. The bag should be labeled with the date of the first day of use. Additionally, single use containers of fluids should be discarded after the day of use.

B. Expired Medical Materials

Expired medical materials or devices may not be used beyond their expiration date; they must be separated from other materials and discarded.

This includes medical materials outside of their sterility date. Expired materials capable of being re-sterilized should be dated with a new expiration date appropriate for the package being used.

The one exception for use of expired medical materials is in acute terminal procedures. Materials intended for use in acute terminal procedures must be stored separately from in-date materials and be clearly labeled "for acute/terminal use only."

Appendix A: Drug Inventory

Each laboratory should 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 with expiration dates. 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 following are general guidelines suggested to help comply with this policy:

1. Store all drugs in one location (to make checking easier). Controlled drugs must be in a double locked location. Non-controlled drugs are not required to be in a locked location.
2. Consider assigning the inventory responsibilities to one specific individual, with another individual assigned as backup.
3. Establish an inventory system which minimizes the amount of drug or medical supplies on hand.
4. Perform regular monthly checks of your inventory and discard all expired drugs or medical materials.

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

Appendix B: Disposal of Expired Drugs

Contact Environmental Health and Safety (EH&S) to schedule a chemical pick-up. This includes Controlled Materials. [Drexel Facilities Chemical Pick-Up Request/Chain of Custody](#)

Appendix C: Recordkeeping

Investigators are required to keep records (in pre-operative, intra-operative, post-postoperative, euthanasia or procedural records) documenting each use of an anesthetic, analgesic, or euthanasia agent in a live animal. These records must include the expiration date of the agent used and must be made available to any IACUC member or the Animal Welfare Education Specialist upon request for review.

If an expired anesthetic or analgesic drug or euthanasia agent is found in working stock and records do not accurately reflect the use of an in-date drug, the investigator will be required to submit a monthly report (of all anesthetic and analgesic drugs) to the IACUC for six months.