

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

POLICY ON THE USE OF EXPIRED DRUGS AND MEDICAL MATERIALS

GENERAL POLICY

According to federal laws, regulations, and policies, the use of expired pharmaceuticals, biologics, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care. Drugs administered for anesthesia, analgesia, veterinary care, or euthanasia should not be used beyond their expiration date, even if a procedure is terminal. Other expired materials must 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.

In addition, all drugs and other medical supplies used on research animals must be properly stored, and appropriately labeled.

EXPIRATION DATES

- **Unopened drugs and medical materials in the original packaging:** expiration date or use by date printed on the label or packaging by the manufacturer.
- **Opened multi-dose vials/bags of injectables:** a multi-dose vial or bag that has been opened or accessed (e.g., needle-punctured) should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial/bag.
- **Aliquots:** expiration date or use by date printed on the label or packaging of stock material.
- **Reconstituted solutions:** expiration date or instructions printed on the label or packaging by the manufacturer. Reconstituted solutions must be stored under the conditions described in the packaging.
- **Dilutions:** discard 28 days after preparation
- **Mixtures / formulations:**
 - NOTE: Any mixture that becomes clouded or precipitates should not be used in animals
 - Discard 28 days after preparation
 - If the stability of an agent in formulation is unknown, prepare fresh prior to each use.

Aliquots, dilutions, reconstitutions, or mixtures of drugs or fluids should be prepared using sterile technique and stored under proper conditions; see Appendix 1 for recommended storage

containers. These materials must be labeled as described in [Labeling Requirements and Expiration Dates for Research Drugs](#) with:

- Contents
- Concentration
- Date of reconstitution/preparation
- Expiration date
- Initials of preparer

An item is considered expired the day after the month or date indicated on the label. For example, an item with the expiration date of January 2021 on the label would be considered expired on February 1, 2021. Expired materials should either be disposed of or segregated to a location physically separated from non-expired materials. The expired materials must be clearly labeled “For Non-survival Use Only”.

SELECT USE OF EXPIRED MEDICAL MATERIALS

Expired anesthetics, analgesics, sedatives, emergency drugs, or euthanasia drugs may never be used in any live animal, regardless of whether the procedure will be terminal.

	Non-Survival Procedures	Survival procedures
Can be used	<p>If the packaging has not been opened or compromised:</p> <ul style="list-style-type: none"> • Parenteral fluids (e.g., saline, Ringer’s, etc.) • Surgical instruments • Suture materials • Supplies (e.g., gauze, needles, butterfly catheters, etc.) • Implantable materials or devices (e.g., cardiac catheters, etc.) 	<p>If items are re-sterilized and their function is not compromised:</p> <ul style="list-style-type: none"> • Surgical instruments • Supplies • Implantable materials and devices <p>The date of re-sterilization must be indicated on the packaging, and the pack must include the appropriate sensor strips indicating successful sterilization.</p>
Cannot be used	<p>Regardless of the packaging’s condition:</p> <ul style="list-style-type: none"> • Physiologically active drugs • Anesthesia, analgesia, emergency drugs • Euthanasia drugs 	<ul style="list-style-type: none"> • All drugs and parenteral fluids (e.g., saline, Ringer’s, etc.) • Functionally compromised devices (e.g., instruments, sutures, etc.).

In order to assure compliance with these regulatory requirements, the IACUC, CCM, and Environmental Health & Safety will conduct periodic audits of animal housing and use sites. Any substances and materials discovered during the course of an audit that are expired, inadequately labeled, or inappropriately stored will be discarded at that time. Failure to comply with this policy may result in suspension or revocation of animal research privileges.

REFERENCES

U.S. Department of Agriculture. [Animal Welfare Act and Regulations](#) (Animal Care Blue Book). Code of Federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Parts 1-4. 2020.

U.S. Department of Health and Human Services. [Frequently Asked Questions, PHS Policy on Humane Care and Use of Laboratory Animals. F. Animal Use and Management, Question 5.](#) Office of Laboratory Animal Welfare, National Institutes of Health: Bethesda, MD, January 9, 2020.

U.S. Department of Health and Human Services. [Guidelines for the Select Use of Expired Medical Products](#) . National Institutes of Health, Animal Research Advisory Committee: Bethesda, MD, September 26, 2018.

U.S. Department of Health and Human Services. [Drug Packaging and Labeling Control - Expiration Dating](#). Code of Federal Regulations (CFR), Title 21, Volume 4, Chapter 1, Subchapter C, Part 211.137. 2020.

U.S. Department of Health and Human Services. [FAQs regarding Safe Practices for Medical Injections - Questions about Multi-dose vials](#). Centers for Disease Control and Prevention: June 20, 2019.

v1.1, February 2005
v1.2, August 2013
v2.1, 20 September 2017
v2.2, 17 February 2021

Appendix 1. Recommended storage containers for aliquots, dilutions, or mixtures/formulations of drugs or fluids

All aliquots, dilutions, and formulations should be prepared using aseptic procedures and should be stored in sterile containers.

For drugs or agents that will be prepared and used on the same day, sterile screw cap vials or tubes like the ones pictured below may be used.



If drugs or agents will be used for more than one day, a sterile container with a rubber septum should be used. An additive free Vacutainer is an acceptable alternative.

