



IACUC Guidance:	<b>TAMU-G-024</b>	Title:	<b>Guidelines for the Use of Expired Medical Materials</b>	
		Location	Effective Date	Review By
		<b>College Station/Dallas/Galveston/Kingsville</b>	06/01/2024	05/31/2027
		<b>Houston</b>	07/01/2024	05/31/2027

**1. PURPOSE**

1.1. To provide guidance on the appropriate use of expired medical materials in or on live vertebrate animals.

**2. SCOPE**

- 2.1. Applies to vertebrate animals used for research, teaching, or other purposes under the oversight of the Texas A&M University IACUC.
- 2.2. See TAMU-G-010 for information regarding the use of pharmaceutical and non-pharmaceutical drugs and compounds.

**3. RESPONSIBILITY**

- 3.1. **Principal Investigators** are responsible for:
  - 3.1.1. Establishing an inventory procedure to facilitate in the identification, segregation and discarding of expired products.
  - 3.1.2. Providing justification in the AUP for the proposed use of expired medical material in non-survival studies before use occurs.
- 3.2. The **IACUC** is responsible for:
  - 3.2.1. Conducting an assessment exploring the potential risks to animal welfare and
  - 3.2.2. Approving exceptions for the use of expired product if the use does not adversely affect the animal's well-being or compromise the validity of the scientific study.

**4. DEFINITIONS AND/OR ACRONYMS**

- 4.1. **Animal:** Any live, vertebrate animal used or intended for use in research, research training, experimentation, teaching, or biological testing or for related purposes.
- 4.2. **AUP:** Animal Use Protocol. Document submitted by the PI indicating the housing and research procedures involving animals.
- 4.3. **IACUC:** Institutional Animal Care and Use Committee. Institutional body responsible for ensuring adherence to federal regulation and institutional policy relating to the care and use of animals in teaching, testing and research. Appointed by the Institutional Official.
- 4.4. **Medical Material:** General category which includes but is not limited to drugs administered for clinical or therapeutic purposes, fluids, substances administered for experimental purposes, implantable materials, catheters, sutures, surgical gloves, skin disinfection solution, and other medical devices and medical materials used in or on live vertebrate animals.
- 4.5. **Non-Survival Procedure:** A procedure in which an animal is euthanized under general anesthesia prior to anesthetic recovery.
- 4.6. **PI:** Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.
- 4.7. **USDA:** United States Department of Agriculture. USDA Animal Care, a unit under the Animal and Plant Health Inspection Service, administers the Animal Welfare Act (AWA) and associated Animal Welfare Act Regulations (AWAR).
- 4.8. **USDA Regulated:** Species or activities which fall under the AWA/AWAR.

**5. GUIDELINES OR PROCEDURE**

5.1. **Dating of Medical Materials:**

5.1.1. See TAMU-G-010 for establishing the date of expiration for drugs and compounds, which for the purposes of this Guidance also applies to non-drug/compound medical materials.

**5.2. Use of Expired Medical Materials:**

5.2.1. **Anesthetic, analgesic, euthanasia, or emergency drugs cannot be used on or administered to live animals beyond the established expiration date under any circumstance.**

**5.2.2. USDA regulated species:**

5.2.2.1. Medical materials of **any type** are not to be used on or administered to USDA regulated species beyond the established expiration date.

**5.2.3. All other species:**

5.2.3.1. All other medical materials (excluded by the list above) cannot be administered to live animals beyond the established expiration dated except when:

5.2.3.1.1. the medical material is proposed to be used or administered during the performance of a **non-survival procedure**, and

5.2.3.1.2. the intended usage, including identification of the specific procedure(s), is described in the AUP prior to use and approved by the IACUC.

**5.3. Inventory, Labelling and Segregation of Expired Medical Materials**

5.3.1. See TAMU-G-010 for general inventory, labeling and segregation requirements for drugs and compounds.

5.3.2. All expired materials that are to be maintained and used for non-survival procedures (with prior IACUC approval) must be clearly and individually labeled as “expired - IACUC approved for non-survival use only” and be physically segregated from in-date stock.

**6. RECORDS**

6.1. Research records, including medical records, must be maintained consistent with Texas A&M University Standard Administrative Procedures (SAPS) 15.99.03.M1.03. and 29.01.03.M0.01

**7. EXCEPTIONS**

7.1. The PI may request an exception to the above standards by describing the departure in the AUP.

7.1.1. The justification provided should include a description of the relative risk of serious infection, material failure (e.g., from expired suture) or other adverse effect on the welfare of the animal and assurance that the use of the expired medical material will not compromise the validity of the study.

7.1.2. In situations in which the total supply of all clinically interchangeable versions of an FDA-regulated anesthetic, analgesic, euthanasia, emergency, or other drug is in shortage to the point of unavailability, PIs may submit documentation to the IACUC for approval for the use of an expired drug.

7.2. For programmatic exceptions, the facility director or manager may submit a request for the exception using TAMU-F-013 Request for Programmatic Exception from Animal Welfare Standards

**8. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION**

**8.1. References**

8.1.1. [Animal Welfare Act](#)

8.1.2. [Guide for the Care and Use of Laboratory Animals, Eighth Edition](#)

8.1.3. OLAW FAQ F.5. [May investigators use expired pharmaceuticals, biologics, and supplies in animals?](#)

**8.2. Resources**

8.2.1. [IACUC/AWO Referenced Documents](#): (requires TAMU NetID authentication)

8.2.1.1. AWO-O-006 Authorized Expired Materials Label

8.2.1.2. TAMU-G-010 Guidelines for the Use of Pharmaceutical and Non-Pharmaceutical Grade Drugs and Compounds

8.2.2. For assistance finding sources for veterinary pharmaceuticals, contact:

8.2.2.1. [CMP](#) at 979-845-7433



8.2.2.2. ARU: at (214) 828-8149

8.2.2.3. PAR: at (713) 677-7471

8.2.2.4. PRF: at (361) 221-0770

**8.2.3. Acknowledgements**

8.2.3.1. This document was partially adapted from materials from the NIH Office of Intramural Research – Office of Animal Care and Use and Boston University.

**9. HISTORY**

Effective Date	Version #	Description
12/06/2019	000	College Station/Galveston: New document. Final review and approval via email.
02/21/2020	001	Houston/Kingsville: New format and content; replaced IBT-216.02
03/31/2020	002	Dallas: New format and content; replaced CD-216.01; site-specific point in 5.5.1.2.1. Final review and approval via email.
11/02/2020	003	College Station/Galveston: Renewal. Reviewed and approved via email.
11/10/2020	004	Dallas: Renewal.
12/01/2020	005	Houston/Kingsville: Renewal. Reviewed and approved via email.
09/01/2021	006	College Station/Galveston: Renewal. Reviewed and approved via email.
10/01/2021	007	Houston/Kingsville: Renewal. Reviewed and approved via email.
10/19/2021	008	Dallas: Renewal.
03/24/2022	009	College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston
10/20/2022	010	College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.
06/01/2024	011	College Station/Dallas/Galveston/Kingsville: Renewal; updated purpose, scope responsibility, definitions and references sections; revision of procedures section to remove text duplicative with TAMU-G-010 and better focus contents on topic of this guidance; expansion of exceptions section to incorporate text from body of document; addition of records section.
07/01/2024	012	Houston: Renewal; updated purpose, scope responsibility, definitions and references sections; revision of procedures section to remove text duplicative with TAMU-G-010 and better focus contents on topic of this guidance; expansion of exceptions section to incorporate text from body of document; addition of records section.