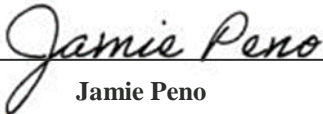
 <div> <div>DIVISION OF RESEARCH &amp; INNOVATION</div> <div>Research Integrity &amp; Compliance</div> </div>		<b>Institutional Animal Care and Use Committee</b>  <b>Standard Operating Procedures</b>	
<b>Title: Use of Expired Materials in Animal Research</b>			
<b>Effective Date:</b>	December 22, 2020	<b>Document Number:</b>	IACUC-SOP-02-20.00
<b>Approval/Date:</b>  <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">               _____  <b>Jamie Peno</b>              Director, Research Integrity and Compliance           </div> <div style="text-align: center;">             12/22/2020              _____  <b>Date</b> </div> </div>			
<b>REVISION HISTORY</b>			
<b>Date</b>	<b>Section</b>	<b>Author</b>	

## PURPOSE

It is not acceptable veterinary practice to use expired medical materials in animals. The use of expired euthanasia, anesthesia, and analgesic agents is never acceptable to use past their expiration date, even for terminal procedures. The use of expired medical materials such as drugs, fluids, sutures, or other implants in a survival surgical procedure is not considered to be acceptable veterinary practice and does not constitute adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act.

For acute terminal procedures (with the exception of euthanasia, anesthesia, and analgesic agents), expired medical materials may be used if the manufacturer is able to verify the efficacy of the product beyond the expiration date, or if the investigator is able to document that it does not adversely affect the animal's wellbeing or compromise the validity of the scientific study.

Animal Lab facilities must either dispose of all such materials or segregate them in an appropriately labeled, physically separate location from non-expired medical materials.

## SCOPE

The Attending Veterinarian and the IACUC are responsible for ensuring that proposed animal activities avoid or minimize discomfort, distress, and pain to the animal; therefore, they must maintain control over the use of expired medical materials.

It is the responsibility of the Principal Investigator to disclose any desired use of expired materials for the study and to provide appropriate justification for such as well as gain approval prior to their use in an animal use protocol.

It is the responsibility of the Principal Investigator to follow the guidelines outlined by

this procedure and to ensure staff are trained in the proper use and storage of expired items.

It is the responsibility of the Principal Investigator and lab staff to employ methods of inventory monitoring and control to ensure expired materials and drugs are routinely removed from useable stock and discarded or stored appropriately.

## **DEFINITIONS AND ABBREVIATIONS**

UNT- University of North Texas, Denton

IACUC- Institutional Animal Care and Use Committee

SOP/SOP's- Standard Operating Procedure(s)

AUP- Animal Use Protocol

PI- Principal Investigator

AV- Attending Veterinarian

## **PROCEDURES**

- I. Expired Materials and Substances**
  - A.** It is not acceptable veterinary practice to use expired medical materials such as drugs, fluids, sutures, or other implants in a survival surgical procedure in animals.
  - B.** Investigators are responsible for ensuring that all drugs and medical materials used in their laboratories are within the expiration date.
  - C.** All drug reconstitutions and preparations that are not stored in their original containers must be labeled with the date of preparation and the earliest expiration date of the component drugs.
  - D.** All materials resterilized or transferred from their original packaging should be labeled with their original expiration date.
    1. Re-useable items in resterilized packaging should have the date of sterilization labeled on the outermost package.
    2. Refer to packaging and method of sterilization for date of needed resterilization.
  - E.** All expired supplies must be labeled "Expired-Do Not Use" and stored separately from non-expired materials if immediate disposal is not possible or desired.
- II. Survival Procedures**
  - A.** No expired drugs or materials may be used in survival surgeries.
  - B.** An item stamped with an expiration date that only includes the month and year of expirations may be considered in-date through the end of the month stated.
    1. ie. 12/2021 is considered expired on January 1, 2021 and can be used through December 31, 2020.
  - C.** If the need to use expired medical materials in a survival procedure arises, justification for its use is required in the approved IACUC protocol the item will be used under.
- III. Acute Terminal Procedures**
  - A.** With the exception of controlled substances and emergency, anesthetic, analgesic, or euthanasia drugs, some expired medical materials may be used in terminal/ non-survival procedures provided:
    1. The use of expired medical materials is explicitly stated in the IACUC protocol and approved.
    2. Materials are marked as "Expired – Use ONLY in TERMINAL Procedures."
    3. Materials are stored in a different location (cabinet, drawer, etc.) than materials used for survival procedures.
    4. The use of expired medical materials does not adversely affect the animal's well-being or compromise the validity of the scientific study.
    5. Proper anesthesia, analgesia, and euthanasia are employed for all such procedures, and

all materials used for anesthesia, analgesia, and euthanasia are in date.

#### **IV. Inventory Control and Storage of Animal Use Substances and Materials**

- A.** In order to prevent the inadvertent use of expired drugs or fluids, each laboratory must establish an inventory procedure to facilitate the identification and discarding of expired drugs.
1. Items with expirations should be individually labeled. Any items not individually labeled by the manufacturer that may be separated from their primary or original packaging with Lot/Exp information should be labeled prior to separation.
  2. All expired items being kept, including anesthetics and analgesics, must be segregated and stored away from in-use stock and clearly marked “EXPIRED” on or before their date of expiration.
  3. Laboratories should develop an inventory tracking system based on their specific needs.
  4. Examples of inventory tracking systems:
    - a) Colored sticker systems can be implemented for easy identification of expiration dates.
      - i. A key should be created and readily available to indicate what colored stickers represent (ie. month of exp.)
      - ii. As inventory is added to stock, it should be labeled with the appropriate sticker.
      - iii. This method allows for quick visual identification of items that should be removed from in-date stock.
    - b) Weekly/Monthly inventory checks.
      - i. Personnel should be assigned a specific time to routinely pull items that will expire before the next scheduled check.
    - c) Database and/or barcode system
      - i. As inventory is added to stock it is checked into a database manually or through a barcode/sticker scanning system to include all relevant information.
      - ii. As items are used they should be removed from the database.
      - iii. Personnel should be assigned to check the database regularly to identify stock that will expire prior to the next check and remove items from in-date stock.

#### **REFERENCES**

1. The Guide for the Care and Use of Laboratory Animals.
2. Animal Welfare Act

#### **APPENDICES**

IACUC Standard Operating Procedures