Policy on the Use of Expired Medical Materials or Devices

Summary/Purpose: To establish proper procedures for the use of expired medical materials and/or devices in regard to animals used in Research or Instruction

Description:

The following addresses the guidance provided in the APHIS Animal Care Resource Guide, Issue Date January 14, 2000 – Policy # 3 regarding Expired Medical Materials (http://www.aphis.usda.gov/ac/polmanpdf.html)

In very rare circumstances a request to use expired medical materials and/or medical devices in acute terminal procedures may be approved by the UM IACUC. If investigators wish to use expired materials or devices, the form entitled “Request to Use Expired Medical Materials or Devices in Acute Terminal Procedures in Animals used in Research or Instruction” must be submitted to and approved by an IACUC Representative/Designee.

Specific Requirements for Acute Terminal Procedures:

Before completing the form, please note the following important information:

- An effective inventory system must be established. The Principal Investigator is responsible for making sure that an effective system is in place and that regular monthly audits of the inventory are performed.

- Outdated anesthetics or analgesics must never be used. It is unacceptable to use outdated drugs to alleviate pain, even in an acute terminal (non-survival) procedure.

- Outdated medical materials (non-drug related items) or devices must not be used in survival surgery areas. Any such requests will not be approved.

- STERILITY DATING (*). Items such as catheters, surgical instruments, sterile gloves, suture materials, and pressure transducers are often labeled with an expiration date to assure sterility. After the expiration date these materials may be used only in procedures involving anesthetized animals in acute terminal (non-survival) procedures.

(*) If needed for survival studies, outdated or items which may no longer be sterile (e.g. catheters, surgical instruments, syringes, etc.), may be repackaged and re-sterilized before use. Re-sterilized items should be labeled with a new expiration date that is appropriate for packaging used (See sop ac. 2.3 for more information).
Procedures to Be Followed:

1. Investigators must read and complete all sections of the form “Request to Use Expired Medical Materials or Devices in Acute Terminal Procedures in Animals used in Research or Instruction”. This form includes a section to provide the justification for such a use, a description of the use, a plan for how sterility will be assured, and procedures for appropriately labeling and storing these materials separately from non-expired materials. A separate request form must be completed for each protocol.

2. The PI must identify a segregated space where the expired medical materials and/or devices will be kept (e.g., a closet, a cabinet, a shelf).

3. The segregated area must be clearly labeled with a label which reads “Expired Medical Materials: For Use in Terminal Procedures Only.”

4. The PI must identify a specific person who will be responsible for monitoring the inventory and making sure that each expired item is appropriately labeled with the label which reads “Expired Medical Materials: For Use in Acute Procedures Only.”

5. Once approved, a signed copy of the Request form must be kept on file at the IACUC Office. From then on, the request form must be submitted in conjunction with the associated protocol renewal application and will be reconsidered on an annual basis.

6. All authorized personnel must be informed of this request and trained in the proper procedures for using the expired materials or devices identified in the form.

NOTE: Animal facility staff will inspect laboratory housing and study/procedure areas once a month while in use (See sop ac. 2.3 “Use of Expired Medical and Research Supplies in Animal Care Facilities” for more information.).

References: AWA Section 13; 9 CFR, part 2, Sections 2.31, 2.32, 2.33, 2.40; 9 CFR, part 3, Section 3.110