



IACUC Policy

Expired Materials in Animals, Use of

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Introduction

In the course of their research, investigators may have questions pertaining to the use of expired materials. The SDSU IACUC policy on this issue incorporates guidance from the NIH Office of Laboratory Animal Welfare (OLAW), the USDA Animal Care Division and AAALAC, International. These materials, as well as policies from a number of other institutions are referenced at the end of this document.

Use of expired drugs and compounds at SDSU

1. Survival Studies: Expired medical materials may not be used on animals in survival studies. Requested exceptions to this policy must be included in the animal use protocol, along with the scientific justification for the use of expired materials. IACUC approval must be granted prior to use. It is never acceptable to use outdated anesthetics, analgesics, antibiotics or emergency drugs in any case.
2. Non-Survival Studies: Expired medical materials such as drugs, fluids and sutures may only be used on anesthetized research animals and the animals may not recover from the anesthetic procedure. Anesthesia for these terminal studies must be induced and maintained using current, non-expired drugs.
3. All expired materials must be clearly and individually labeled as "Expired - for acute use only" and kept together in a labeled area physically separate from all other medical materials and drugs.

Definitions

Expiration Date: The date printed on the label or package by the manufacturer for products specifically designed for medical use including pharmaceutical grade compounds

Expiration of Prepared Compounds

Compounds should be formulated and used on an “acute” basis, in particular if the time to degradation is unknown. Preservative free containers or formulations should be discarded within 1-7 days from first use. Working solutions of anesthetics must be used within 3 weeks of solution preparation. All solutions used in animals should be used within 30 days after preparation of the compound.

An expiration date can be determined using the following:

- For formulations made from single compounds use the date listed on the original bottle or box.
- For mixtures/compounds where expiration dates of the components are known, use the earliest date listed on any agent which is mixed or compounded.
- For experimental compounds, an expiration date may need to be determined based on a number of factors. Investigators should be prepared to provide information about the stability and shelf-life of the product based on information from various sources (i.e., manufacturer, chemical supply house, compounding pharmacy or literature) to support the expiration date. If no information is available, then an expiration date of 30 days from the date of preparation can be used. However, since shelf-life is unknown, long term storage (>30 days) is strongly discouraged.

NOTE: Any formulation or compound will be considered to be expired, regardless of the expiration date on the label if any of the following are observed:

- **The agent fails to perform in a manner that is consistent with what is expected.**
- **The sterility of the compound has been compromised.**
- **The solution has changed in color and/or is cloudy, precipitated, or otherwise altered.**
- **The solution is no longer physiologically compatible.**

Solution Preparation Guidance

- All containers must be labeled with material name, concentration, date prepared, storage requirements, expiration date and the initials of the person making the solution.
- The solution should be passed through a 0.2 micron filter.
- Administration and storage of formulations should be appropriately considered with the aim of maintaining sterility and quality. (i.e., to prevent inadvertent co-administration of infectious agents or contaminants).

See IACUC Policy on Non-pharmaceutical Grade Substances and Compounds for more information.

Use of Expired Drugs and Materials

The use of expired medical materials such as drugs, fluids, or sutures on animals is not considered to be acceptable veterinary practice and does not constitute adequate veterinary care as required by current animal care and use regulations. Medical materials, such as catheters, gloves, or sutures, are often imprinted with an expiration date, beyond which the manufacturer does not guarantee the safety or stability of the item. However, in some instances there may be a rationale for utilizing expired materials such as an instance where the efficacy and safety of the product(s) in question can be assured past the expiration date and the item(s) are difficult to replace.

Applicable Guidance

The following is excerpted from OLAW FAQ's (5):

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. The veterinarian and IACUC must maintain control over the use of expired medical materials in order to meet their responsibilities to avoid or minimize discomfort, pain or distress to animals.

The USDA Policy #3 states (1): The use of expired medical materials (e.g., drugs, fluids, sutures, anesthetics, sedatives, or analgesics) during any survival surgical procedure on a regulated species is not considered acceptable veterinary practice and therefore not consistent with adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act.

With regard to acute terminal procedures the policy states: Expired medical materials except analgesics, sedatives, anesthetics, and euthanasia solution may be used in acute terminal procedures where an animal is anesthetized during the study and euthanized without recovery if such use does not adversely affect the animal's well-being or compromise the validity of the scientific study. Facilities permitting the use of expired medical materials in acute terminal procedures should have a policy on the use, storage and disposal of such materials which is in accordance with all relevant institutional, local, state, and federal requirements where applicable; and/or require investigators to describe the intended use in the animal study proposal.

Conditional Use of Expired Materials

The SDSU IACUC has established the following with regard to the use of expired materials:

- Expired anesthetics, analgesics, sedatives or euthanasia agents may NEVER be used, even in non-survival procedures.

- Outdated materials may be used only if their use does not adversely affect the animal's well-being or compromise the validity of the study and only in non-survival procedures.
- Expired materials may not be used in survival procedures unless specifically approved by the IACUC. Such approval must be obtained prior to the use of the expired materials in survival procedures.
- Requests to use outdated items in survival studies will be considered by the IACUC only if the sterility of the outdated medical materials (catheters, gloves and sutures) is verified either by repackaging and re-sterilizing the item or by obtaining information from the manufacturer which documents that a particular material or instrument has been shown to remain sterile beyond the date on the packaging.
- Expired/outdated items must be kept physically separated from other similar in-date items and clearly labeled "Outdated Materials – For Terminal Procedures Only" (or similarly). It is recommended that each laboratory establish an inventory procedure to facilitate the identification and removal of expired drugs and materials utilized for research purposes involving animals.
- Once an expired item is used in non-survival or (in rare cases) survival procedures it should be discarded and not repackaged or re-used unless the item is irreplaceable or prohibitively expensive and such re-use has been described and approved by the IACUC.

Proper Disposal Procedures

The SDSU EHS has established the following procedures for disposal of unwanted or expired pharmaceutical and non-pharmaceutical grade therapeutics i.e. anesthetics, analgesics, euthanasia agents, antibiotics, etc. including experimental compounds, i.e. test compounds:

Note: Unwanted or expired pharmaceutical and non-pharmaceutical therapeutics including experimental compounds must never be disposed in biohazardous red bags or sharps wastes container.

- For unwanted or expired controlled therapeutics or experimental compounds (including diluted or reconstituted controlled substances):
 1. Contact the Controlled Substance Program Manager at x42865 to schedule an appointment to surrender and transfer custody of the controlled substances to EHS for proper disposal.
 2. Complete and submit the Controlled Substance Surrender Record form.
 3. Surrender unwanted and expired controlled substances including empty containers and completed Dispense Record of the controlled substance.
- For unwanted or expired non-controlled therapeutics or experimental compounds:
 1. Contact EHS at x46778 and request for waste pick up of expired non-controlled therapeutics or experimental compounds.

References:

1. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care, Policy 3-Veterinary Care, March 14, 2014.
http://www.aphis.usda.gov/animal_welfare/policy.php
2. OLAW Frequently Asked Questions-Use of expired pharmaceuticals, biologics, and supplies in animals.
http://grants.nih.gov/grants/olaw/faqs.htm#useandmgmt_5
3. Florida State University Use of Non-pharmaceutical Grade Compounds and Expired Materials in Animals, July 2007
http://www.research.fsu.edu/acuc/Policies_Guidelines/Nonpharmaceutical_Expired%20Drugs.pdf
4. University of Pennsylvania Expired Drugs and Materials, 8/27/2013.
<http://www.upenn.edu/regulatoryaffairs/Documents/iacuc/guidelines/iacucguideline-expireddrugs.pdf>