

IACUC Guideline for Expired Drugs and Medical Materials at UWM

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Last Review:

Revision History:

Background

The use of expired drugs or medical materials (i.e., fluids, disinfectant solutions, catheters, sutures) in animals is considered inadequate veterinary care and poor experimental technique. These materials may lose potency, function, or even degrade to toxic byproducts if stored after their expiration dates, resulting in unpredictable effects that can jeopardize animal welfare and research outcomes.

Responsibility

Each PI and laboratory staff are responsible and accountable for ensuring that expired materials are not used for animal research and that expired drugs, medical supplies and/or devices are properly disposed of by their expiration date. Proper labeling will allow the IACUC and researchers to distinguish expired from nonexpired materials stored in secondary containment. Expired drugs are not to be used for survival or non-survival procedures. Medical Materials used for non-survival procedures must be labeled as such.

Definitions

Drug: for this policy, any regulatory agency approved or investigational substance, agent, biologic, or chemical listed in a pharmacopeia, chemical supply catalogue, synthesized or isolated in a laboratory, and administered to animals by any route, including injection, inhalation, topical application, or injection, for use in the investigation, diagnosis, cure, mitigation, treatment or prevention of disease or biology in humans or animals. Examples include antibiotics, controlled substances, anesthesia agents, analgesia agents, etc.

Controlled Substance: Any drug, substance or analog compound that falls under any of the five (I-V) Schedules identified by the United States Department of Justice/Drug Enforcement Administration and as defined by the Controlled Substance Act (CSA).

Medical material: A non-bioactive substance intended to be administered to animals for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or a substance intended to affect the structure or function of the body. Food is not considered to be a medical material. (e.g. catheters, sutures)

Medical materials such as catheters, surgical instruments, sterile gloves, suture materials are often labeled with an expiration date to assure sterility. In general, after the expiration date these materials must be discarded. Expired materials capable of being re-sterilized should be sated with a new expiration date appropriate for the package being used. If the PI obtains information from the manufacturer that provides documentation that a particular material or instrument has been shown to remain sterile beyond the date on the packaging, a request to use the item in survival studies will be considered by the IACUC.

Chemical: A lab substance not intended for use in animals. Examples include bleach, ethanol, etc.

Expiration Dates & Proper Labeling

All chemicals used on or in animals must have an expiration date clearly labeled on the container. The EXP date is the date printed on the label/package for materials with a manufacturer's expiration.

Expired materials found in the vivarium may be discarded at any time by the Animal Resource Center Staff or the IACUC unless materials are clearly labeled "not for use in animals" and are stored separately from materials for use in animals.

- i. **Secondary containers that hold an unadulterated solution** (*i.e.*, a drug or material from an original stock to which no drug has been added) must be clearly labeled with the name of the drug or material and the expiration date of the original stock.
- ii. **For dilutions, preparations, reconstitutions, or mixtures of drugs or fluids** made by the PI or their laboratory staff, prepared using aseptic, and under proper storage conditions:
 1. **Best practice** – is to open or prepare the smallest quantity of drug required for that day's work and discard any remaining drug at the end of the day. Containers must be labeled with name, final drug concentration or dilution, and the new expiration date as soon as they are prepared. Expiration dates of each component in a drug mixture should be listed in laboratory records so that the potential expiration date of the mixture can be accurately verified upon request (*i.e.*, during a facility inspection).
 - a. A pharmaceutical grade drug with an added diluent or substance (*e.g.*, combining Ketamine and Xylazine) used as an analgesic, anesthetic, antibiotic, or euthanasia agent **expires 30 days** beyond the date of preparation, or until the manufacturer expiration date if sooner than 30 days.
 - b. Sterile fluids used as diluents expire on which ever date occurs first:
 1. The manufacturer expiration date,
 2. 72 hours after opening when administered intravenously,
 3. Or 30 days after opening when administered via a route other than intravenous.

When PIs wish to access sterile diluents multiple times (*i.e.*, to obtain small volumes for administration and drug mixing), the investigators can do so only if they do not add any chemical to the fluid, they access the

fluid(s) aseptically and they store the fluid(s) as recommended by the manufacturer.

2. Acceptable practice – If a drug is diluted or mixed with another compatible drug and put into a sealed, sterile container, the container must be labeled by name, final drug concentration or dilution, preparation date, and new expiration date.
- iii. **For powdered forms of drugs or compounds that do not list an expiration date** - the PI should determine the stability of the drug to identify a reasonable shelf-life. This is commonly obtained from the manufacturer. If stability is unknown, best practice dictates that the drug should not be used beyond one year. Use a light-proof, airtight container and label the container with a one-year expiration and the name of the drug.
- iv. **For drugs or solutions that are reconstituted for use:**
 1. Reconstituted drugs and compounds that do not contain expiration or efficacy guidelines in the directions must be labeled for expiration **30 days after reconstitution** in a glass container. The final container must contain the name of the drug and/or compound with the EXP date.
- v. **For Chemicals** - PI-made chemical preparations in secondary containment must be labeled by name, hazards present, chemical concentration, preparation date, and new expiration date. Chemical transferred or aliquoted to secondary containment must be labeled by name, hazards present, and expiration date of the original stock. Expired chemicals must be labeled as “EXPIRED,” prior to disposal.
For questions regarding chemical labeling and disposal please contact the Laboratory safety coordinator.
- vi. **Medical materials** – Most medical materials (e.g., gloves, catheters, sutures, etc.) are imprinted with an expiration date. All medical materials and supplies used in live animals, including acute procedures, should be individually labeled with an expiration date or a sterilized date.
Instruments or supplies sterilized by the investigator must be marked with an expiration date based on the date of sterilization. They must be marked with an external “process indicator” (e.g., autoclave tape) and must contain a sterilization indicator (usually a chemical indicator strip that indicates exposure to sufficient heat or ethylene oxide to sterilize). Cloth-wrapped or paper-wrapped sterilized equipment has a shelf life of six months. Plastic-wrapped sterilized items (e.g., peel-packs) have a shelf life of six months. Medical materials and devices without a manufacturer-provided expiration date must be labeled by name, and PI-determined, lab-specific expiration date.
 1. Expired sterilized items that are capable of re-sterilization must be re-sterilized and labeled with the new expiration date.
 2. Items sterilized in-house must be labeled with the date of sterilization and an expiration date.

A. Discarding expired drugs, chemicals, and medical materials

1. No expired drugs or fluids may be administered to animals for any research or instructional purpose, including terminal procedures.

2. Expired drugs, solutions, dilutions, ext., must be labeled as “EXPIRED - not for use in animals,” prior to disposal. Items must be clearly labeled and segregated from non-expired items until they can be appropriately discarded. Do not store in animal use areas.
3. Expired medical materials – The use of expired medical materials for survival procedures is not permitted. Medical devices marked with an expiration date cannot be used for survival procedures after that date, and should usually be discarded or, if applicable, re-sterilized. If retained past the expiration date, these materials must be stored in a separate location from all other medical materials and drugs and labeled “expired materials–for non-survival procedures only.”

B. IACUC Recommendations

- i. Appropriately discard all expired surgical materials and supplies.
- ii. Prepare and access all medications aseptically and store according to manufacturer guidelines.
- iii. It is best practice to open or prepare the smallest quantity of drug required for that day’s work and discard any remaining drug at the end of the day.
- iv. Uncontaminated multi-dose vials must be stored according to manufacturer’s recommendations and can be used up to the manufacturer’s expiration date if they show no signs of contamination. Use a new, sterile needle for each entry into the container. Use should be discontinued if the rubber stopper appears damaged, solution is discolored or there are other signs of contamination.
- v. Expired anesthetics, analgesics, and euthanasia solutions must never be used, and must be disposed of properly.
- vi. Perform regular checks of your inventory and properly dispose of drugs or medical materials that will expire in the forthcoming month. Please contact ARC, EH&S, or IACUC for assistance with disposal.
- vii. Store all expired drugs and medical materials in a clearly labeled (“Expired – Do Not Use/Expired – Not for Animal Use”) container or drawer while they await pickup for disposal or return to manufacturer.
- viii. Follow all federal requirements for DEA registration, storage, and disposal of controlled substances.

IACUC Regulations

[Guide for the Care and Use of Laboratory Animals](#). Eighth Edition, p. 123.

[PHS Policy on Human Care and Use of Laboratory Animals](#). FAQ F.5.

[USDA Animal Care Resource Guide Policy 3](#).