Purpose

Medical materials include drugs, medical supplies and devices. The purpose of this policy is to describe how medical materials used in animal research, testing or training are to be used, handled, diluted, compounded, labeled and stored and to describe when and how expired medical materials may be used, handled, labeled and stored.

Scope

This policy applies to the use of all medical materials, as defined below, used with or on animals used for research, testing or training on a Princeton University IACUC approved protocol.

Regulatory Background

Expired medical materials may lose potency or integrity, or may degrade to toxic byproducts if stored beyond their expiration dates, and their use may result in unpredictable effects that may jeopardize animal welfare or negatively impact research results.

According to the USDA Animal Welfare Regulations Animal Care Policy #3 on Veterinary Care, “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.”

“Acute Terminal Procedures: Expired medical materials except analgesics, sedatives anesthetics, and euthanasia solutions 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”

The 8th edition of The Guide for the Care and Use of Laboratory Animals (The Guide) supports these requirements, stating “Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use recorded, and disposed of legally and safely.”

According to OLAW FAQ F5 “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.”

Responsibility

The Attending Veterinarian (AV) and the IACUC are responsible for ensuring that proposed animal activities avoid or minimize discomfort, distress, and pain to the animal, including maintaining control over the use of expired materials in accordance with regulations and policies.

The IACUC may, during their evaluation of appropriate veterinary care, review medical material expiration dates during scheduled semiannual facility inspections, and on an as-needed basis.

The Principal Investigator (PI) is responsible for ensuring the appropriate use of medical materials, including proper handling, labeling, diluting, storage, and use prior to their expiration date. Except for expired controlled substances which should be discarded and disposed according to Environmental Health and Safety (EHS), the PI is responsible for discarding expired medical materials. The PI must provide scientific justification for the use of expired materials that must be reviewed and approved by the IACUC, except for those circumstances outlined below in this policy (e.g. acute terminal procedures).

Definitions

Acute terminal procedure - An anesthetized procedure, surgical or non-surgical, from which the animal never recovers from anesthesia prior to euthanasia.

Medical materials - These include but are not necessarily limited to drugs, fluids, sutures, anesthetics, sedatives or analgesics. Examples include:

- Drug - A substance used as medication, including controlled substances.
- Medical Supplies or Devices - Materials, other than drugs, for use in animals that have an expiration date (saline, sutures, ointments, gauze packs, capillary tubes, blood collection tubes, syringes, needles, surgical gloves, catheters, etc.).

Expired Medical Materials - The date provided by the manufacturer beyond which the drug or material is considered inappropriate for medical use. With respect to sterilized materials or instruments, this is 6 months after the date of sterilization. For materials in which a manufacturer expiration date is not provided, refer to section III on labeling.
Disinfectants, Cleaners and Other Chemical Products Used for Animal Research -
Includes chemicals used to disinfect or sterilize surgical equipment and animal research work surfaces.

Policy

I. Use of Expired Medical Materials for Survival Procedures

The use of expired drugs, medical supplies and/or devices is not acceptable veterinary practice and does not constitute adequate veterinary care. The use of expired medical materials for survival procedures in animal research studies is generally prohibited. Any exception must have scientific justification and be approved by the IACUC.

II. Use of Expired Medical Materials for Acute Terminal Procedures

The use of expired medical materials may be permissible for acute terminal procedures, under the following terms and conditions:

- Anesthetics, analgesics, euthanasia agents, controlled substances, and emergency drugs (e.g. cardio-pulmonary resuscitation and life support) are never to be used beyond their expiration date, even in acute terminal procedures.
- Unused surgical materials (i.e. sutures, drapes, gauze pads, and catheters) may be used beyond their expiration date if use of such materials does not adversely affect the animal’s well-being or compromise the validity of the study.
- For any other medical materials being considered beyond their expiration date (e.g. drugs or compounds administered during anesthesia), the PI must justify to the IACUC that such use would not impact animal welfare nor compromise the validity of the study.
- The medical materials must be labeled “for acute terminal use only” and stored in a separate location (i.e. cabinet or drawer).

Individual laboratories must establish a procedure to facilitate the removal and/or storage of expired medical materials.

Expired medical materials must be clearly labeled and separated from other medications and medical supplies.

Controlled substance storage and disposal is managed by Environmental Health & Safety (EH&S), and authorized users must abide by the policies provided by EH&S. [Visit the Princeton University Environmental Health & Safety website](https://ehs.princeton.edu/laboratory-research/animal-research/controlled-substances/%20Storage%20and%20Control%20-%20Controlled%20Substances)
III. Labeling

Investigators are responsible for ensuring that all drugs and medical materials used in their laboratories are within the expiration date and labeled appropriately. Individual laboratories must establish a procedure to facilitate the identification of medical materials and chemical products.

All containers in the lab must contain a label that identifies the contents of the container. Each label should include the name of drug(s), concentration of drug(s), and expiration date. For controlled substances, a unique ID will be assigned by EHS. [https://ehs.princeton.edu/node/466](https://ehs.princeton.edu/node/466)

Each laboratory must establish a practice by which sterilization and/or expiration dates for sterilized materials are easily identified. Medical supplies, such as catheters, surgical instruments, sterile gloves, and suture materials, are often labeled with an expiration date to assure sterility. After this date, the materials are considered expired and cannot be used, except in acute terminal procedures as described in this policy. The use of re-sterilized unused surgical materials and supplies, including catheters and implantable devices, in survival procedures is permissible. Re-sterilized materials and supplies require a new labeled expiration date of 6 months following the re-sterilization.

Medical supplies with a statement indicating that the contents are “sterile if packaging is undamaged” may be used. Medical supplies within packages that appear damaged may be re-sterilized. Packages that contain deteriorated medical supplies should be discarded.

Powdered forms of drugs or compounds that do not contain an expiration date, should be labeled with an expiration date of 1 year from the open date provided that it is stored in an air tight, light protective container.

For drugs or solutions that are reconstituted for use, the expiration date may vary from the labeled expiration date. Reconstituted drugs and compounds that do not contain an expiration date or efficacy guidance should be labeled with an expiration date 30 days after reconstitution.

All labels must remain legible at all times.
IV. Labeling Disinfectants, Cleaners and Other Chemical Products Used for Animal Research

Products used to disinfect or sterilize surgical equipment and animal research work surfaces must be approved by Laboratory Animal Resources.

When possible, the manufacturer’s labels on all chemical products used for animal research should be kept intact. If a product is transferred to another container, the new container must be labeled with the name of the product, active ingredients, hazard warning (i.e. flammable, toxic, or corrosive) and expiration date.

Chemicals used in animal research but not on live animals, such as formalin, that do not have a manufacturer’s expiration date should be labeled with the date the container was opened and an expiration date no longer than 12 months post opening date.

V. Diluting and Compounding Drugs

Diluted drugs and other compounds used in survival procedures must be sterile (excluding oral or topical administration). Suitable diluents include bacteriostatic sterile water, PBS, or sterile saline for injection. These commercial diluents are typically contained in 10-ml or 20-ml bottles designed for multi-use. The drug should be diluted directly into these bottles.

If the primary container of the diluent is not used as the working solution container, an empty sterile container must be used (e.g. empty red-top vacutainers). If diluents are made in the laboratory they must be processed through a sterile 0.2µm syringe filter into a sterile container. The sterile container of diluted drug should be accessed using aseptic technique.
Unsuitable diluents include, but are not limited to, solutions made in the laboratory using non-pharmaceutical grade chemicals (e.g. Sigma), laboratory-made solutions not appropriately filtered to produce a sterile solution, or diluents removed from a container not designed for sterile multi-use (e.g. large bottles of saline or PBS).

Conical centrifuge tubes (e.g. Falcon) or similar non-sterile containers may be used for diluted drugs for non-survival procedures and only on the day when the dilution was made.

Because diluting a drug may change the pH or other characteristics of the solution, potentially changing the potency/efficacy of the diluted drug, the expiration date for drug dilutions is 30 days after the solution is made, or the actual expiration date of the drug or diluent if less than 30 days.

References


AMVA Guidelines for Veterinary Prescription Drugs (https://www.avma.org/KB/Policies/Pages/Guidelines-for-Veterinary-Prescription-Drugs.aspx)

IACUC policy 318 Use of Non-Pharmaceutical Grade Compounds
## Version History

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