The University of Pennsylvania’s Institutional Animal Care and Use Committee (IACUC) has developed the following guideline to help research investigators properly dispose of expired drugs or materials. It is the responsibility of the Principal Investigator (PI) to institute adequate inventory and laboratory management procedures to ensure that expired drugs and medical materials are identified and properly disposed of in a timely fashion.

The Animal Welfare Act (AWA) and Animal Welfare Regulations (AWR) mandate that all animals in research facilities receive adequate veterinary care and treatment to ensure that pain and distress are minimized. Such care includes appropriate use of anesthetic, analgesic, tranquilizing drugs, or euthanasia. Expired drugs and medical materials, including euthanasia agents, have unknown purity, potency, stability, and efficacy. As such their use in live animals is not an acceptable standard of veterinary practice and does not constitute appropriate veterinary care. [1-5]

The purpose of this guideline is to clarify the requirements of the Principal Investigator (PI) and the Institution with regards to use and disposal of expired drugs. All investigators, laboratories, and facilities are expected to adhere to the minimum standards addressed in this IACUC guideline.

This guideline offers guidance on the following topics:
- Information and classification of drugs, medical materials, and expiration dates
- Clarification on expired drug use for survival and terminal procedures
- Proper disposal of expired drugs
- Noncompliance

Definitions

**Drug:** Any substance or chemical designed to be administered by injection, inhalation, topical application, ingestion, electroporation, or suppository that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals (examples: tamoxifen, meloxicam, intravenous (IV) fluids, triple antibiotic ointment). This definition excludes food items normally consumed by the applicable species. [6]

**Medical Material:** Any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals and articles intended to affect the structure or any function of the body of humans or animals. [6] (Examples: gauze, suture, osmotic mini pumps, catheters).

**Expiration Date:** The date printed on the label/package for materials with a manufacturer’s expiration date. For dilutions, preparations, reconstitutions or mixtures of drugs or fluids prepared using sterile technique and under proper storage conditions the expiration date should be one month from the date of preparation, unless otherwise indicated. Such materials should be labeled by name, drug concentration, and include the new expiration date as soon as they are prepared (see example on the right). An item is considered expired the day after...
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the month or date indicated on the label. (Example: Item labeled Aug. 2017 would be considered expired on Sept. 1, 2017).

**Survival Procedures** - Anesthesia is administered to an animal until loss of consciousness, a research procedure/surgery is performed, and the animal returns to consciousness for any length of time.

Expired drugs or medical materials may NEVER be used in any live animal undergoing a survival procedure. [1, 3]

**Terminal Procedures** – Anesthesia is administered to an animal until loss of consciousness, a research procedure/surgery is performed, and the animal is euthanized and does not regain consciousness.

It is NEVER acceptable to use expired anesthetics, analgesics, emergency drugs or euthanasia drugs in any animal regardless of whether the procedure will be terminal. [1, 3]

1. Expired non-emergency drugs and fluids, other than anesthetics, analgesics, or euthanasia solutions, may be used in anesthetized animals undergoing a terminal procedure provided such use does not adversely affect the animal’s well-being or compromise the validity of the scientific study. [1, 3]
2. Expired medical materials (suture, bandage material, catheters, etc.) may be used in anesthetized animals undergoing a terminal procedure provided such use does not adversely affect the animal’s well-being or compromise the validity of the scientific study. [1]
3. Any expired drugs or medical materials must be disposed of or kept separated from in-date materials/drugs/stock. The expired and separated materials must be clearly labeled identifying the items as “Expired-terminal procedures only.”

**Proper disposal of Expired Drugs**

**Non-Controlled, Non-Hazardous Medical Materials:** May be disposed of as municipal (i.e. ‘regular trash’) waste. (Examples: unused gauze, unused suture material with no needle, unused bandage material).

**Non-Controlled Pharmaceuticals Both Hazardous and Non-Hazardous:** Drugs classified as hazardous must be disposed of in compliance with federal regulations (40 CFR 261.33). Please see the EHRS policy on [Hazardous Drugs](#) for more information on the safe handling and disposal of Hazardous drugs. (Examples of hazardous drugs: cisplatin, chloramphenicol, fluorouracil, streptozocin, tamoxifen, or steroids such as testosterone, estradiol, and megestrol).

Whether hazardous or non-hazardous, all expired or unwanted drugs should be disposed of properly; please use the [EHRS online chemical waste disposal form](#) to arrange for collection. If you have additional questions, you can contact EHRS during office hours, Monday through Friday, 8 AM to 5 PM at 215-898-4453 or email [chem_waste@ehrs.upenn.edu](mailto:chem_waste@ehrs.upenn.edu).

**Sharps:** Medical materials that have a component that is capable of puncturing or penetrating a plastic bag are considered “sharps.” (Examples: needles, syringes, scalpels). All sharps must be handled and disposed of in accordance with the [EHRS Laboratory Sharps SOP](#). Sharps that have come into contact with blood or bodily fluids should be disposed of in an infectious waste sharps container.
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Sharps that have come into contact with a hazardous chemical substance such as chemotherapy drugs, certain antivirals, hormones, and bioengineered drugs must be disposed of in a separate sharps container clearly labeled "CHEMICAL CONTAMINATED SHARPS -- DO NOT AUTOCLAVE" and should not be comingled with infectious waste sharps. Labels for sharps containers are available from EHRS. Please contact Stericycle or Curtis Bay for collection when your sharps container is 1/2 to 2/3 full. If you do not currently have an account with a company for disposal of sharps EHRS can help you to establish an account.

**Controlled Substances:** Expired controlled substances must be kept separate from non-expired drugs, but under the required secure storage conditions in accordance with the Controlled Substances Act (21 CFR 130), labeled as “Expired” and be disposed of by approved means in compliance with the Controlled Substances Act. If you are uncertain whether the substance you have is controlled, please visit [DEA Controlled Substance List](#). (Examples: Ketamine, Buprenorphine, Pentobarbital).

**Controlled Substances Disposal Events:** EHRS and the Office of Animal Welfare (OAW) host periodic controlled substances disposal events. A licensed reverse distributor will be onsite to accept unwanted materials. These events are free of charge, but registration is required through submission of an electronic drug transfer form one week prior to the event. Additional information about the event and copies of the transfer form can be found on the [EHRS Controlled Substances Webpage](#).

If you are not a DEA registrant, and you are required to regularly dispose of controlled substances, or for more information, please see the [DEA Controlled Drug Disposal Webpage](#).

**Non-Compliance with this Guideline**

Shared facilities, in which more than one investigator/laboratory may share storage or procedure space, must designate a responsible individual who will oversee inventory management procedures to ensure compliance with this guideline.

The ULAR veterinarian and the IACUC should be notified of any inadvertent or intentional failure to comply with this policy.

**References**

1. USDA APHIS Animal Care Resource Guide Policies, AC 3.1
3. NIH OLAW FAQ F.5, “May investigators use expired pharmaceuticals, biologics and supplies in animals?”
4. Public Health Service Policy on the Humane Care and Use of Laboratory Animals, Section IV., OLAW