IACUC POLICY
EXPIRED DRUGS AND MATERIALS

The University of Pennsylvania 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.

Expired drugs and medical materials 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]

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 at right). Secondary containers which hold an unadulterated solution (i.e. a drug or material from an original stock in which no other drug has been added to) should be clearly labeled with the name of the drug or material and the expiration date of the original stock. An item is considered expired the day after the month or date indicated on the label, e.g. an item labeled Aug. 2013 would be considered expired on Sept. 1, 2013.

**Survival Procedures** (defined as administering anesthesia to the animal until unconscious, then research procedure/surgery performed, then the animal is allowed to awaken to consciousness)

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

Terminal Procedures (defined as administering anesthesia to the animal until unconscious, then research procedure/surgery performed, then 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 at Penn

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, megestrol)

Whether hazardous or non-hazardous all unused vials, 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.

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. 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
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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 of the way 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](https://管制 substances). (Examples: Ketamine, Buprenorphine, Pentobarbital)

**HUP (Hospital of the University of Pennsylvania) Pharmacy** accepts DEA controlled substances for disposal. Please contact the HUP pharmacy directly to arrange for transfer of your controlled substances. The HUP Pharmacy can be reached at 215-662-2909, please use the [HUP Pharmacy Transfer Form](https://transfers). For more information please see the EHRS policy on [Controlled Substances Disposal](https://controlled substances).

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

**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