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| Internal Regulation Title | Use of Expired Drugs & Medical Supplies | | | | |
| Date Last Revised | 09/14/2017 | Date Created | 01/28/2005 | Revision # | |
| Regulation Number | 13 | Required by: | <input type="checkbox"/> OHRP <input type="checkbox"/> Funding Agency <input type="checkbox"/> OLAW | | |
| Applicability | <input type="checkbox"/> RGC Internal | | <input checked="" type="checkbox"/> Researcher | | <input type="checkbox"/> Institutional |
| Subgroup | <input type="checkbox"/> NKU Compliance | <input type="checkbox"/> IRB | <input checked="" type="checkbox"/> IACUC | | <input type="checkbox"/> IBC |

1.0 PURPOSE

The Northern Kentucky University Institutional Animal Care and Use Committee (IACUC) has developed the following regulation to help Principal Investigators (PI) properly dispose of expired drugs or materials. It is the responsibility of the PI to maintain adequate inventory and institute 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.

2.0 GENERAL INFORMATION AND SCOPE

The Principal Investigator is responsible for ensuring compliance with this regulation.

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 procedure to ensure compliance with this regulation.

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: 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. 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: Administering anesthesia to the animal until unconscious, research procedure/surgery is performed, then the animal is allowed to awaken to consciousness.

Terminal Procedures: Administering anesthesia to the animal until unconscious, research procedure/surgery is performed, then the animal is euthanized and does not regain consciousness.

3.0 DETAILS

A. EXPIRED DRUGS AND/OR MATERIALS

- Expired drugs or medical materials may never be used in any live animal undergoing survival procedures .
- 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.
- Expired 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.
- Any expired drugs or medical materials must be disposed of or kept separated from in-date materials/drugs stock and labeled as “Expired”.

B. PROPER DISPOSAL OF EXPIRED DRUGS AND/OR MATERIALS AT NKU

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

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). Examples of hazardous drugs include cisplatin, chloramphenicol, fluorouracil, streptozocin, and tamoxifen.

Whether hazardous or non-hazardous, all unused drug solutions, including those that are expired, or unwanted should be disposed of properly. Contact [NKU Safety and Emergency Management](#) for additional information.

Sharps: Medical materials that have a component that is capable of puncturing or penetrating a plastic bag are considered “sharps”. Examples include needles, syringes, and scalpels. 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 must be disposed of in a separate sharps container clearly labeled “Chemical Contaminated Sharps – Do not Autoclave” and should not be comingled with infectious sharps. Contact [NKU Safety and Emergency Management](#) to request sharps containers and/or to dispose of used sharps containers.

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 Substance Act](#), 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](#).

C. NON-COMPLIANCE WITH THIS GUIDELINE

The PI must notify the IACUC of any inadvertent or intentional failure to comply with this policy by submitting an Adverse Event and Unanticipated Problems Form. The IACUC may request the Principal Investigator to explain this deficiency or recurring deficiencies at a convened meeting.

4.0 REFERENCES

[USDA APHIS Animal Care Resource Guide Policies, AC 3.1](#)
[USDA APHIS Animal Welfare Regulations, 9 CFR § 2.33 \(2008\).](#)
[NIH OLAW FAQ F.5, "May investigators use expired pharmaceuticals, biologics and supplies in animals?"](#)
[Public Health Service Policy on the Humane Care and Use of Laboratory Animals, Section IV. , OLAW](#)
[National Research Council. Guide for the Care and Use of Laboratory Animals. 8th Ed. Washington, DC: National Academies Press, 2011.](#)
[Federal Food, Drug and Cosmetic Act, 21 USC § 321 \(2013\).](#)
[Guide for the Care and Use of Laboratory Animals Eighth Edition](#)
[Controlled Substance Act](#)
[DEA Controlled Substance List.](#)

5.0 FORMS OR ATTACHMENTS

6.0 DEFINITIONS

Approvals

| Title | Approved | Date Approved | Not Applicable |
|---------------------------------|-------------------------------------|---------------|-------------------------------------|
| Manager of Research Compliance | <input checked="" type="checkbox"/> | 06/13/2018 | <input type="checkbox"/> |
| IACUC Chair | <input checked="" type="checkbox"/> | 06/13/2018 | <input type="checkbox"/> |
| Institutional Official | <input type="checkbox"/> | | <input checked="" type="checkbox"/> |
| Safety and Emergency Management | <input checked="" type="checkbox"/> | 11/01/2017 | <input type="checkbox"/> |

Revisions

| Title | Approved | Date Approved | N/A | Summary |
|--------------------------------|--------------------------|---------------|--------------------------|---------|
| Manager of Research Compliance | <input type="checkbox"/> | | <input type="checkbox"/> | |
| IACUC Chair | <input type="checkbox"/> | | <input type="checkbox"/> | |
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