



Policy on Use of Expired Drugs and Materials and Use of Non-Pharmaceutical Grade Compounds in Animals

Policy:

- Pharmaceutical grade compounds and medical grade materials should be used in live animal procedures.
- Non-pharmaceutical grade compounds or drugs may be used only if an acceptable veterinary or human pharmaceutical-grade product is not available.
- Euthanasia, anesthesia and analgesia agents may not be used beyond their expiration date, even for a terminal procedure.
- Expired medical materials other than these agents may be used for terminal procedures if their use does not adversely affect animal wellbeing or compromise scientific validity.
- Expired medical materials must be discarded or segregated in an appropriately labeled, physically separate location from non-expired materials.
- Exceptions may be granted by the IACUC based on scientific necessity.

Background:

Federal regulations indicate non-pharmaceutical- grade chemical compounds may only be used in animals after specific review and approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product^{1,2}. Cost savings or convenience are not an adequate justification^{1,2}. Federal regulations^{1,2,3} also prohibit the use of expired medical materials such as drugs, fluids, or sutures. Such use is not acceptable veterinary practice and does not constitute adequate veterinary care as required by the Animal Welfare Act^{1,3}.

Investigator Responsibility:

- The principal investigator is responsible for ensuring that only pharmaceutical grade compounds and medical grade materials are administered to animals by project personnel.
- The investigator and project personnel must allow internal and external inspectors access to drugs, materials, and storage areas.
- Expired drugs or medical materials should be discarded according to campus regulations, or stored separately and labeled as expired.
- Because federal regulations require that “all expired medical materials found in a licensed or registered facility are to be brought to the attention of the responsible official” and because compliance with federal regulations is a condition of animal use, investigators and project personnel are responsible for bringing any expired materials in shared facilities to the attention of the responsible individual for disposal.

Definition of “drug” and “medical” material:

The Federal Food, Drug, and Cosmetic Act⁴ indicates drugs or medical devices are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals and articles (other than food) intended to affect the structure or any function of the body of man or animals. Pharmaceutical and medical materials are usually identified regarding intended use and usually have a manufacturer's expiration date. A package label or insert stating the item “is not intended for diagnostic use” or something similar indicates the product is not pharmaceutical or medical grade.

Records and Disposal of drugs:

Holders of DEA and State of Illinois controlled drug licenses are required to keep detailed records of every use of the controlled drugs, and to follow specific procedures for disposal when the drugs expire or are no longer needed^{5,6,7}. Expired drug containers should be clearly labeled “Not to be used.”

Role of the IACUC:

The IACUC is responsible for implementation and oversight of this policy. The IACUC is responsible for semi-annual inspections of the animal facilities and farms to ensure that no non- pharmaceutical or unapproved expired medical materials are present.

Role of the Agricultural Animal Care and Use Program (AACUP):

AACUP veterinarians can assist investigators in the use of anesthetics and analgesics and other drugs in approved protocols. AACUP also provides consulting and training to investigators regarding drug use.

Role of the Division of Animal Resources (DAR):

DAR maintains a DEA license and can provide investigators with drugs as well as assisting investigators with use of drugs in approved protocols. DAR also provides consulting and training to investigators regarding use of anesthetics and analgesics.

Reference(s):

1. [USDA Animal Care Resource Guide Policies AC 3.1. Policy: Expired Medical Materials; Policy: Pharmaceutical-Grade Compounds in Research](#)
2. [NIH OLAW FAQ F.4. May investigators use non-pharmaceutical grade compounds in animals?](#)
3. [NIH OLAW FAQ F.5. May investigators use expired pharmaceuticals, biologics, and supplies in animals?](#)
4. [FDA Regulatory Information, Legislation, Federal Food, Drug, and Cosmetic Act \(FD&C Act\) SEC. 201. \[21 U.S.C. 321\] Chapter II.](#)
5. [Federal Registration site for DEA controlled drugs](#)
6. [Disposal of Controlled Drugs \(Federal\)](#)
7. [State of Illinois main controlled drugs page](#)

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