

University of Louisville
Institutional Animal Care and Use Committee
Policies and Procedures

Use of Pharmaceutical-Grade Medications and Outdated Drugs or Supplies

Policy: Pharmaceutical grade medications must be used whenever they are available, including for non-survival procedures or euthanasia. The use of expired medical materials such as drugs, intravenous fluids, and supplies, including materials used for *in vitro* assays that might impact animal treatment or disposition, is prohibited unless specifically approved by the IACUC. Expiration dates on such materials must be monitored, and materials disposed of appropriately to avoid their accidental use.

Rationale: The use of expired medical materials in animal research is not considered to be acceptable veterinary practice as required by the PHS Policy and Animal Welfare regulations, because manufacturer's guarantees do not extend to expired materials. Therefore, it should be considered a scientific as well as veterinary care imperative to use pharmaceutical-grade material and only while "in-date." Data obtained from *in vitro* assays are often used to determine treatment or humane endpoints; therefore, materials used in such assays should also be used while "in-date."

Procedures, Guidelines, and Exceptions:

I. Medications (Anesthetics, analgesics, therapeutic agents, etc.):

A. Pharmaceutical Grade

1. Pharmaceutical grade medications must be used whenever they are available, including for non-survival procedures and euthanasia.
2. Exceptions for use of non-pharmaceutical grade (*i.e.*, chemical-grade) medications may be allowed after review and approval by the IACUC. Requests for exceptions must be submitted in writing as a part of an approved *Proposal*.
 - a. All non-pharmaceutical-grade medications must be identified as such in the *Proposal*.
 - b. A justification for the use of each agent must be included. If a pharmaceutical grade equivalent is not available, then that is adequate justification, however if a pharmaceutical grade equivalent is available, then scientific justification for not using the pharmaceutical grade formulation must be provided in the *Proposal*. Cost-savings alone is not an adequate justification for using non-pharmaceutical grade medications.
 - c. For each of the non-pharmaceutical grade products consideration in writing should be given to the quality of the material (grade, purity, *etc.*), methods of ensuring sterility and physiological compatibility (pH, pyrogenicity, osmolality, *etc.*), expected shelf-life (stability, expiration date or discard timeframe that will be used), site and route of administration, and effectiveness (pharmacokinetics, *etc.*) of the chemical or substance to be administered, as well as any potential animal welfare and scientific issues relating to its use.

B. Expired Medications/Biologics

1. The use of expired pharmaceuticals, biologics, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care.
2. 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

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efficacy beyond the expiration date. Expired medications used to support surgical procedures, including anesthetics, analgesics, or agents used in peri-operative care (*e.g.*, heparin), cannot be used, even for non-survival procedures. Other expired medications, such as experimental therapeutic agents and other test substances, can only be used with specific IACUC approval.

3. Special precautions and procedures for disposal of expired DEA-controlled substances must be followed as per DEHS policies < <http://louisville.edu/dehs/waste-program/guide-misc/> >.

II. Materials (fluids, sutures, catheters, diagnostic strips, etc.):

1. The use of expired medical materials (fluids, sutures, catheters and other supplies) in animal research is not considered acceptable veterinary practice as defined by the Animal Welfare regulations and PHS Policy. Exceptions may be granted for use of such materials generally for *non-survival* procedures only, although re-sterilization may be deemed acceptable for survival procedures. Use of such materials must be approved by the IACUC. If such usage is approved by the IACUC, expired supplies must be conspicuously labeled with the appropriate IACUC number(s) and the terms “Expired,” and “for non-survival use only,” and stored in a physically separate location from non-expired materials to avoid accidental use in survival procedures.
2. The use of expired materials employed in diagnostic assays (glucose test strips, blood collection tubes, *etc.*) is not considered acceptable veterinary practice as the information obtained from such assays is often used to determine treatment regimens or to identify humane endpoints. Use of expired materials for other reasons and the storage of expired materials within the Research Resources Facilities is strongly discouraged. If such materials are kept, they should be conspicuously labeled with the appropriate IACUC number(s) and the term “Expired” and stored in a physically separate location from non-expired materials to avoid accidental use in diagnostic assays that might impact animal health and well-being.
3. Exceptions to the use of expired medical materials may be granted by the IACUC on a case-by-case basis. Requests for exceptions must be submitted in writing as a part of an approved *Proposal*.

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