

SOP #: 104.02

Title: SOP - Use of Non-Pharmaceutical Grade Compounds and/or Expired Medical Materials

Approvals:

Attending Veterinarian

Date: 10/02/2019

IACUC Chairman

Date: 10/03/191. Purpose

1.1 The Animal Welfare Act (AWA) requires that all regulated animals be provided adequate veterinary care.

2. Responsibility

2.1 The Attending Veterinarian (AV) and the Institutional Animal Care and Use Committee (IACUC) are responsible for ensuring that proposed animal activities avoid or minimize discomfort, distress, and pain to the animal. These responsibilities cannot be met unless the AV and IACUC maintain control over the use of expired medical materials.

2.2 Investigators are expected to use pharmaceutical-grade medications whenever they are available, even in acute procedures.

3. Definitions

3.1 AWA: Animal Welfare Act

4. Guidelines

4.1 Expired Medical Materials

4.1.1 The use of expired medical materials such as drugs, fluids, or sutures on regulated animals is not considered to be acceptable veterinary practice and does not

constitute adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act.

- 4.1.2 All expired medical materials found in a licensed or registered facility are to be brought to the attention of the responsible official.
- 4.1.3 The facility must either dispose of all such materials or segregate them in an appropriately labeled, physically separate location from non-expired medical materials.
- 4.1.4 The Animal & Plant Health Inspection Service (APHIS) has no jurisdiction over facilities using expired medical materials for non-regulated animals or non-regulated activities.
- 4.1.5 For acute terminal procedures, APHIS does not oppose the use of expired medical materials if their use does not adversely affect the animal's well-being or compromise the validity of the scientific study and approved by the IACUC. Proper anesthesia, analgesia, and euthanasia are required for all such procedures.
- 4.1.6 Drugs administered to relieve pain or distress and emergency drugs must not be used beyond their expiration date. The Attending Veterinarian and the IACUC are responsible for ensuring that proposed animal activities avoid or minimize discomfort, distress, and pain to the animal.
- 4.1.7 Expired materials should not be used unless the manufacturer verifies efficacy beyond the expiration date, or the investigator is able to document to the satisfaction of the IACUC that such use would not negatively impact animal welfare or compromise the validity of the study.
- 4.1.8 For guidance on disposal of expired medical materials (including expired controlled/scheduled substances) contact the Controlled Substance Safety Officer at 305-348-2621.

4.2 Pharmaceutical-Grade Compounds in Research

- 4.2.1 Non-pharmaceutical-grade chemical compounds should only be used in regulated animals after specific review and approval by the IACUC for reasons such as
 - 4.2.1.1 scientific necessity
 - 4.2.1.2 non-availability of an acceptable veterinary or human pharmaceutical-grade product.
 - 4.2.1.3 Cost savings alone are not an adequate justification for using non-pharmaceutical-grade compounds in regulated animals.

4.2.2 In preparing proposals to use non-pharmaceutical-grade chemical compounds, investigators should address the quality of the preparations they propose to use, i.e. issues of purity, stability and sterility. Investigators should explain if and to what extent purity and sterility will be maintained in the preparation and administration of the compound, in particular when it is administered parenterally. Information about stability and pharmacokinetics should be given when available.

4.3 Use of reconstituted drugs or drugs cocktails used in research animals

4.3.1 Prescription medications have expiration dates on their original containers.

However, when reconstituted, some drugs might have a much shorter expiration date that is provided by the manufacturer.

4.3.2 When various drugs are mixed together, aseptic condition should be observed during the preparation of the vial. The vial should be labeled with the mixture name, strength of the drug, initial of the person preparing the solution, date the solution was mixed. An expiration date of 30 days post mixing should be assigned to the vial.

5. References

5.1 Animal Welfare Act (9 CFR, Part 2, Sections 2.31, 2.32, 2.33, 2.40)

5.2 Animal and Plant Health Inspection Service, USDA, Policy #3 --- Veterinary Care--- March 25, 2011.

5.3 Frequently Asked Questions about the Public Health Service Policy on Humane Care and Use of Laboratory Animals. <http://grants2.nih.gov/grants/olaw/faqs.htm#useandmgmt> 4.

5.4 Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources, National Research Council, 8th Ed. 2011.

6. Revisions

6.1 Rev. 02 – Added paragraph 4.3 the use of reconstituted drugs and drug cocktails.