**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**
**Policy #21**
**USE OF NON-PHARMACEUTICAL GRADE COMPOUNDS**
In concurrence with
TTUHSC El Paso Assurance #D19-01056
and Federal Regulations and Guidelines

1. **Purpose:**
For teaching or research that involve animals, investigators are expected to use pharmaceutical-grade compounds and other substances when available. These pharmaceutical grade compounds must be used to avoid toxicity or side effects that threaten the health and welfare of vertebrate animals and / or interfere with the interpretation of research results

The use of non-pharmaceutical-grade chemical compounds in experimental animals under certain circumstances has been, and will continue to be, a necessary and acceptable component of biomedical research. OLAW and the USDA have determined that their use should be based on (1) scientific necessity, (2) nonavailability of an acceptable veterinary or human pharmaceutical-grade compound, and (3) specific review and approval by the IACUC [32]. In preparing and reviewing proposals to use non-pharmaceutical-grade products, investigators and IACUCs should consider a number of related animal welfare and scientific issues including safety, efficacy, and the inadvertent introduction of research-complicating variables. Although one can assume that issues such as sterility, pyrogenicity, stability, pharmacokinetics, and quality control have been addressed during the course of producing pharmaceutical-grade drugs, one cannot say the same for substances produced in the research laboratory using non-pharmaceutical-grade chemical compounds. Cost savings alone do not adequately justify the use of non-pharmaceutical-grade compounds in animals. Although the potential animal welfare consequences of complications are less evident in nonsurvival studies, the scientific issues remain the same.

AAALAC defines a pharmaceutical-grade compound as any active or inactive drug, biologic or reagent, for which a chemical purity standard has been established by a recognized national or regional pharmacopeia (e.g., the U.S. Pharmacopeia (USP), British Pharmacopeia (BP), National Formulary (NF), European Pharmacopoeia (EP), Japanese Pharmacopeia (JP), etc.). These standards are used by manufacturers to help ensure the products are of the appropriate chemical purity and quality, in the appropriate solution or compound, to ensure stability, safety, and efficacy
It should be noted that NIH/OLAW allows for the use of non-pharmaceutical grade pentobarbital as a substitute for the pharmaceutical grade drug as the current price of the latter is so excessive as to render the drug unavailable. This is a special case decision by NIH/OLAW and does not apply to other drugs at the time of this writing (April 2013 and October 2013).

2. **Procedure to obtain IACUC Approval**
Non-pharmaceutical-grade chemical compounds (including, but not limited to, expired pharmaceutical drugs) is acceptable in research or teaching when animal use is required, if reviewed and approved by the IACUC prior to the first use of the compound. The following factors must be presented for consideration by the IACUC:

A. Use must be compliant with applicable national or regional regulatory guidelines and requirements and the requirements of relevant funding agencies;

B. A scientific justification is provided;

C. The pharmaceutical-grade compound is not available in the appropriate concentration or formulation or the appropriate vehicle control is unavailable

D. The compound is required to generate data that are part of an ongoing study or that are comparable to previous work;

E. The chemical properties of the compound are appropriate for the study and the route of administration (e.g., the purity, grade, stability in and out of solution, solution vehicle properties, pH, osmolality, sterility, pyrogenicity, side effects and adverse reactions, phamacokinetics and compatibility of the solvent and other components of final preparation). In some cases the reagent-grade of the compound may be as or more pure than the pharmaceutical-grade.

F. The method of preparation, labeling (i.e., preparation and use-by dates), administration and storage of formulations should be appropriately considered with the aim of maintaining their stability and quality (i.e., to prevent inadvertent co-administration of infectious agents or contaminants).

**References**

1. Animal Care Policy Manual, Policy #3 Veterinary Care https://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Policy%20Manual.pdf
2. Frequently Asked Questions About the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* http://grants.nih.gov/grants/olaw/references/lab_animal2003v32n9_wolff.htm#q3
3. Jerald Silverman, et al. The IACUC Handbook. Vol. 3rd edition, CRC Press, 2014.
4. Wolff, Axel, et al. “Frequently Asked Questions about the Public Health Service Policy on Humane Care and Use of Laboratory Animals.” *Lab Animal*, vol. 32, no. 9, 2003, pp. 33–36., https://doi.org/10.1038/laban1003-33. (Lab Animal. 2003; 32(9):33-36)
5. AAALAC Frequently Asked Questions: C. Institutional Responsibilities 9. Non-Pharmaceutical-Grade Compounds
6. Office of Laboratory Animal Welfare (ARCHIVED - OLAW Policy & Guidance)

**Related policies**

Investigators must comply with all other institutional policies at TTUHSC El Paso and Federal Guidelines. This list includes, but is not limited to, the following:

IACUC policy # 2: Veterinary Care
IACUC policy # 9: Rodent Euthanasia
IACUC policy # 10: Experimental Neoplasia in Rodents
IACUC policy # 15: Survival Surgery
IACUC policy # 24: Expired Drugs
IACUC policy # 27: Veterinary Administrative Approval for Significant Protocol Changes (VVC)