

**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. Background

For teaching or research that involve animals, investigators are expected to use pharmaceutical-grade compounds whenever they are available, even for acute and/or terminal procedures.

Issues such as sterility, pyrogenicity, stability, pharmacokinetics, and quality control have usually been addressed during the course of producing pharmaceutical-grade drugs, but one cannot say the same for substances produced in the research laboratory. The use of non-pharmaceutical-grade chemical compounds in experimental animals is acceptable if particular conditions are met.

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 circumstances must be presented for consideration by the IACUC:

- A. Scientific necessity;
- B. Lack of availability of an acceptable veterinary or human pharmaceutical-grade compound.

Note: Cost savings alone do not adequately justify the use of non-pharmaceutical-grade compounds in animals.

In preparing proposals that will incorporate the use of non-pharmaceutical-grade chemical compounds, investigators should address the quality of the preparations (i.e., issues of purity, stability and sterility). Investigators should explain to what extent purity and sterility will be maintained in the preparation and administration of the compound, especially when administered parenterally. In addition, the methods and routes of administration of the compound must be described. Information about stability and pharmacokinetics should be given when available.

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