

Center for Biomedical Research / IACUC Standard Operating Procedure - Guidelines

Use of Non-Pharmaceutical Grade Compounds

Guidelines:

- Investigators are expected to use pharmaceutical-grade preparations of compounds whenever they are available, even in acute procedures.
- If pharmaceutical-grade compound preparations are not available, investigators must address the following points in their protocols:
 - All injected compounds and diluents must be of the highest grade and sterile when used.
 - Investigators must address the grade, purity, pH, pyrogenicity, osmolality, stability, site and route of administration, formulation, and compatibility.
 - Investigators must describe the pharmacokinetics of unknown chemicals or substances that will be administered, or address the *in vitro* pharmacokinetics of the drug prior to animal use.
 - Investigators should consider relevant welfare and scientific issues, including safety, and efficacy when using non-pharmaceutical grade compounds.
 - Exceptions to these guidelines must be justified and submitted to the IACUC for review. Exceptions may be granted for reasons including scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product.
 - Cost savings alone are not an adequate justification for using non-pharmaceutical grade compounds.

NOTE: "Recent exorbitant cost increases of pentobarbital have placed it logistically into the unavailable category. Pentobarbital from a reagent or analytical-grade powder, properly prepared by a pharmacist or other knowledgeable individual (e.g., chemist, veterinarian, researcher), with assurance of appropriate storage and handling, and approval by the IACUC, is acceptable." [March 2012 NIH/OLAW Webinar].

If you need to use a non-pharmaceutical grade compound but were previously approved for only pharmaceutical grade, please submit an amendment to the Protocol request. In this amendment, you must include all of the relevant information described above, including your handling practices and justification.

References:

USDA Animal Welfare Act:

http://www.aphis.usda.gov/animal_welfare/downloads/policy/policy3.pdf

NIH Office of Laboratory Animal Welfare:

<http://grants.nih.gov/grants/olaw/faqs.htm#f4>