



The University of Georgia

Office of the Vice President for Research

UGA IACUC Policy on the Use of Outdated Drugs and Materials, Non-pharmaceutical Grade Drugs, and Controlled Substances

Approved by the UGA IACUC

Effective 1-17-08

Revised 10-16-14

Use of expired pharmaceuticals, biologics, and supplies in animals

The use of expired pharmaceuticals, biologics, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care. 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 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. The Attending Veterinarian and IACUC maintain control over the use of expired medical materials in order to meet their responsibilities to avoid or minimize discomfort, pain or distress to animals according to the Public Health Service Policy and the Animal Welfare Act Regulations. These provisions do not apply to the use of non-pharmaceutical grade compounds as described below.

Use of non-pharmaceutical grade compounds in animals

A pharmaceutical-grade compound is defined 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. 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.

The UGA IACUC recognizes that the use of non-pharmaceutical-grade compounds is often necessary for research. Where the use of non-pharmaceutical-grade substances may be essential for the conduct of science, the goal of the IACUC (or comparable oversight body) should be to consider the health and well-being of the animals while aiding the researcher in minimizing potentially confounding experimental variables and maximizing reproducibility of the research.

The NIH Office of Laboratory Animal Welfare and the United States Department of Agriculture consider that the use of non-pharmaceutical grade compounds should be based on:

1. Scientific necessity
2. No availability of an acceptable veterinary or human pharmaceutical-grade compound
3. Specific review and approval by the IACUC

In addition to the regulatory requirements outlined above, the UGA IACUC along with investigators will consider the following factors in accepting the use of non-pharmaceutical grade compounds:

1. Use must be compliant with applicable national or regional regulatory guidelines and requirements and the requirements of relevant funding agencies
2. The pharmaceutical-grade compound is not available in the appropriate concentration or formulation or the appropriate vehicle control is unavailable

Use of Outdated Drugs and Materials, Non-pharmaceutical Grade Drugs, and Controlled Substances

3. The compound is required to generate data that are part of an ongoing study or that are comparable to previous work
4. 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, 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
5. 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)

Investigators and the IACUC then will consider relevant animal welfare and scientific issues including safety, efficacy, and the inadvertent introduction of new variables with the use of non-pharmaceutical grade 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 non-survival studies, the scientific issues remain the same and the principles and need for professional judgment still apply.

Controlled substances requirements

The procurement, distribution, use, security, and record keeping of controlled substances regulated by the Drug Enforcement Administration (DEA) are guided by the regulations detailed in *21CFR 1300-1308* (http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfrv9_02.html). Each PI or unit using controlled substances must have their own controlled substance registration with federal and state DEA agencies.

Registered faculty or units must ensure controlled substances are stored in an area of limited access securely locked in a substantially constructed cabinet. Controlled substances must be secured behind two locks. Laboratory doors can be considered one lock, if doors of unattended labs are kept locked.

Registered faculty or units are responsible for maintaining accurate records of controlled substances used while in their possession by logging the amount used, and the amount remaining in each vial. Best practices advise that other information should consist of the date of use, initials of the person drawing up or administering drugs, and identification of the animal or group of animals to which the drugs were given. Various means of documenting controlled substance use may be used but the ability to audit these records must be ensured.

Laboratories, storage cabinets, logs of use, and inventory records are subject to unannounced inspections and audits by the DEA, and semi-annual inspections by the IACUC.