



## **Policy on the Use of Outdated Drugs and Materials, Non-Pharmaceutical-Grade Drugs and Controlled Substances**

### **Use of Expired Pharmaceuticals, Biologics and Supplies in Animals:**

The use of expired pharmaceuticals, biologics and supplies is generally not consistent with acceptable veterinary practice or adequate veterinary care. Euthanasia, anesthesia and analgesia agents must not be used beyond their expiration date, even if a procedure is terminal.

Other expired materials, whether for use in survival or terminal procedures, 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. When using such materials beyond their expiration date, the materials must be appropriately labeled as expired, and physically segregated from non-expired materials. In addition, materials that are only appropriate for non-survival procedures must be labeled as such.

The URAR veterinary staff 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 is 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:

- Scientific necessity
- Lack of availability of an acceptable veterinary or human pharmaceutical-grade compound
- Specific review and approval by the IACUC

In adhering to the regulatory requirements outlined above, the UGA IACUC along with investigators should consider the following factors in determining the acceptability of using non-pharmaceutical-grade compounds:

- The availability of the pharmaceutical-grade compound in the appropriate concentration or formulation, and the appropriate vehicle control
- The compound's importance to generating data that are part of an ongoing study or that are comparable to previous work
- The appropriateness of the compound's chemical properties 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
- Use must be compliant with applicable national or regional regulatory guidelines and requirements and the requirements of relevant funding agencies
- 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 should also 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:**

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 [21 CFR 1300-1308](#). 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.