Guidelines for the Use of Drugs and Chemicals in Animal Research

The University of Texas at Austin
Institutional Animal Care and Use Committee

These guidelines have been written to assist faculty, staff, and students in performing vertebrate animal procedures in a humane manner and complying with pertinent regulatory requirements. Under some circumstances deviations from these procedures may be indicated but such variances must be approved in advance by the IACUC.

Guided research commonly involves drug or chemical administration to animals as research subjects. In order to promote the humane use of drugs and chemicals, both the NIH and the USDA have issued guidelines for investigators, and the IACUC is charged with ensuring compliance with these guidelines. In general, the use of drugs in animals falls into one of two usage categories: standard veterinary care or experimental use. These guidelines apply to both types of administration. This document provides an overview of requirements that must be met when using drugs and chemicals in laboratory and animal research. It is organized into six sections:

Section A – Requirements
Section B – Suggestions to Implement These Guidelines
Section C – Disposal of Substances
Section D – Who to Contact for More Information
Section E – References
Section F – Acknowledgements

Section A – Requirements

1. **Current standards for the veterinary care of research animals state that pharmaceutical grade medications should be used for routine medical treatment.** Pharmaceutical grade drugs are tested for purity to reduce the possibility that they are contaminated with toxic compounds that may harm an animal. Examples of routine veterinary procedures that involve the use of drugs include surgery, treatment of infection, administration of pain control, and euthanasia. Drugs used for these procedures (including anesthetics such as ketamine, pentobarbital, or isoflurane; analgesics such as carprofen or buprenorphine; antibiotics; supportive fluids; parenteral nutrients; etc.) used either as part of the IACUC-approved study or a veterinarian-approved treatment plan should be obtained from a veterinary supply house or from a pharmaceutical supplier licensed by the FDA, if it is available from such sources. Typically, drugs obtained this way will be in a form that is packaged, labeled, and licensed for either animal or human clinical use.

2. **Chemicals and compounds administered to research animals for experimental objectives should also be of the highest purity possible.** There are two categories of drugs used for experimental purposes: already in clinical use or not approved for clinical use. If the drug is currently approved for clinical use (either in human or animals), then the investigator should determine whether a formulation of the drug is available that is suitable for the experiment in question. Most drugs are formulated to contain excipients that are safe for clinical use, but may interfere with experimental objectives. If the excipients do not confound the study, then the drug should be obtained from a veterinary supply house or from a pharmaceutical supplier licensed by the FDA. If excipients interfere with the experimental objectives or if the chemical is not approved for clinical use, the investigator is allowed to formulate the drug or chemical provided that purity and stability of the drug is maintained. In this case, the investigator must submit a protocol that describes and justifies the proposed use of the drug or chemical formulation, and the IACUC must review and approve the protocol before experiments are carried out. For example, the pharmaceutical version of a drug marketed for IV injection may not be formulated with an appropriate concentration or vehicle for administration via an intracerebral cannula or osmotic minipump. Furthermore, controlled scientific studies may require a control group dosed with the vehicle only, and the vehicle...
may not be readily available. Finally, some studies will use novel chemicals or mixtures of chemicals either synthesized or isolated from natural sources. These chemicals should be of the highest purity attainable (either from commercial sources or from laboratory procedures during their preparation) and formulated in an appropriate manner for a specific route of administration. When new drug or chemical formulations are proposed, the IACUC may consider factors such as the grade, purity, sterility, pH, pyrogenicity, osmolality, stability, site and route of administration, formulation, compatibility, and the pharmacokinetics of the chemical or substance to be administered. Investigators are encouraged to contact a veterinarian regarding the preparation of the protocol before submission to the IACUC, but in some instances a pharmacologist or toxicologist consult may be warranted.

3. **Expired drugs or fluids must not be administered to research animals without explicit IACUC approval.** All expired drugs, including anesthetics and analgesics, must be segregated and clearly marked “EXPIRED” on or before their date of expiration. If the PI feels that any use of expired materials is justified (e.g., used of as part of a brief non-survival procedure) this must be specifically submitted for IACUC approval in advance.

4. If an investigator is going to request IACUC approval to use a non-pharmaceutical grade medication or expired drug, they must check the “I Do Not Agree” response at the bottom of this guideline in the specific eProtocol in which the request is made, and provide an explanation and justification in the text box provided.

**Section B – Suggestions to Implement these Guidelines**

The following are best practices suggested to facilitate the implementation of these guidelines:

- **The IACUC recommends that each laboratory establish an inventory procedure to facilitate the identification and discarding of expired drugs.** Expired drugs must be separated. Disposal services for expired controlled substances are available at no cost to the investigator by calling Environmental Health and Safety (EHS) at (512) 471-3511.

- **Drugs without expiration dates should be dated upon receipt.** The investigator should determine the stability of the drug to come up with a reasonable shelf-life. This is commonly obtained from the manufacturer, and for most stable organic compounds the shelf-life is up to three years. If stability is unknown, the drug should not be used beyond one year. Dates must be tracked and unused drugs must be segregated and clearly marked “EXPIRED” after the labeled shelf-life has expired.

- **All dilutions and mixtures of drugs removed from the manufacturer’s primary packaging are to be discarded after one month from the date of preparation unless the manufacturer specifies a longer dilution shelf-life.** Drugs and chemicals could degrade after dissolution or dilution and they may be more prone to bacterial contamination. For these reasons, even if it is earlier than the manufacturer’s drug expiration date, all dilutions or mixtures made from a drug must be discarded after one month. The IACUC will consider deviations from this policy if the investigator submits a compelling justification explaining why the stability and purity of the compound is expected to be maintained longer than one month.

- Consider assigning the inventory responsibilities to one specific individual, with another individual assigned as backup.

- Establish an inventory system that minimizes the amount of drug or medical supplies on hand.

- Perform monthly checks of your inventory and segregate, label, and discard all expired drugs or medical materials.

- Place all expired drugs and medical materials in a clearly labeled container while they await pickup for disposal or return to manufacturer.
Section C – Disposal of Substances

For proper disposal of controlled substances, go to the EHS website at: http://www.utexas.edu/safety/ehs/lab/controlled_substances.html.

For proper disposal of hazardous waste (e.g., chemical, microbiological, animal products, human blood, etc.), go to the EHS website at: http://www.utexas.edu/safety/ehs/disposal/.

Section D – Who to Contact For More Information

For questions about these guidelines, contact the Office of Research Support (ORS) at (512) 475-8650.

For assistance finding sources for veterinary pharmaceuticals, contact the Animal Resources Center (ARC) at (512) 471-7534.

For questions regarding the disposal of pharmaceuticals and chemicals, contact EHS at (512) 471-3511. EHS can also provide advice on how to properly dispose of other drugs, some of which may be considered hazardous material or chemical waste.

Section E – References


Section F – Acknowledgements

This document contains content that was adapted from materials obtained from the University of California, San Francisco.