Guiding Principle

It is the responsibility of the NDSU IACUC to mandate proper pharmaceutical management for the use, documentation, and storage of all drugs used in research animals. All drugs must be stored, labeled, and disposed of according to the procedures outlined in this Guiding Principle.

Requirements


Title 21, CFR Section 1301.71(a), required that all registrants provide effective controls and procedures to guard against theft and diversion of controlled substances.

USDA APHIS/AC Policy 3 the use of expired materials such as pharmaceuticals "on regulated animals is not considered to be acceptable veterinary practice and is not consistent with adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act.

Procedures

1. Expired Drugs
   1.1. The use of expired drugs is not considered to be acceptable veterinary practice. Please refer to Expired Medical Materials Guiding Principle for more complete information.

2. Pharmaceutical Grade Drugs/Reagents
   2.1. Only pharmaceutical grade drugs (includes reagents, compounds, diluents, fluids) should be used on animals in research or instruction unless otherwise justified, reviewed, and approved by the IACUC. Please refer to the Nonpharmaceutical Grade Compound Use in Animals Guiding Principle for more complete information.

3. Labeling All Drugs
   3.1. You must label all secondary drug containers with the following information:
3.1.1. Drug Name
3.1.2. Drug Concentration
3.1.3. Expiration Date
3.2. If mixing drugs you must label all drugs that are in the cocktail.
3.3. The expiration date of the drug or diluents/vehicle in the cocktail that expires first must be written on the secondary container, and any unused portion of the cocktail must be disposed of by this date.

4. **Storage and Inventory (See Section 6.4 for Controlled Drug Storage)**
4.1. All drugs should be kept in a secure area.
   4.1.1. Do not store controlled and uncontrolled drugs in the same primary storage container.
4.2. Limit the number of personnel who have access to secured drugs.
4.3. Establish a system for inventory control:
   4.3.1.1. Employ regular inventory schedule—recommend bi-monthly.
   4.3.1.2. Minimize the amount of drugs that are kept in inventory to avoid drugs expiring.
   4.3.1.3. Place all expired drugs and materials in a clearly labeled container prior to disposal or pickup.

5. **Discarding Expired Drugs (See Controlled Drug Section 6.5 for additional instructions)**
5.1. Dispose of remaining drug contents by expelling into an absorbable material such as blue absorbent pads, coffee grounds, kitten litter, or other chemical absorbent material and then place into covered waste container.
5.2. Black out the name of the drug on the container.
5.3. Place the empty bottle into a sharps container or a glass disposal container.
   5.3.1. Do not pour drugs/chemicals/compounds down the sink or into any other drain that flows into the sewer.
   5.3.2. For large amounts of drug disposal, chemicals, or other compounds, please contact the NDSU Safety Office for additional guidance and instructions.

6. **Controlled Drugs**
6.1. A controlled (scheduled) drug is one whose use and distribution is tightly controlled because of its abuse potential or risk.
6.2. Controlled drugs are rated in the order of their abuse risk and placed in Schedules by the DEA.
   6.2.1. The drugs with the highest abuse potential are placed in Schedule 1, and those with the lowest abuse potential are in Schedule V.
   6.2.2. These schedules are commonly shown as C-I, C-II, C-III, C-IV, and C-V.
6.3. Drug Disposition Records/Usage Logs must be maintained for all controlled drugs.
   6.3.1. Inventory records must be retained for a minimum of two years according to DEA 21CFR.
6.3.2. A Drug Disposition Record is required for each controlled drug on hand and must document the receipt, administration, and disposal of each of those drugs.

6.3.3. For each drug, the disposition record must reflect the total volume of drug on hand. (e.g. 10-10ml bottles of Ketmaine=100 mls.) For each use deduct from the total volume on hand.

6.3.4. A witness should be present and initial the log to attest that the drug was legitimately disposed of.

6.3.5. You may contact the IACUC Office to request the recommended Controlled Drug Disposition Record or you may develop your own form.

6.4. Proper Storage of Controlled Drugs

6.4.1. Controlled drugs should be stored under double lock and key separate from other (uncontrolled/unscheduled) drugs.

6.4.2. Store in double lock safe constructed of tamper proof material. Options include:

6.4.2.1. Store in a locked box in a locked drawer, with the keys stored out of site.

6.4.2.2. Store in a locked drawer in a lab or office that remains locked at all times when not occupied, with keys stored out of site. (The “locked room” must always be locked when it is not occupied by either the registrant or authorized user.)

6.4.3. Controlled drugs should be stored in the physical location registered with the DEA.

6.4.3.1. Drugs may be removed for up to 24 hours from the registered storage location for use in facilities and treatment rooms. (For more information about the registered storage locations on file please contact the DEA).

6.5. Disposal of expired or unused stock of controlled drugs

6.5.1. Smaller Amounts:

6.5.1.1. In the presence of a witness expel the remaining contents of the drug into an absorbent disposable paper or cloth and place into a garbage container.

6.5.1.2. Record the amount of drug disposed of in the controlled drug log including the signatures of the person disposing of the drug and the witness.

6.5.1.3. Black out the name of the drug on the label.

6.5.1.4. Place the empty bottle into a sharps container or a glass disposal container.

6.5.2. Larger Amounts:
6.5.2.1. To dispose of larger amounts of expired or unused controlled drugs contact the Chicago Division at 312-353-7875 or visit DEA Disposal of Controlled Substance.

6.6. Registration procedures for North Dakota follow federal regulations as indicated below.

6.6.1. New applicants, who do not currently possess a DEA license to conduct business with controlled substances in the following categories must apply using Form 225 and 225a for renewal

6.6.1.1. Manufacturer
6.6.1.2. Distributor
6.6.1.3. Researcher
   6.6.1.3.1. Exemption from application fee applies to federal, state, or local government official or institution. The applicant's superior or agency officer must certify exempt status. The signature, authority title, and telephone number of the certifying official must be provided. The address of the fee exempt institution must appear in Section 1.

6.6.1.4. Online application forms are available at:
   http://www.deadiversion.usdoj.gov/drugreg/index.html#1

6.6.1.5. Analytical Laboratory
6.6.1.6. Importer
6.6.1.7. Exporter

6.7. For information on obtaining forms and assistance please contact the following field office for North Dakota:

6.7.1. Chicago Division
   John C. Kluczynski Federal Building
   Suite 1200
   230 S. Dearborn St.
   Chicago, IL 60604
   Phone (312)-353-7875

   North Dakota Contact Numbers
   Fargo (701) 476-5500
   Bismarck (701) 250-4550

For additional information please see the Office of Diversion Control Website-Practitioners Manual: