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 live vertebrate 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 Substance 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 Substance 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 Substances
6.1. A controlled (scheduled) substance is one whose use and distribution is tightly controlled because of its abuse potential or risk.
6.2. Controlled substances are rated in the order of their abuse risk and placed in Schedules by the DEA.
   6.2.1. The substances 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. Controlled Drug Ordering
   6.3.1. To order schedule I or II controlled substances registrants will need to submit a DEA form 222 with the order.
6.3.1.1. The supplier will complete the packages shipped and date shipped columns on the 222 form.

6.3.1.2. When the shipment is received the registrant will complete the packages received and date received columns of the 222 form.

6.3.1.3. Individuals that have been identified as delegates may order schedule II controlled substances for a registrant ONLY if a power of attorney form is fully signed and in place.

6.3.2. To order schedule III-V controlled substances a 222 form is not required; however the registrant will need to maintain the invoice.

6.3.2.1. The recipient should sign/initial and date the invoice.

6.3.3. Audits: registrants or authorized agents are encouraged to perform weekly to monthly audits of controlled substance inventories to accurately track inventory and avoid discrepancies.

6.3.3.1. Audits must be dated and include the signatures of the registrant/an authorized agent and a witness.

6.4. Drug Receipt-Disposition Records/Usage Logs must be maintained for all controlled substances.

6.4.1. All controlled substance records must be retained for a minimum of two years according to DEA 21CFR.

6.4.1.1. Records include: inventory forms, DEA form 222s, invoices, usage logs, DEA form 106 (Drug Theft/Loss), DEA for 41 (Record of Controlled substances Destroyed)

6.4.1.1.1. DEA Regulations require a biennial inventory. Perpetual inventory records can be labeled with the biennial inventory date and attached to the biennial inventory form.

6.4.1.2. Records management is the responsibility of the DEA registrant.

6.4.2. A Drug Disposition Record is required for each controlled substance on hand and must document the receipt, administration, and disposal of each of those drugs.

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

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

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

6.5. Proper Storage of Controlled Substances

6.5.1. Controlled Substances should be stored under double lock and key separate from other (uncontrolled/unscheduled) drugs.
6.5.2. Store in **double lock safe** constructed of tamper proof material. Options include:

6.5.2.1. Store in a **locked box** in a **locked drawer**, with the keys stored in a secondary location.

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

6.5.3. Controlled substances should be stored in the physical location registered with the DEA.

6.5.3.1. 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 IACUC Office or DEA).

6.5.3.2. Schedule I and II controlled substances must be stored separately from Schedule III-V substances. The separation may be a divider in a drawer or different shelf within a storage unit.

6.5.3.3. Compounded solutions containing controlled substances prepared within the laboratory should be labeled with: name of controlled substance(s), lot number(s), date vial was opened/prepared, final concentration(s) and amount(s) per container, and expiration date of <7 days unless product stability data suggests otherwise.

6.6. Disposal of expired or unused stock of controlled substances

6.6.1. Smaller Amounts:

6.6.1.1. 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.

6.6.1.2. 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.

6.6.1.3. Complete DEA form 41.

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

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

6.6.2. Larger Amounts:

6.6.2.1. To dispose of larger amounts of expired or unused controlled drugs contact the IACUC Office.

6.7. **Registration procedures** for North Dakota follow federal regulations as indicated below.
6.7.1. New applicants, who do not currently possess a DEA license to conduct business with controlled substances in the following categories must apply for a DEA registrations using Form 225 and 225a for renewal. Applicants must also have authorization from the North Dakota State Board of Pharmacy.

6.7.1.1. Researcher

6.7.1.1.1. North Dakota Requirements: Researchers are required to provide a Researcher Request for State Authorization to Obtain DEA Registration letter to the North Dakota State Board of Pharmacy. The letter must include the following:

6.7.1.1.1.1. A copy of researcher protocols including IRB and IACUC approval if using human or animal subjects.

6.7.1.1.1.2. A list of controlled substances that will be used and approximate quantities of each that will be used on an annual basis and the quantity that will be on inventory at one time.

6.7.1.1.1.3. The address at which controlled substances will be stored.

6.7.1.1.1.4. The security requirements that will be employed for storage.

6.7.1.1.1.5. A list of individuals that will have access to the controlled substances and how usage will be recorded.

6.7.1.1.1.6. A list of anticipated suppliers, their address and DEA Registration.

6.7.1.1.2. 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 certifying official for NDSU is the VP for Research and Creative Activity.

6.7.1.1.3. Online application forms are available at:

http://www.deadiversion.usdoj.gov/drugreg/index.html#1

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

6.8.1. Minneapolis Diversion Control Office
100 Washington Ave. S.
Suite 800
Minneapolis, MN 55401
Phone (612)-344-4136

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