Policy 11 – Use of Drugs and Expired Materials
Version 2.0
Approval Date: 9/17/09, 3/5/13

**Purpose** – The purpose of this policy is to instruct investigators as to the proper use, storage, and documentation of drugs (especially concerning controlled substances and non-pharmaceutical grade compounds) and the acceptable use of expired medical materials (syringes, suture, needles, etc.).

**Background** –

The use of expired pharmaceuticals, biologics, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care. (1,2,3)

**Definitions:**

Expiration - The month *after* the date indicated on the container

Non-drug medical materials - Includes things like sutures, wound clips, catheters, needles, and syringes

Non-survival procedure (aka acute procedure, terminal procedure) – A procedure in which the animal is euthanatized before anesthetic recovery (3)

Survival procedure - A procedure from which the animal recovers (from anesthesia)

Pharmaceutical grade - Compounds or agents intended for use in human or veterinary medicine; meet the highest standards for purity and bioavailability

Chemical grade - Compounds or agents which may be chemically identical to their pharmaceutical grade counterparts, but do not conform to recognized standards for purity and bioavailability

Controlled drugs (4) - Controlled substances are drugs (or other substances) regulated under the Controlled Substances Act (CSA, enforced through the DEA and FDA). The scheduling of a particular drug (I-IV) depends on medical use, potential for abuse, and safety. Controlled substance drugs are labeled with a ‘C’ and the corresponding schedule number. Examples of controlled drugs that are commonly used in research animals include ketamine (III), buprenorphine (III), sodium pentobarbital, and Euthasol (III).
Policy –

Expired drugs -

- Include name, concentration, and expiration date on each drug container aliquoted from stock solutions
- All dilutions and mixtures of drugs are to be discarded after one month from the date of preparation, unless a longer/shorter dilution shelf life is specified by the manufacturer
- All expired drugs should be discarded as soon as possible through the appropriate channels (especially important regarding controlled substances); contact EOHSS for more information

The use of all expired drugs is prohibited
The use of expired drugs is prohibited for both survival and non-survival procedures (any procedures involving live animals)

Expired non-drug materials -

- Expired non-drug materials can be used only in non-survival studies (1,2)
- All expired materials must be individually labeled as “EXPIRED-ACUTE USE ONLY”
- Expired and non-expired medical materials must be physically separated to avoid confusion

Non-pharmaceutical grade compounds

Consideration of non-pharmaceutical grade compounds should include -
- Lack of acceptable/available veterinary or human pharmaceutical-grade compounds
- Investigation of novel therapeutic drugs
- Specific review and approval by the IACUC
- grade, purity, sterility, pH, pyrogenicity, osmolality, and stability (1)

Avertin (tribromoethanol) – Use of avertin requires scientific justification. The side effects of avertin include acute inflammatory changes, local irritation, fibrous adhesions in the abdominal cavity, and mortality following one or repeated IP injections. Stock solutions must be kept in dark vials at 4°C and discarded within 2 weeks after preparation (7).

Cost savings alone are not an adequate justification for using non-pharmaceutical-grade compounds in animals
Controlled drugs

Record of use - The use/administration of controlled substances must be recorded every time the drug is administered to an animal. When a controlled drug is incorporated into a drug cocktail (such as ketamine/xylazine, common in rodents), the initial amount of controlled drug used to create the cocktail must be recorded, then an additional log sheet should be created for the cocktail. The cocktail vial should include date of creation, expiration date, concentration of each component, and dosing information. Individual administration of cocktail (volume) should then be recorded. A sample controlled drug log sheet is included in appendix I.

Storage (5) – Controlled substances must be secured within a locked steel cabinet, drawer, or safe that cannot be moved or transported. The storage cabinet must be kept in a room within the laboratory that can be locked as well.

General guidelines -
- Store all drugs in a secure, dedicated location
- Assign responsibilities to one specific individual, with another individual as backup
- Establish an inventory system that minimizes the amount of drug or medical supplies on hand
- Perform regular monthly checks of inventory and discard all expired drugs or medical materials following federal and state regulations; contact EOHSS for drug disposal (6)

Any exceptions to this policy must have IACUC approval

References -

1. OLAW: Q &A Expired drugs: http://grants.nih.gov/grants/OLAW/faqs.htm#useandmgmt_5

(Appendix 1 on proceeding page)
Appendix 1 – Sample controlled substance log

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<td>Total quantity supplied</td>
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<td>Expiration Date</td>
<td>Date Issued</td>
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<td>Principal Investigator</td>
<td>Research Staff Signature</td>
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<td>TRC Staff Initials</td>
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<th>Amount Used</th>
<th>Balance</th>
<th>Initials</th>
<th>Purpose</th>
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*For disposal only*

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