INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
INFORMATIONAL MEMO

In order to provide better service to our principal investigators, research staff, and administrative managers, the Office of Institutional Animal Care and Use has compiled this informational memo of answers to frequently asked questions. Please feel free to call the Office of Institutional Animal Care and Use staff if you have any questions or require further clarification about any items in this memo. Also, please refer to the Institutional Animal Care and Use Committee (IACUC) web site which includes such topics as recent updates, guidelines, standard operating procedures, current application forms, and training information. The IACUC website address is http://www.med.unc.edu/iacuc

1. EXPIRED DRUGS AND/OR BIOLOGICALS

The IACUC acts in accordance with USDA Policy 3 – Expired Medical Materials when providing instructions on expired drugs and/or biologicals. Although the Drug Enforcement Agency (DEA) has separate regulations pertaining to expired drugs, the IACUC is mandated to adhere to policies that are part of the United States Department of Agriculture Animal Welfare Act.

Drugs administered to relieve pain or distress, including all anesthetic and analgesic agents, must not be used beyond their expiration date. Other medical materials such as saline and suture material must be labeled "For Acute/Terminal Use Only" and must be used only in non-survival/terminal procedures.

The USDA Policy 3 states that “Facilities allowing the use of expired medical materials in acute terminal procedures should have a policy covering the use of such materials and/or require investigators to describe in their animal activity proposals the intended use of expired materials. The attending veterinarian and the Institutional Animal Care and Use Committee (IACUC) are responsible for ensuring that proposed animal activities avoid or minimize discomfort, distress, and pain to the animal. These responsibilities cannot be met unless the veterinarian and the IACUC maintain control over the use of expired medical materials.”
All expired medical materials found in a licensed or registered facility are to be brought to the attention of the responsible official. The facility must either dispose of all such materials or segregate them in an appropriately labeled, physically separate location from non-expired medical materials.


2. **DRUG STORAGE AND STOCK ROTATION**

During IACUC inspections and outside audits by USDA and AAALAC – International, inspectors and site visitors will ask to inspect your drugs, medications, and biologics. Inspectors will assess the following: 1) controlled substances are maintained in a locked container when not in use 2) a system is in place for conducting product inventory and ensuring that drugs, medications, and biologics are within expiration date 3) expired agents (not including analgesics or anesthetics) used in acute procedures are labeled “For Acute or Terminal Use Only” 4) all expired agents used to relieve pain (analgesia) or for anesthesia are disposed.

All expired medical materials found in a licensed or registered facility are to be brought to the attention of the responsible official. The facility must either dispose of all such materials or segregate them in an appropriately labeled, physically separate location from non-expired medical materials. Controlled drugs that are used for controlling pain and/or providing analgesia should be set aside in a physically separate location (see # 3 below) for proper disposal of controlled substances.

3. **DISPOSAL OF EXPIRED CONTROLLED SUBSTANCES**

Following the IACUC’s semi-annual facility inspection, several investigators requested clarification regarding disposal of controlled substances. According to the rules and regulations of the North Carolina Controlled Substances Act, Chapter 45, Subchapter G, Section .0408: “The destruction of a controlled substance in Schedule II, III, IV and V by a registrant or practitioner or by his authorized agent shall be witnessed by a state or federal official authorized to enforce the Federal Controlled Substance Act or the North Carolina Controlled Substance Act …”

Conversations with agents in the Raleigh office of the Department of Health and Human Services, indicated that in research settings, the above statement should be broadened to include Schedules I (cocaine, heroine, etc) through VI (includes marijuana). In addition, small quantities of contaminated controlled substances can be disposed of in front of a witness “provided a record of destruction is made on a controlled substance disposition record showing the date, time, quantity, manner of destruction, and type of controlled substance, and the initials or signatures of persons destroying and witnessing the destruction….A record of this destruction shall be kept available by the registrant or practitioner for a minimum of two years.”
In order for you to ensure proper disposal of controlled substances contact the Raleigh office of the Department of Health and Human Services. Contact Carolyn Wagner at (919) 875-3736 for questions and/or to set up a visit with a state official.

4. **ANIMAL BREEDING, CAGE CARDS, AND IACUC APPROVED ANIMAL NUMBERS**

Federal law requires explanation and justification of the numbers of animals to be used in an animal proposal. The application must provide a detailed justification for the numbers of animals required. The committee needs enough information to determine if the requested number is appropriate in order to approve your application.

The issue of mouse/rat breeding colonies complicates the number justification as well as the cage card distribution. Applications that describe breeding in addition to experimental procedures should include details for both in item F. Break the numbers explanation into “Numbers of Animals Required for Breeding/Maintaining Lines” and “Numbers of Animals Required for Experimental Procedures.” When calculating the animal number, realize that animals that will be weaned and kept will count against the number of animals proposed for a study. So be sure to include all mice/rats that live beyond the three week weaning period into the total animal number approved for the application. Be sure to include this total number in your animal number required for the three-year approval period. (See the IACUC Application Instructions *APPENDIX III a through d* for some detailed examples of animal numbers. [http://www.med.unc.edu/iacuc/appguide.htm](http://www.med.unc.edu/iacuc/appguide.htm))

The approved animal number on your application is entered into a computer tracking program owned and operated by Division of Laboratory Animal Medicine (DLAM). As you order animals through DLAM as well as wean animals and separate them into individual cages, your total animal number associated with your application is reduced accordingly. Animal ordering and requests for cage cards are the two triggers for deducting from your approved animal number.

Animal orders are permitted only on currently approved animal applications. Be certain the application you reference on your animal order form for DLAM is the correct number. Also be certain that you have accounted for all animals required for your experiments including animals required for breeding as well as those that live beyond the three-week weaning period.

DLAM tracks animal use and DLAM personnel will inform an investigator when the number of animals has reached its approved limit. (Please contact DLAM personnel for specific issues dealing with cage card distribution and ordering of animals.)

If you exceed your originally approved animal number you must file an amendment with the IACUC. The committee will review the amendment and, if approved, will attach the
amendment to the original application and will alert DLAM regarding the addition to the animal number.

5. **EXPIRED APPLICATIONS AND CAGE CARDS**

At the end of the three-year approval period, your animal use application expires and must either be terminated or continued as a new application. The new application is reviewed by the full IACUC de novo. The IACUC members do not refer back to the old application during the review process. If you are continuing your project in a new application, it is important to indicate on the first page that the application is a continuation.

Animals that remain on the expired application must be factored into the total animal number for your continuation application. (See May 2000 IACUC Informational Memo on IACUC web site [http://www.med.unc.edu/iacuc/welcome.htm](http://www.med.unc.edu/iacuc/welcome.htm)) When a new application is submitted for review the IACUC staff checks to see if it is a “continuation” application. This is indicated on the first page of the application in the box “Continuation of ID#: ____.” The IACUC runs an animal inventory report on the original application to determine if any animals are still housed under the original application number. The IACUC transfers the animals from the old application to the new “continuation” application. The number of animals moved to the new application are subtracted from the total number available on the new application. In order for you to have the total number of animals necessary for the three-year approval period of your new application, it is important for you to account for these transferred animals in the section indicated on the first page of the animal application.

After IACUC transfers the animals from the old application to the new “continuation” application, the IACUC notifies DLAM personnel, who then print replacement cards and deliver them to the appropriate room slot in the DLAM animal quarters. Then ensure that your research staff places the new cage cards on your animal cages for rapid identification with the appropriate application. Discard the old cards.

6. **APPENDIX A – IACUC Training Information/Training Record/Technique Sheet**

Every Principal Investigator, Co-investigator, and all individuals listed on the animal use application must complete Appendix A to provide the IACUC with necessary demographic information as well as training information. Appendix A for each individual is attached to the application and reviewed by the IACUC members during the monthly meeting. These forms are used by the IACUC as an assessment of research personnel animal training. The IACUC uses the form to make an assessment of whether additional training is required by your research personnel. It is essential for you to fill out the form accurately and completely. In addition, be certain to sign the form. This will save both you and the IACUC staff time as the IACUC staff is required to contact you prior to the monthly IACUC meeting to obtain a complete and signed copy.