In order to be in compliance with USDA policies and the Animal Welfare Act, the Committee on Animal Research (CAR) has instituted the following policy, effective October 1, 1999:

1) **No expired drugs or fluids are allowed for use on animals in research or instruction.** All expired drugs, including anesthetics and analgesics, must be discarded on or before their date of expiration. No expired drugs are allowed for use on animals, even for terminal procedures.

2) **No expired medical materials or devices may be used beyond their expiration date and must be discarded, except in the case of acute terminal procedures and unless a written proposal is submitted to and approved by the CAR.** The proposal must include the following information: a) a description of their intended use, b) a plan for how sterility will be assured, and c) procedures for appropriately labeling and storing these expired materials separately from non-expired materials.

3) **The CAR recommends that each laboratory establish an inventory procedure** to facilitate the identification and discarding of expired drugs. Disposal services for expired drugs and/or controlled substances are available at no cost to the investigator by calling EH&S at 476-0544.

4) **Any incident of noncompliance with this policy will be referred to the Committee on Animal Research and appropriate sanctions will be applied** up to and including suspension of the approval of the research protocol for which the expired drug or material is being used. Any expired drugs or materials identified or discovered during inspections will be discarded immediately.

For questions about this policy, call the office for Committee on Animal Research at 476-2197.

**Implementation Strategies**

Over the next few weeks LARC staff will be conducting site visits to assist the investigators in achieving compliance with the new Policy. The following are general guidelines intended to assist the investigators in complying with the policy:

1. Establish an inventory system, which minimizes the amount of drug or medical supplies on hand.
2. Perform regular monthly checks of your inventory and discard all expired drugs or medical materials.
3. Store all drugs in one location (to make checking easier). Please contact LARC if you would like assistance in obtaining a lockable box for your drugs.
4. Consider assigning the inventory responsibilities to one specific individual.
5. Contact your suppliers to see if they will accept the return of some expired drugs or medical supplies for credit. Some do.
6. Contact 476-0544 to dispose all expired drugs or medical supplies.

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7. Place all expired drugs and medical materials in a clearly labeled container while they await pickup for disposal or return to manufacturer.

8. Please contact LARC staff at 476-2204 if you need any assistance on this issue.

During the recent USDA site inspection, UCSF was issued a number of protocol-related violations. The following is a listing of some of the most common reasons for the violations and ways to prevent their reoccurrence:

1. **Unauthorized personnel performing procedures.**
   Please make sure that all personnel are listed in your approved version of the protocol. You must submit a request to add personnel to the CAR Office and obtain approval before any new personnel can work on your protocol.

   **All personnel listed in the protocol must read and fully understand all the commitments made in the protocol prior to starting work.**

2. **Untrained personnel performing procedures.**
   All new users are required to take the basic regulatory and ethical training course prior to starting work on any procedure. These courses are offered by LARC. Species-specific training is also available upon request. Please contact 502-7408 to enroll in these courses.

3. **Procedures written in protocol not being followed.**
   It is extremely important that investigators follow all the procedures described in their written protocols as approved by the CAR. This includes the various monitoring procedures (e.g. blood pressure, temperature, respiration, heart rate) as described in the protocol. USDA considers any deviation from the written procedures to be a major infraction and as such it requires that CAR take immediate actions to correct a protocol violation. This includes, at minimum, not allowing the violation to continue unresolved. Please make sure that staff involved in the study are thoroughly familiar with the details of the protocol and that they follow the procedures exactly as described.

   In addition, the internal CAR inspections identified a number of protocol violations which included:

4. **Lack of Monitoring.**
   The term "continuous monitoring" means the presence of an individual in the room during the entire procedure to observe, monitor and record the parameters listed in the protocol. The use of electronic or automated monitoring/recording devices without the presence of an authorized individual does not satisfy the requirement and constitutes a violation of the protocol.

   All personnel listed in the protocol must read and fully understand all the commitments made in the protocol prior to starting work. Many protocol violations appear to be the result of investigators or their authorized staff not following or being aware of the details in their approved protocols. It is important that all personnel listed in a protocol read and fully understand their approved procedures prior to beginning any studies with animals. If modifications to a protocol have been approved by the CAR, then all listed personnel must be fully informed of these modifications to be certain that studies with animals are conducted in accordance with current authorized procedures. Please review your protocols and modifications to be certain that the currently approved procedures are followed in any research involving animals.

**IMPORTANT NOTE:**

Before implementing any changes in any aspect of the CAR-approved protocol, including the addition of new personnel, you must submit a formal written request to the CAR and obtain CAR approval.
Most species of macaques, e.g. rhesus, cynomolgus and pig tail monkeys, can carry a herpes virus known as B-virus (Herpesvirus simiae or Cercopithecine herpesvirus 1), although it is most frequently associated with rhesus macaques (Macaca mulatta).

Although B-virus is common in macaques, it causes little or no detectable clinical illness. It may present in macaques like human herpes simplex causing blister-like lesions in or around the mouth. All macaques should be presumed to be actively shedding B-virus in bodily fluids: blood, saliva, urine and feces. The occurrence of B-virus is lower in young macaques and increases significantly as the animal reaches sexual maturity (around 3 years of age).

Humans can be infected from contact with macaque tissues/fluids, bites, scratches, splashes (including urine and feces) and contaminated needle sticks. In humans, B-virus infections cause encephalomyelitis. It is fatal in over 70% of cases. Often there are initial symptoms of fever, malaise, herpetic blisters, itching at the site of the bite or scratch, swelling of the glands and/or limb numbness.

In the 1950’s, around the time of extensive testing of polio virus vaccines in macaques, deaths from B-virus infection were reported in laboratory workers. Few cases were identified between the 60’s and late 80’s, possibly due to the increased use of ketamine anesthesia, squeeze cages and wider use of protective clothing during work with macaques.

During the 1980’s, a new generation of researchers and animal caretakers entered the field, often without having full knowledge of the potential risks of B-virus infection and the importance of appropriate outer-clothing. As a result, many persons working with macaques did not take appropriate precautions for preventing injury, did not report injuries when they occurred, and/or did not adequately cleanse wounds inflicted by macaques. This was evidenced by eight reported cases of human B-virus infections in Florida in 1987.

In response to this cluster of B-virus infected personnel the ‘Guidelines for the Prevention and Treatment of B-Virus Infections in Exposed Persons’ were developed. The availability and implementation of these guidelines have precipitated an increase in the reporting of injuries received from macaques, or related equipment. As a result, health care professionals have had the opportunity to administer appropriate “post-exposure” treatment to their patients. According to Dr. Julia Hilliard, Director of the National Institute of Health, B Virus Laboratory at Georgia State University, there have been no deaths from Herpes B-virus since the late 80’s in cases where immediate and proper first aid has been administered.

In humans, B-virus infections cause encephalomyelitis. It is fatal in over 70% of cases.

Although the risk of acquiring B-virus infections from macaques is low, this infection must be taken seriously as shown by the recent death of a worker at the Yerkes Primate Center in Georgia on December 10, 1997. The exposure occurred on October 29, 1997, while the worker moved the animal within cages during a routine capture of free-ranging monkeys. She was not wearing protective eyewear because the activities in which she was engaged involved caged macaques, and the activities were judged by the primate center to carry a low risk for exposure to B virus.

Personnel working directly with macaques must follow posted protective clothing requirements while working with macaques. In addition to protective clothing, first aid training and follow-up care are essential ingredients for minimizing opportunities for transmission of the B-virus to personnel in the laboratory environment. All exposure incidents are treated as having the potential for B-virus infection.

Along with providing protective clothing, the LARC provides and maintains Monkey Bite/Scratch Emergency kits outside of each macaque housing area. These kits contain all the supplies needed for administering initial treatment when an exposure has occurred. Order information for additional kits for labs and surgical/procedure areas can be obtained through the LARC, or on the LARC web site. To receive information on post-exposure first-aid training or to access additional information about B-virus, contact Cary McDonald @ 476-6140.
As you are aware due to increased research activity we are experiencing shortages of rodent housing space. We are in the process of planning a brand new facility at the Parnassus Campus (detailed information will be provided in future editions) as well as studying other options to increase the housing capacity. In the meantime the Animal Users Advisory Committee is charged with the review and approval of requests for new or additional rodent housing. If you require rodent housing please submit a written request to:

Animal Users Advisory Committee
Box # 0942

In your request please include a description of the need and a justification of the necessity for increased capacity.

New sections have recently been added to the Laboratory Animal Resource Center web site; the material contained on these pages will help you gather information for your research, grant applications, and business activities. Among the sections added:

• New Large Animal Ordering Procedures; Small and Large Animal Order Forms
• Electronic versions of LARC Newsletters
• Species-specific data, including information on normative values, animal identification, analgesia, and anesthesia
• LARC Organization Charts
• LARC Program Description containing information required on some grant applications.