



Berkeley Animal Care News

April 2012
Volume 1
Issue 2

Animal Care and Use Committee (ACUC)
acuc@berkeley.edu

(510) 642 - 8855
www.acuc.berkeley.edu

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Welcome!

The USDA completed their annual unannounced site inspection of our campus animal program at the beginning of March and we received two citations. Although this number of citations in the so-called "age of enforcement" is low compared to our peer institutions - our goal is zero citations. Accordingly, we want to update you on changes to our protocol review process aimed at preventing these issues from recurring.

The *first citation* was to our IACUC (i.e. ACUC). The USDA inspector felt the committee had not required adequate justification for the numbers of animals used in a protocol. We recently revised Attachment A of our AUP forms to facilitate justification of numbers but the protocol in question was written before this revision. We will soon be making available on our website (acuc.berkeley.edu) a specific guidance document for how to complete Attachment A, including adequate justification of animal numbers. Additionally, we are in the process of developing and posting much more guidance to our animal user community on diverse issues. We encourage you to visit the site and provide feedback to us at acuc@berkeley.edu.

The *second citation* was for animal health issues that arose due to a breakdown in communication when transferring of animals between OLAC and PI care. While new safeguards for staff training were implemented to prevent recurrence, this incident highlights that critical aspects of animal care work best with dual oversight. We encourage researchers to both know and work closely with their animal caretakers at OLAC.

Sincerely,
Bill Sha
ACUC Chair

Eileen Lacey
ACUC Vice-Chair



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CLEB Announcement for Animal Users

Effective immediately, all experiments that involve the use of recombinant DNA and/or biological agents and research animal subjects shall require Committee for Laboratory and Environmental Biosafety (CLEB) approval *prior to* review and approval by the ACUC. CLEB requires submission of a complete Biological Use Authorization (BUA) application at least 30 days before a convened CLEB meeting to address all biosafety containment issues. Generally, CLEB will notify applicants within one week of the meeting of the committee's decision. Investigators need to plan ahead to ensure CLEB approval because ACUC can no longer approve new or revised AUPs contingent on subsequent CLEB review and approval of a BUA.

The BUA application form and dates of the meetings are available at:
<http://ehs.berkeley.edu/hs/71-biosafety-program.html>

If you have any questions, please contact a Biosafety Officer at 643-6562 or 643-1397.

Pharmaceutical Availability

We continue to face challenges obtaining several pharmaceutical agents. The most notable of these has been pentobarbital, but in recent months, we have also seen shortages of buprenorphine, diazepam, fentanyl, dexmedetomidine, and others. There are several reasons for this. First, market factors have led to shortages of many pharmaceuticals in both veterinary and human medicine. Although these shortages no longer make the nightly news the situation is still problematic. Layered on these shortages are two other regulatory-based developments. First, the US Department of Agriculture (USDA) and National Institutes of Health (NIH) are taking a stronger stance about use of non-pharmaceutical grade compounds. As a result, justifying use of these products, such as pentobarbital from Sigma, has become more challenging.

Secondly, federal agencies are taking a more strict approach to laws regulating extra label drug use. Without delving into the details of the various laws and policies, these changes mean that several options we once had to obtain alternate forms of pharmaceuticals are no longer available. In conjunction with other UC campuses, we are working with University of California Office of the President (UCOP) and vendors to investigate potential solutions. However, it appears that the situation will not change in the foreseeable future. As always, we encourage you to work closely with OLAC veterinarians to plan options for pharmaceutical agents used in your research.



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Upcoming AAALAC Site Visit

AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care International) is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. AAALAC evaluates participating institutions to ensure minimum standards are met as required by law, and also to ensure institutions are going the extra step to achieve excellence in animal care and use. UC Berkeley has been accredited by AAALAC since 1994 and will seek to renew accreditation this Fall (2012). The OACU along with OLAC may be scheduling brief meetings with animal users at Berkeley through the summer to ensure we are prepared for the AAALAC inspection this fall.

AAALAC Highlights Top 3 Deficient Areas

Which Deficiencies Were Most Often Noted by AAALAC? During 2011, AAALAC noted three main areas of reoccurring deficiencies (in accordance to the *Guide*) in animal care and use programs.

- 1) Occupational Health and Safety Program, deficiencies such as;
 - OHSP not fully or inconsistently implemented;
 - Inadequate risk assessments;
 - Lack of follow up after initial medical assessment, and;
 - Lack of safety training (a particular concern for student employees).
- 2) IACUC Protocol Reviews, deficiencies such as:
 - Lack of intensity of AUP review;
 - Animal procedures not clearly identified;
 - Administration of analgesia not clearly defined, and;
 - Inadequate/inappropriate committee composition.
- 3) Heating, Ventilation and Air Conditioning (HVAC) System, deficiencies such as:
 - Inadequate maintenance of temperature;
 - Inappropriate relative air pressure differential;
 - Environmental data not being recorded;
 - Inadequate air changes, and;
 - Inability to maintain humidity.



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Signage in Animal Housing and Procedural Areas

According to USDA/APHIS (Animal and Plant Health Inspection Service) and the Guide for the Care and Use of Laboratory Animals, institutions that use animals in research must develop methods for reporting and investigating animal welfare concerns. In addition, the OACU will begin to post signage in animal housing and procedural areas. The OACU will also schedule time to briefly meet with individual labs to place signage in areas where animals are brought to the PIs lab, specifically.

Post-Inspection Follow-ups

The OACU will begin to conduct post-inspection follow-ups (PIFS) of animal facilities and laboratories.

- PIFs—If and when deficiencies were found during an ACUC site inspection, the ACUC has a responsibility to follow-up to ensure corrective action has been completed. If it is determined a follow-up is needed, the OACU will contact the responsible party to schedule a time for the follow-up. However, the PIF may be conducted without prior scheduling notice.

PIFs also give an opportunity for the OACU to update personnel in regard to the latest news, policies, and regulations as it applies to animals in research. It also is an opportunity for research personnel to ask questions of the ACUC in regard to protocol approval processes, inspections, policies and guidelines, and other topics related to ACUC and animal use at Berkeley.

Updated Website

The ACUC website (www.acuc.berkeley.edu) has been recently updated to showcase pertinent information in a more user-friendly and convenient manner. For example, the website more clearly outlines:

- How to report animal concerns
- Processes for protocol review and submission
- Congruency reviews for grants, Material Transfer Agreements, and Sponsored Research Agreements
- Information on the procurement of custom antibodies
- Useful links to relevant websites, published literature, and federal, state, and university regulations, policies and guidelines



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Update on OACU-related Processes

Grants

As of November 1, 2011, the OACU is no longer reading grant proposals upon submission to the agency. Once the funding agency requests ACUC verification, the OACU will send an email to the PI (as before) outlining any missing personnel, procedures, etc. If any revisions to the Animal Use Protocol (AUP) are needed based on the email, please modify your AUP as soon as possible.

In view of this procedural change by the OACU, it is strongly recommended that PIs (grant applicants) notify the Sponsored Projects Office (SPO) of grant-related positive feedback from the funding agency as soon as possible. PIs should initiate the review and comparison process as soon as possible to avoid a delay in potentially imminent funding.

Revision Request Form

In order to streamline administrative processes as well as speed up the review and approval of most AUP revisions, the ACUC and OACU have rolled out a new [Revision Request Form](#). This form must be submitted along with the revision at the time of submission to be considered for review.

Reminder: *Ethics in Animal Research* presentation

The Animal Care and Use Committee (ACUC) revised its Training Policy to introduce students who use animals or freshly euthanized animals in classes, to some underlying concepts of the use of animals in research and teaching; as well as informing them about the rigorous review and approval process. The ACUC requires Principal Investigators (Instructors) to provide their students with the *Introduction to Animal Care and Use: Regulations and Responsibility* presentation. This PowerPoint presentation will be e-mailed to PIs with teaching protocols prior to the start of Fall 2012 semester. This PowerPoint presentation of approximately 16 slides, covers the basic principles of animal welfare regulations, ethics and protocol compliance, and reporting animal concerns as they relate to animal care and use at UC Berkeley. ACUC recommends that this presentation be given on the first day of instruction for each course or class that uses animals.