Welcome back!

As we start a new academic year, we wanted to highlight several issues that are discussed in our August issue.

First, during the next year we – in coordination with the Physician in the Occupational Health Clinic – will be phasing in a new program to remain compliant with the federal requirement to have an Occupational Health and Safety Program for all animal users. For researchers, this will involve filling out an Animal Exposure Questionnaire to help identify individuals who may have occupational health issues in working safely with animals.

Second, in concert with the continuing AAALAC accreditation of our campus animal program, AAALAC will conduct a site visit to our campus on October 15th and 16th to review our program and talk to animal researchers. Please stay tuned for further updates.

Finally, as part of our overall efforts to improve service to campus animal research community, we would like to congratulate Linda Tripp, one of our OACU Analysts, on receiving a coveted Certified Professional IACUC Administrator credential. Well done!

Sincerely,
Bill Sha
ACUC Chair

Eileen Lacey
ACUC Vice-Chair
Occupational Health and Safety Program

The ACUC adopted a revised policy describing Animal Occupational Health and Safety Program (AOHSP) effective July 1, 2012. This policy can be found on ACUC’s website. Participation in the AOHSP is required for:

- All individuals currently listed on a research or teaching Animal Use Protocol (AUP),
- All individuals that are to be added to an AUP, and;
- Any individual through their employment who has contact with or exposure to live animals,

The purpose of the program is to protect the health of individuals working with animals. In addition, PHS Policy and the Guide require institutions to provide an occupational health program for all personnel who work in laboratory animal facilities or have frequent animal contact. The emphasis of the AOHSP is to identify workplace risks and in the prevention of injury or illness when working with animals.

To improve this program, the Occupational Health Clinic (OHC) and the ACUC have revised the Animal Exposure Questionnaire (AEQ). This new questionnaire must be completed by all individuals to be listed on an approved AUP. The AEQ is an on-line form requiring CalNet authentication in order to access and the questionnaire will only be viewed by a Board Certified Occupational Health Physician at the Occupational Health Clinic.

Starting this month, PI’s will be notified at the time of their annual renewal to complete the AEQ and they must inform all individuals listed on their AUP to complete the AEQ by the end of that month. Individuals who do not respond, will be contacted by staff from the Office for Animal Care and Use (OACU) for a reminder that completing the AEQ is now required in order to continue working with animals and to be listed on an approved AUP. This process will continue over the coming year until all individuals listed on AUPs have completed the AEQ. ACUC may revoke access to and the privilege of animal use for non-responders.

A one-page handout has been developed to assist instructors in addressing potential health concerns in classes. This will be emailed to PIs of teaching protocols and be available on our web site.

If PIs wish to add new personnel at any time henceforth, said individual(s) will need to complete the AEQ as well as CITI training before s/he can be added to the AUP and given access to animal facilities and labs. Please contact the OACU if you have any questions.
CLEB & Radiation Safety Committee 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.

BUAs are also required for individuals using nonhuman primates due to the human health risk associated with this species.

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

Similarly, any experiment using radioisotopes and/or radiation-producing devices on “live vertebrate” animal subjects must have approval from the EH&S Radiation Safety Office prior to review and approval by the ACUC. The Radiation Safety Office requires the submission of a complete Radiation Use Authorization (RUA) application. Approval of an RUA may take up to 6 months pending the complexity of the request. Therefore, investigators need to plan ahead to ensure RUA approval prior to ACUC approval.

The RUA form is available at: [http://www.ehs.berkeley.edu/rs/133-radiation-use-authorization-rua.html](http://www.ehs.berkeley.edu/rs/133-radiation-use-authorization-rua.html). For assistance, please contact a member of the Radiation Safety Team at radsafety@berkeley.edu.

OLAC, ACUC and Changes in Federal Expectations

The ACUC and OLAC are aware of a number of recent changes in federal expectations that have led to “regulatory creep” by regulatory agencies, including the Office for Laboratory Animal Welfare (OLAW), United States Department of Agriculture (USDA). For example:

- For no apparent reason, OLAW did a surprise inspection to the University of Pennsylvania under the threat of revoking the university’s funding
- Several universities incurred fines up to $65,200 by the USDA for minor infractions that did not have pertained to animal welfare, such as dusty trash cans, standing water on the floor of indoor and outdoor animal rooms or enclosures, and a forgotten pen on the floor. The largest reason for the fines was a lack of documentation. (continued on page 4)
OLAC, ACUC and Changes in Federal Expectations (continued)

Even the guidelines outlined in the Guide for the Care and Use of Laboratory Animals have become more detailed. For example, the use of non-pharmaceutical grade chemicals or substances (i.e., any compound introduced into a live animal) is a new exception to the 8th edition of the Guide, and must therefore be justified in the animal use protocol and approved by the ACUC.

Although many of these changes are federal laws or policies and therefore not subject to negotiation, the ACUC and OLAC understand that this “regulatory creep” significantly affects animal researchers. Therefore, we are trying to assist the PIs during this age of heightened expectation. For example, the OACU has over-hauled the ACUC website to make information more easily accessible and user-friendly for new and current PIs and their laboratory staff. All of the guidelines and policies are being updated and will be available online to clearly outline the acceptable practices/methods. A new program being developed revolves around post-inspection monitoring, which will help reduce the number of findings during site inspections (see details below).

Please contact the OACU if you have any questions or concerns.

AAALAC’s site visit October 15th & 16th

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 is seeking to renew accreditation this Fall (2012). The OACU along with OLAC may schedule brief meetings with animal users at Berkeley over the next two months to ensure we are prepared for the AAALAC inspection this fall. Further updates will be forthcoming via listserv.

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 was e-mailed to PIs with teaching protocols on August 20, 2012. This 16-slide PowerPoint presentation 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.