



Jim McGuire photos

Berkeley Animal Care News

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

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INSIDE THIS ISSUE

- 1 Chair's Message
- 2 eProtocol Update
- 3 AAALAC Site Visit
Planned for Fall 2015
- 4 Post Approval Monitoring
Program
- 5 NIOSH Updates
Hazardous Drug List
- 6 Increased Frequency of
DMR, Administrative
Submission Deadlines
- 7 New ACUC Policies &
Procedures on Protocol
Review
- 8 OLAC Update: Changes in
Sentinel Testing Program

RESOURCES

- 1 Animal Care and Use
Committee (ACUC)
- 2 Office for Animal Care and
Use (OACU)
<http://www.acuc.berkeley.edu/>
- 3 Office for Laboratory
Animal Care (OLAC)
<http://www.olac.berkeley.edu/>

eProtocol Rollout Continues

In October, ACUC began implementing the web-based AUP management system eProtocol. All new and *de novo* submissions of AUPs must now be submitted using the eProtocol system. eProtocol was successfully implemented on the human subjects side at Cal four years ago and on the IACUC side at Stanford over a decade ago. ACUC and OACU staff are now reviewing the fifth monthly group of submissions, and with each group we continue to improve the system and our processes to help PIs transition to the new system.

Because OACU staff will work closely with all investigators who are submitting online protocols for the first time, **it is extremely important for PIs to start early to prepare their submissions.** OACU is notifying PIs several months in advance of their *de novo* submissions deadlines. Once you receive your notification, contact OACU staff at acuc@berkeley.edu or 642-8855 to arrange an orientation to the new system. It will save you time in the end!

Advantages of a web-based system to PIs will include significantly shorter review times for revisions to AUPs and improved service to the animal research community through new initiatives such as the quicker administrative review process discussed below (item 7 in this issue). A major change like this always required some adjustment, but we expect that in the long run this change will be highly beneficial.

Other upcoming events include the anticipated opening of the Mouse Barrier Facility in LSA later this spring and, in the fall, our next site visit by the Association for Assessment and Accreditation for Laboratory Animal Care (AAALAC). ACUC, OACU and OLAC staff will be working with researchers to prepare for another successful AAALAC visit and renewal of our AAALAC accreditation.

Finally, just in case you missed the news, Professor Jim McGuire, Curator at the Museum of Vertebrate Zoology, discovered a new species of frog in the rain forests of Indonesia's Sulawesi Island (pictured above); this find is particularly exciting because this species gives live-birth to tadpoles. To learn more, please see: <http://newscenter.berkeley.edu/2014/12/31/unique-sulawesi-frog-gives-birth-to-tadpoles/>.

Kind regards,

Bill Sha
ACUC Chair

Eileen Lacey
ACUC Vice Chair

INSIDE THIS ISSUE

- 1 Chair's Message
- 2 eProtocol Update
- 3 AAALAC Site Visit Planned for Fall 2015
- 4 Post Approval Monitoring Program
- 5 NIOSH Updates Hazardous Drug List
- 6 Increased Frequency of DMR, Administrative Submission Deadlines
- 7 New ACUC Policies & Procedures on Protocol Review
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eProtocol Update

The UC Berkeley Office for Animal Care and Use (OACU) and the Animal Care and Use Committee (ACUC) began transitioning from a paper-based protocol submission and review process to a web-based system called *Berkeley eProtocol* in August 2014.

How does this impact you?

- All new protocols must be submitted online via eProtocol.
 - See the [ACUC web site](#) for submission deadlines.
- Protocols due for their *de novo* (three-year) review must be submitted online via eProtocol.
- Revisions to existing "electronic" protocols ("eProtocols") will be made using the eProtocol system.
- Annual reviews and revisions to existing "paper" protocols can continue to use the paper-based process up until the protocol's *de novo* submission.
- Investigators may opt to submit a revision as a new electronic eProtocol and they are strongly encouraged to contact the OACU Director at acuc@berkeley.edu regarding this possibility.

Where can I get help with eProtocol?

- **Start early!** Please plan on spending more time preparing your protocol in eProtocol than you have in the past.
- Make an appointment to meet with a member of the OACU staff as you begin to prepare your new eProtocol.
- There are several user "quick guides" available on the ACUC web site, http://www.acuc.berkeley.edu/eprotocol_guides.html.
- Contact the OACU office at 642-3885 or ACUC@berkeley.edu.

AAALAC Site Visit Planned for Fall 2015

The Association for Assessment and Accreditation for Laboratory Animal Care (AAALAC), International will be conducting a review of the UC Berkeley animal care and use program this year, which will include a **site visit this fall**. ACUC, OACU and OLAC will be working closely with investigators during the course of the year to prepare for a successful visit. For further guidance, please see the "[How to Prepare for an AAALAC Site Visit](#)" [Self-assessment Checklist](#) on the ACUC website. For questions, please contact the OACU at 642-8855 or acuc@berkeley.edu.

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- 1 Chair's Message
- 2 eProtocol Update
- 3 AAALAC Site Visit Planned for Fall 2015
- 4 Post Approval Monitoring Program
- 5 NIOSH Updates Hazardous Drug List
- 6 Increased Frequency of DMR, Administrative Submission Deadlines
- 7 New ACUC Policies & Procedures on Protocol Review
- 8 OLAC Update: Changes in Sentinel Testing Program

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Post-Approval Monitoring

The OACU will begin conducting post-approval monitoring (PAM) reviews this year on approved protocols. We will begin contacting labs as early as January to schedule times to meet and observe procedures and lab documents. Post-approval monitoring of approved Animal Use Protocols (AUPs) is done to ensure that research and teaching activities involving live vertebrate animals are conducted in accordance with all applicable federal law, regulations, policies, and are consistent with the Principal Investigator's (PI) ACUC-approved AUP. This monitoring is necessary to ensure: 1) animal welfare; 2) institutional regulatory compliance; 3) compliance of animal procedures with approved ACUC protocols; 4) proactive self-regulation by researchers; and 5) transparency with improved communication between the ACUC, OLAC, OACU and researchers. It also provides an opportunity to meet with personnel actively engaged in animal research to discuss concerns and/or changes needed in active projects.

NIOSH Updates Hazardous Drugs List

In 2014, the National Institute for Occupational Safety and Health (NIOSH) published an updated list of hazardous drugs identified as antineoplastic agents, carcinogens, teratogens, and reproductive toxins, available at http://www.cdc.gov/niosh/docs/2014-138/pdfs/2014-138_v3.pdf. The list includes numerous drugs used in animal research, such as chloramphenicol, choriogonadotropin, colchicine, cyclosporine, diethylstilbestrol, estrogen/progesterone combinations, fluorouracil, streptozocin, oxytocin, tamoxifen, and uracil mustard. Appropriate engineering controls and work practices must be in place to minimize potential exposure for researchers handling these drugs and should be documented in a SOP. Additionally, cage cards must be labeled to alert animal care staff and special procedures for cage changing and collection of potential-contaminated bedding may be required. For templates or assistance please contact Sara Souza of EH&S at sarasouza@berkeley.edu.

Increased Frequency of DMR, Administrative Submission Deadlines

In an effort to speed along the review of revisions that qualify for Administrative or Designated Member Review, the OACU is now processing protocol submission weekly instead of every other week. Submission will be processed every Monday (or Tuesday, in cases of holidays). The new submission deadline calendar can be found on the ACUC website: <http://www.acuc.berkeley.edu/calendar.html>. Submissions that must go to full committee review (FCR) will continue to be processed monthly.

ACUC Policies and Procedures on Protocol Review

INSIDE THIS ISSUE

- 1 Chair's Message
- 2 eProtocol Update
- 3 AAALAC Site Visit Planned for Fall 2015
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- 5 NIOSH Updates Hazardous Drug List
- 6 Increased Frequency of DMR, Administrative Submission Deadlines
- 7 New ACUC Policies & Procedures on Protocol Review
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In August 2014, The Office for Laboratory Animal Welfare (OLAW) issued guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) on significant changes to animal activities. To support of the use of performance standards, the professional judgment of laboratory animal veterinarians, and to reduce regulatory burden, IACUC-reviewed and -approved policies may now allow for the administrative handling of some significant changes. The ACUC recently revised its [Policy and Procedures on Protocol Review](#) to reflect this guidance. In addition to the revised Policy, we have also posted [Guidance on Administrative Review, ACUC - DMR/FCR Review](#) which outlines the criteria used for determining the review path, including examples of common revisions/amendments.

Administrative Review with Veterinary Verification & Consultation (VVC):

Some significant changes to an approved protocol may be handled administratively by OACU staff in consultation with an OLAC veterinarian if they meet the criteria described below. The OLAC veterinarian is the subject matter expert who verifies that the proposed significant change meets the ACUC policy for Administrative Review with VVC and does not require committee review.

Significant changes eligible for administrative review with VVC include:

- Changes to compounds or dosage of experimental substances, if they are fundamentally similar compounds documented in the literature regarding safety and toxicity in the same species.
- Changes to compounds or dosage of anesthesia, analgesia, or sedation that are consistent with UCB IACUC guidelines.
- Changing euthanasia method to any method approved in the AVMA guidelines (including UCB IACUC euthanasia guidelines).
- A greater than (>) 10% increase in the originally approved number of animals of any one species.

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In summary, the following review procedures are used based on the criteria outlined in the ACUC Policy and Procedures on Protocol Review:

- **New or *de novo* submissions** are always reviewed at a convened meeting by a quorum of ACUC members, i.e., Full Committee Review (FCR).
- **Changes/Amendments**
 - If **significant**, are reviewed by either:
 - FCR, or
 - Administrative Review with VVC
 - If **minor**, are reviewed by either:
 - Designated Member Review (DMR), or
 - Administrative Review

Please note: an amendment can only go through the VVC review process if *all* aspects of the changes qualify as described above. For complete details on ACUC procedures for protocol review, please refer to the [Policy](#). For questions, please contact the OACU at acuc@berkeley.edu or 642-3884.

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- 8 OLAC Update: Changes in Sentinel Testing Program

OLAC Update: Changes in Sentinel Testing Program

Due to recent advancements in serology testing, we are now able to perform pathogen testing with as little as a drop of blood. In some cases, this allows direct testing of animals whose health status is in question; thus allowing a reduction in the number of sentinel animals needed while improving testing sensitivity. Additionally, this advancement allows reduction in the time incoming animals spend in quarantine to as little as 3-5 weeks. For more information, please see the [IDEXX Research Web Site](#). For questions, please contact OLAC veterinary staff at 642-9232.

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