



# Berkeley Animal Care News

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Animal Care and Use Committee (ACUC)  
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## INSIDE THIS ISSUE

- 1 Special eProtocol Edition
- 2 ACUC/OACU Launches eProtocol
- 3 MAUP Conversion to AUP(s)
- 4 Points to Consider
- 5 eProtocol Roll out Plans

## RESOURCES

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

## Special eProtocol Edition

This fall, the ACUC will launch a three-year program to implement the web-based protocol management system, eProtocol. This is the same system that has been in use by the UCB Office for Protection of Human Subjects (OPHS) since 2009 and is currently in use at multiple other academic institutions such as the University of Texas (Austin), Colorado State University, Harvard University, and Stanford University. In short, the system is known to be an efficient way of handling research compliance protocols. Some of the benefits of the eProtocol system include:

- “One-stop shopping” for investigators submitting human and animal research protocols (one PI dashboard to navigate from).
- PIs can designate up to two other people to have “editing” & “submitting” access to protocols. All other team members will have ready access to the protocol through the “view only” option.
- Automatic email reminders notify the PI, Lab Contact and third designated individual on a protocol of annual renewals and three-year *de novo* submissions due dates, acknowledge receipt of submissions, announce review comments from the ACUC/OACU, and to report when a protocol has been approved.
- PIs can “clone” (i.e., copy) protocols and cut and paste from a Word document when writing/developing new protocol submissions.
- Secure, worldwide access (where the internet is available) for PIs to edit and to submit protocols.
- No version control issues because documents (animal use protocols, review questions, attachments) reside within the web-based system.
- After initial change to eProtocol, amendments, annual reviews and subsequent *de novo* submissions will be greatly simplified and the approval process should be faster.
- More effective assurance of compliance, particularly for USDA-regulated species.

We realize that the process of converting to eProtocol will require some additional initial effort on the part of PIs. The ACUC and OACU will work closely with all PIs over the next three years to facilitate the transition to the new system. Additional details regarding this process are included in this newsletter.

Sincerely,

Bill Sha  
ACUC Chair

Eileen Lacey  
ACUC Vice Chair

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## ACUC/OACU Launches eProtocol

The UC Berkeley Office for Animal Care and Use (OACU) and the Animal Care and Use Committee (ACUC) are transitioning from a paper-based protocol submission and review process to a web-based system called **Berkeley eProtocol** beginning in July 2014. This is the same system that has been in use by the UCB Office for Protection of Human Subjects (OPHS) since 2009. Within eProtocol, the two different protocol systems are designated as eProtocol IACUC (animals) and eProtocol IRB (human subjects).

### How will this impact you?

- Effective July 1, 2014, all new protocols must be submitted online via eProtocol.
  - eProtocol will be available for submissions starting July 31, 2014.
  - New submissions received prior to August 25, 2014, will be reviewed at the October 8<sup>th</sup> ACUC meeting. See the [ACUC web site](#) for submission deadlines.
- Protocols due for their *de novo* (three-year) review in October 2014 and after **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 until the protocol’s *de novo* submission and conversion to eProtocol.
- Investigators may opt to submit a revision as a new protocol in eProtocol before their *de novo* transition date, and they are strongly encouraged to contact the OACU Director at [acuc@berkeley.edu](mailto:acuc@berkeley.edu) regarding this possibility.

If you have any questions regarding eProtocol, please contact the OACU office at 642-3885.

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## MAUP Conversion to AUP(s)

As part of the transition to eProtocol, the campus will be transitioning from a model based on one research MAUP per PI to a model based on one or more AUP's, with the exact number of protocols per PI determined by the nature of the research covered. For example, given the differences between Public Health Service policy and the Animal Welfare Act (AWA), research projects using AWA-covered species (e.g., NHP, hamsters, guinea pigs, rabbits, wildlife, etc.) must have their own individual protocol (AUP).

The majority of UCB's animal research protocols do not use regulated species. For these protocols, we are recommending that MAUPs be divided up so as to be consistent with your research aims and/or projects as you've described them. Based on our (ACUC Chair, AV, OACU Director & staff) review of your current MAUP, we will be recommending the number of AUPs that we think you should have. If, based on scientific justification, you feel that more or fewer AUPs is appropriate, please contact the OACU Director, Dr. Becky Armstrong, at 642-8855 to discuss your concerns.

## Points to Consider

While the ACUC cannot "extend" your *de novo* approval period, we will work with you during this transition period to make your *de novo* due date(s) as convenient as possible. Some things you may wish to consider as we move forward include:

- What is your major agency grant submission cycle and how does that impact your renewal/expiration dates?
- Do you want all of your protocols to come up for renewal in one year? One month? Or to be more staggered?
- For teaching protocols, ideally these should be reviewed & approved at least 2 months prior to the semester in which the course is taught.
- Do you have students or post docs pursuing different research aims than you? Perhaps "your work" should be under one protocol and all other lab members under one or more different protocols.
- Do you do field work in very different parts of the world? With different species, techniques and procedures? Maybe you should have multiple protocols to cover these differences.
- Perhaps you are no longer pursuing a particular aim or no longer actively using a certain species of animal - this is the ideal time to streamline your protocol and research activity records.
- Would you like to transition to eProtocol sooner than your *de novo* expiration date? We would be happy to help you do that!

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## eProtocol Rollout Plans

We want to encourage PIs who will end up with more than one AUP - especially those impacted in years 2 & 3 of this rollout - to think ahead and to use this transition to make adjustments to the timing of their protocol reviews that work to their advantage. Below is the approximate timetable OACU is using to provide advance notice to PIs. Please note: AUP submission dates will remain as posted on our website:

<http://acuc.berkeley.edu/calendar.html>.

- MAUPs are grouped together for notification and implementation purposes as follows:
  - Group 1 = OCT & NOV 2014 *de novos*
  - Group 2 = JAN-JUNE 2015 *de novos*
  - Group 3 = AUG-NOV 2015 *de novos*
  - Group 4 = JAN-JUNE 2016 *de novos*, etc. through SEPT 2017
- Groups of PIs will be notified about 4 months in advance of their group undergoing the eProtocol transition.
- In addition to the usual OACU expiration notices, you will receive emails with more detailed information about the transition (MAUP to AUP) from Dr. Becky Armstrong, the Director of OACU.
- OACU staff would like to meet with you or your designated administrator early in the process of your entering your AUP into eProtocol so we may answer questions, trouble-shoot, and facilitate this transition.
- OACU staff will be available by phone and email to answer questions as needed. Ms. Jennifer Lee, OACU Assistant Director, is the eProtocol Project Manager.

We wish to thank you in advance for your patience and cooperation while working with us to rollout eProtocol for animal research and teaching at UC Berkeley. Our goal during this process is to minimize the impact on your research or teaching programs while ensuring compliance. Please call if you any questions.

Sincerely,

Becky Armstrong, DVM, PhD  
Director, OACU

Jennifer M. Lee  
Assistant Director, OACU