

PHS funds may not be used in support of unauthorized activities².

The PHS *Policy* stipulates that only the IACUC may approve activities involving animals but does not dictate which administrative actions may or may not be taken after approval has lapsed³. Actions taken by the IACUC Chair or the committee should be consistent with the institution's approved Assurance and internal policies. One wonders whether the Chair was authorized by the Assurance or internal policies to take these actions. This potential concern is supported by the facts that the mice were not euthanized when Linder failed to meet the second deadline and that Covelli did not involve the IACUC until fairly late in the process.

The committee members' decision was to euthanize the animals if other investigators could not use them. Unfortunately, this decision may result in additional animals being used if Linder later decides to seek approval to resume her project. In keeping

with the spirit of the principle of reduction, the decision to euthanize animals should be made with due diligence.

In general, Great Eastern University's IACUC has acted in accordance with NIH and OLAW policy, but the IACUC Chair may have exceeded his authority. Most Great Eastern University investigators seem to be adequately informed about the policy on protocol expiration, because they do not appear to readily support Linder's position. To avoid this situation in the future, the IACUC should first re-examine its procedure for handling protocols that are approaching expiration to ensure that PIs are given adequate notice and response time to continue IACUC approval. Next, the IACUC should refine its policy for handling a lapse in protocol approval in order to specify the maximum amount of time that animals may remain on the holding protocol; the justification needed to keep animals on the holding protocol beyond the specified time period; and

those actions that are delegated to the Chair versus those that require majority vote of a quorum. Finally, the IACUC should amend its Assurance as needed and publicize the revised policy among investigators.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals — Frequently Asked Questions*. Protocol Review, Question D-2. (US Department of Health and Human Services, Washington, DC, 2006; revised 2010). <<http://grants.nih.gov/grants/olaw/faqs.htm#d2>>
2. National Institute of Health Office of Policy for Extramural Research Administration. *Transcript of OLAW Online IACUC Staff Seminar: When Terms and Conditions Are Not Met*. 4 December 2008. <http://grants.nih.gov/grants/olaw/081204_seminar_transcript.pdf>
3. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals — Frequently Asked Questions*. IACUC Composition, Functions and Authority, Question B-10. (US Department of Health and Human Services, Washington, DC, 2006; revised 2010). <<http://grants.nih.gov/grants/olaw/faqs.htm#b10>>

Richerson is the Assistant Chief Veterinary Medical Officer with the Department of Veterans Affairs Office of Research and Development in Nashville, TN.

A word from OLAW

In response to the issues raised in this scenario, the Office of Laboratory Animal Welfare (OLAW) offers the following clarification and guidance:

OLAW has previously commented on a similar situation concerning administrative extension of an expired animal study protocol¹. For animal activities funded by the Public Health Service (PHS), the PHS *Policy on Humane Care and Use of Laboratory Animals (Policy; section IV.C.5.)* states that "the IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this *Policy* at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1.-4. at least once every three years"². In order to extend the project, the IACUC must carry out a complete review and approve the protocol either at a full committee meeting or by designated member review². If a protocol expires, all animal activities conducted under that protocol must cease. Continuation of animal activities in the absence of a valid approval is a serious violation of both the PHS *Policy* and the terms and conditions of the grant³. These violations must be reported to OLAW and the funding component³. If the project is PHS-supported, funds may not be drawn from the grant for any animal activities during the expired period⁴.

If an approved research protocol expires and animals are held under a holding protocol under which no research work is done, then reporting is not required. Use of a holding protocol, though permissible, should be viewed as an emergency stopgap and should not be a regular practice. Institutions should have policies and procedures in place to ensure that protocols are reviewed in a timely fashion. By allowing the investigator to keep animals on a holding protocol for an extended period of time without a compelling reason, Great Eastern University's IACUC is encouraging disregard for its authority and oversight of the animal care and use program. The IACUC needs to carry out a comprehensive review of its policies and procedures and to communicate them clearly to all investigators.

1. Brown, P.A. A word from OLAW. *Lab Anim. (NY)* **36**, 14 (2007).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. Office of Laboratory Animal Welfare. Guidance on Prompt Reporting to OLAW. NOT OD-05-034. (National Institutes of Health, Washington, DC; 24 February 2005; updated 15 April 2010). <<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>>
4. Office of Laboratory Animal Welfare. Guidance Addressing the NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are Not Upheld. NOT OD-07-044. (National Institutes of Health, Washington, DC; 26 January 2007; updated 15 April 2010). <<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-044.html>>

Patricia Brown, VMD, MS, DAACLAM

*Director
OLAW, OER, OD, NIH, HHS*