

The IACUC should have instituted policies outlining an exact set of procedures for expired protocols. These should include the following: (i) written notification to the PI that he or she cannot use animals until a protocol is approved and that if the renewal is not received within 30 days of the protocol expiring, the animals will be euthanized or transferred; (ii) a definite time period during which animals can be housed on a holding protocol; (iii) notification to the IACUC that the PI's protocol has expired; (iv) post-expiration reminders to the PI to submit a renewal protocol; (v) a procedure for transferring animals from a research protocol to the holding protocol; (vi) a way to ensure the animals are not used experimentally; and (vii) a procedure to inform the Grants Office upon expiration of the PI's protocol.

It is important to develop programmatic ways of addressing IACUC issues that promote consistency, efficiency and compliance with federal, state and institutional regulations. In order to have a quality animal care program that functions smoothly, the institution must spend time completing this kind of 'foundational' work. It may be difficult, in the fray, to find time to improve the program when it seems barely possible to keep up with it, but to end the cycle of 'barely keeping up', programmatic measures must be taken.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
2. Animal Welfare Act Regulations, 9 CFR (Chapter 1).

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RESPONSE

Three strikes; PI's out!

Matthew Panarella, DVM

I think a baseball analogy perfectly describes the clear lack of responsibility on the part of the principal investigator (PI) Linder. The IACUC, as reported, gave her three chances to respond to notices that

her protocol was nearing expiration. As PI, Linder is solely responsible for making sure that she is compliant with all regulations. Unfortunately for IACUC Chair Covelli, the 'pain' does not end here.

Because Linder did not respond promptly to the IACUC notification, her protocol is no longer approved. If her research is federally funded, then her non-compliance must be reported to the Office of Laboratory Animal Welfare (OLAW) in accordance with the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (section IV.F.3)¹. In addition, Covelli is incorrect in calling the protocol a holding protocol with the IACUC as PI. This is not an acceptable interim solution. An individual (possibly the facility director or veterinarian) can submit a new protocol to maintain the animals until a decision can be made about Linder's animals, in the hope of salvaging the mice as part of the research study.

Covelli acted ethically but not swiftly enough. He should have brought the issue to the IACUC immediately after the protocol expired to address the non-response by the PI and the possible reassignment of the mice to another individual PI. I also think that Covelli should be in contact with the Institutional Official (IO), as Great Eastern now needs to contact OLAW and the funding agency. Linder has shown disregard for the IACUC, the institution and the animals themselves. She was given ample opportunity to submit a revised protocol; by ignoring the IACUC, she has created a completely unnecessary and avoidable situation. The IO should be concerned about Linder's commitment to ethical research, compliance training and responsibility to the university and granting agency. The probable euthanasia of the mice (loss of precious research resource) should be a large motivator for Linder; she, Covelli and the IO should meet to discuss a solution.

Research is a collaborative process that includes the PI, the IACUC, the animals and all the staff caring for them. All participants, especially the PI in this case, must accept responsibility and act ethically, or the process may break down. One could argue that IACUC did not do enough to notify the PI (possibly a phone call was warranted in addition to the three notices, warning Linder of the consequences of her inaction), but PIs must be held

responsible for their obligations. Maybe for the future, Covelli, the IACUC and the IO could include training for PIs to inform them that non-compliance can have negative consequences for the animals, the university and the people involved.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).

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RESPONSE

IACUC acted appropriately, but...

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The Great Eastern University IACUC seems to have an established procedure for addressing expiring protocols, which is consistent with policies of the National Institutes of Health (NIH) and Office of Laboratory Animal Welfare (OLAW). OLAW guidance states unequivocally that IACUCs do not have the authority to administratively extend approval beyond 3 years¹. The IACUC sent Linder three notices of pending protocol expiration, but it is unclear how much advance notice she actually received. Submitting and obtaining approval of a renewal protocol well in advance is essential, because a protocol expires even if it is under review by the IACUC on the expiration date².

Linder's statement that "[w]e're only talking about a week, maybe less, and you're making me jump through bureaucratic hoops and stop funded research?" suggests that her grant period may be ending very soon. Consequently, she doesn't see the need to renew her protocol. Nonetheless, NIH and OLAW policy is clear: "continuation of animal activities in the absence of valid approval is a serious and reportable violation of PHS [Public Health Service] Policy [*Policy on Humane Care and Use of Laboratory Animals*]"¹. Therefore, Covelli, the IACUC Chair, is correct to state the IACUC must ensure that research manipulations stop and to point out that