

directly to the granting NIH institute or center, as well as to the OLAW⁴. In this situation, the NIH has the authority to request itemized documentation of the charges no longer allowed due to expiration of the protocol⁴.

As a part of routine processing, GEU has labeled the protocol with the same number with the suffix 'H' added. This numbering system may lead to confusion as to whether or not the protocol allows procedures approved in the original

protocol. This point must be clarified to prevent additional non-compliance.

Given that the GEU IACUC would serve as the PI on the holding protocol, there are concerns related to conflict of interest in the review and approval process. Both the PHS *Policy on Humane Care and Use of Laboratory Animals* and the Animal Welfare Act and Regulations clearly indicate that no IACUC member may be involved in IACUC review or approval of a protocol for which there is a conflicting interest^{1,2}.

Responsibilities for the method of payment, provision of veterinary recommendations and euthanasia of animals would all need to be addressed before animals could be transferred to the holding protocol. In addition, the potential length of time that the animals could remain on the IACUC holding protocol should be clarified. Under the GEU IACUC's current practice, USDA-covered species could be maintained up to one year and other species up to three years; this seems an unreasonable amount

A word from OLAW and USDA

In response to the questions posed in this scenario, the Office of Laboratory Animal Welfare (OLAW) and the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) offer the following clarification and guidance:

In the described scenario, the PI's approved research protocol expired and a period of time passed before the animals were transferred to an approved holding protocol. APHIS and OLAW consider the intervening period as a lapse in IACUC approval. It is very important for IACUCs to have policies and procedures that prevent such lapses.

When IACUC approval expires, the research protocol is no longer valid. Continuation of research activities beyond the protocol expiration is a violation of both the Animal Welfare Regulations (AWRs)¹ and the PHS *Policy on Humane Care and Use of Laboratory Animals* (PHS *Policy*)². This noncompliance with PHS *Policy* must be promptly reported to OLAW³. Additionally, the Office of Management and Budget Cost Principles and the NIH Grants Policy Statement do not permit charges to grant awards for the conduct of animal activities after IACUC approval has lapsed; such charges are a violation of the terms and conditions of the grant award and must be reported to the NIH Institute or Center supporting the award⁴. (NIH expects grantees to continue to maintain and care for animals. NIH funding components may allow expenditure of grant funds for such maintenance and care on a case-by-case basis⁴.)

Specifically, in this scenario, the IACUC should develop a practice for handling protocols due for annual or triennial review prior to the expiration of the protocol.

IACUCs are empowered with the flexibility to develop methods that meet the needs of the institution. One option the IACUC could consider is to place the animals on an approved holding protocol prior to the expiration of the research protocol. Local institutional procedures may require the use of a holding protocol to ensure that the appropriate funding source is charged for maintaining the animals. Alternatively, the IACUC could choose to maintain the animals using IACUC-approved standard operating procedures (SOPs) for housing and routine animal care. Although the AWRs and the PHS *Policy* do not require holding protocols or SOPs, both options are permitted and are acceptable to APHIS and OLAW.

Additionally in the described scenario, the PI of the Great Eastern animal holding protocol is the entire IACUC, making it unclear who is responsible for the animals. APHIS and OLAW concur that the practice of appointing the entire IACUC as PI is not recommended. The *Guide for the Care and Use of Laboratory Animals* describes the PI as the individual "who has precise knowledge of both the objectives of the study and the proposed model"⁵. Should an institution choose to maintain the animals under a holding protocol, the PI position would be best served by an individual who takes responsibility for the animals, such as a veterinarian or animal facility manager, rather than the entire IACUC. Similarly, an SOP for holding animals should designate an individual with primary responsibility for the animals.

1. Code of Federal Regulations, Title 9, Chapter 1, Part 2, Subpart C, §2.31(c)(6)(7).
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). <<http://grants.nih.gov/grants/olaw/references/phspol.htm>>
3. Office of Laboratory Animal Welfare. Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals. Notice 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. Notice NOT-OD-07-044. (National Institutes of Health, Washington, DC, 26 January 2007) <<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-044.html>>
5. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. 27 (National Academies Press, Washington, DC, 2011).

**Patricia Brown, VMD, MS,
DACLAM**
Director
OLAW, OER, OD, NIH, HHS

**Chester Gipson,
DVM**
Deputy Administrator
USDA, APHIS, AC