

**RESPONSE**

**A waste of time**

**M. Babette Fontenot, DVM, PhD, DACLAM & Dana L. Hasselschwert, MS, MS, DVM, DACLAM**

Dr. Romansky’s protocol essentially expired, and therefore, in the eyes of the IACUC, the study came to an end. By setting a historic precedent allowing Romansky to continue activities after his protocol has expired, Great Eastern University has failed to comply with federal regulations. According to federal regulations<sup>1</sup>, Ms. Gates was working under the correct assumption and acted appropriately when she notified Dr. Romansky to cease and desist pending renewal of the expired protocol. Furthermore, while Ms. Gates’s letter to Romansky on behalf of the IACUC interrupted the unapproved activities, it does not constitute an official suspension of activities as defined in the Animal Welfare Regulations<sup>2</sup>, which requires a review and decision by a quorum of the IACUC. The protocol simply expired.

While there is no federal regulation that prevents Romansky from requesting to add research animals that were assigned to the expired protocol to an approved one, the IACUC must determine whether or not Romansky’s request constitutes a minor or major amendment to the protocol. Major changes typically include an increase in the number of animals or number of studies or treatment groups. If there is no increase in the number of animals used or procedures performed on each animal, and there is no change in the objectives of the proposed study, then Romansky’s request may be considered a minor change by the IACUC. However, the additional treatment group may very well change the objectives of the study, and therefore will likely be considered a major change. This amendment will require review and approval by the IACUC prior to implementation<sup>3</sup>. The criteria for categorizing a change to activities proposed to an approved protocol must be delineated in the PHS Assurance for Great Eastern University, and should be in place prior to any further consideration of Romansky’s request.

**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:*

This scenario raises a number of issues. Can the IACUC administratively extend approval of a project that has expired? No<sup>1</sup>. For animal activities funded by the Public Health Service (PHS), the PHS Policy on Humane Care and Use of Laboratory Animals 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”<sup>2</sup>. In order to extend the project, the IACUC must conduct a complete review and approve the protocol either at a full committee meeting or by designated member review<sup>2</sup>. If a protocol is allowed to expire, 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 grant<sup>3</sup>. These violations must be reported to OLAW and the funding component<sup>3</sup>. If the project is PHS-supported, funds may not be drawn from the grant for animal activities during the expired period<sup>4</sup>.

Should the IACUC consider the transfer of animals from one project to another as a significant change? This is a more complex question with implications in several areas. The IACUC has some latitude in defining what it considers a significant change, or it can establish a mechanism for determining significance on a case-by-case basis<sup>5</sup>. Significant changes require IACUC approval by either (1) full-committee review by a convened quorum of the IACUC or (2) designated member review by one or more members in accordance with the Policy at IV.C.2. and as previously clarified by OLAW<sup>5</sup>. The IACUC must clearly define its policy and mechanism for determining significance and communicate this to its investigators.

In the scenario described, it is clear that the investigator’s proposal to ‘amend’ an ongoing protocol to accommodate work described in an expired protocol represents a change in the approved objectives of the ongoing study that would require IACUC review<sup>6</sup>. It is also clear that the reason for the investigator’s proposal, including the transfer of mice, has no scientific basis and is actually based on his failure to submit a request for protocol renewal to the IACUC in a timely manner. OLAW expects IACUCs to adhere to the letter and spirit of provisions of the PHS Policy and Animal Welfare Act regulations and recommends that they refuse to consider disingenuous proposals such as the one described. The IACUC has set a precedent for flouting federal regulations by allowing investigators to have additional time before suspending animal activities on an expired protocol. The IACUC needs to conduct a comprehensive review of its practices and revise its policies and procedures so that it is conducting business in accordance with federal requirements.

1. Frequently Asked Questions, Protocol Review, Question No. 2. [http://grants.nih.gov/grants/olaw/faqs.htm#proto\\_2](http://grants.nih.gov/grants/olaw/faqs.htm#proto_2).
2. Public Health Service Policy on Humane Care and Use of Laboratory Animals, Amended August, 2002. <http://grants.nih.gov/grants/olaw/references/phspol.htm>.
3. NOT OD-05-034, Guidance on Prompt Reporting to OLAW. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>.
4. NOT OD-07-044, Guidance Addressing the NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are not Upheld. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-044.html>.
5. Frequently Asked Questions, Protocol Review, Question No. 3. [http://grants.nih.gov/grants/olaw/faqs.htm#proto\\_3](http://grants.nih.gov/grants/olaw/faqs.htm#proto_3).
6. Frequently Asked Questions, Protocol Review, Question No. 9. [http://grants.nih.gov/grants/olaw/faqs.htm#proto\\_9](http://grants.nih.gov/grants/olaw/faqs.htm#proto_9).

**Patricia Brown, VMD, MS, DACLAM**

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

Provided he can supply adequate justification for the change in objectives, requiring an additional treatment group, while not illegal, may be considered unethical. Considering the ethical nature of Romansky's request, it appears to be one of convenience. The IACUC must determine that the changes in objectives are justified in the review process. Given the necessity of an IACUC review process, whether he submits his renewal or submits an amendment to an existing protocol, he has not saved time. Romansky has actually delayed the process by fighting the system in the first place. Covelli should advise Dr. Romansky of these facts and encourage him to comply, thus shortening the amount of time that the study is halted. Importantly, Dr. Romansky must be reminded that changes to existing protocols or renewal of expired protocols must be approved prior to implementation or the study will be suspended, and the suspension will be reported to regulatory and governmental funding agencies<sup>4</sup>.

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1. 9 CFR, 2.31 (d) 5.
  2. 9 CFR, 2.31 (d) 7.
  3. 9 CFR, 2.31 (c) 7.
  4. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* IV.C.1.b. (US Department of Health and Human Services, Washington, DC, 1986; reprinted 2002).

*Fontenot is Head of Division of Behavioral Sciences and IACUC Veterinarian and Hasselschwert is Head of Division of Veterinary Sciences and IACUC Chair, University of Louisiana at Lafayette-New Iberia Research Center, New Iberia, LA.*