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Communication between collaborating IACUCs

Trying to be a good neighbor can, at times, be trying. New Antigen Inc. was a small biotechnology company located near Great Eastern University. The company leased animal facility space from the school, submitted protocols for review and approval by the school's IACUC and then carried out its research at the school. However, New Antigen also had its own IACUC because the company had a small business grant from the US Public Health Service (PHS) that required euthanizing animals at New Antigen, not at Great Eastern. For that grant, Great Eastern ordered the animals and housed them at the school. When New Antigen was ready for the animals, they would be transported to New Antigen by New Antigen employees, where they would be immediately euthanized for a tissue harvest. The transport process and

euthanasia were approved by the Great Eastern and New Antigen IACUCs.

During a Great Eastern IACUC semiannual inspection, an inspector casually asked whether the IACUC had approved the transport of the mice he had just seen being taken to New Antigen. He was told that no, the New Antigen animals being used on the PHS grant were rats, not mice, and they were not being moved that day. The mice he had seen were part of a different New Antigen study and should never have left Great Eastern. A quick phone call to New Antigen revealed that the Great Eastern IACUC had approved the mouse study, that all of the work was to be done at Great Eastern and that the mice were being taken to New Antigen for euthanasia. "But you don't have authorization from the IACUC to move those animals," said Thai Morris, a Great

Eastern animal facility supervisor. "Yes, we do," was the response from New Antigen. "The study is over. Moving the mice to New Antigen for euthanasia was approved by our IACUC after the study started."

We have a problem. The Great Eastern IACUC approved the entire study to be completed at the school. However, the New Antigen IACUC subsequently approved the transportation of the mice to its own premises where the animals would be euthanized. Both institutions and IACUCs were acting in good faith, but there was a breakdown in communications. Is the transportation and euthanasia of the mice at New Antigen a protocol violation? If it is, is it reportable to NIH/OLAW, and if so, which IACUC should make the report? How can future problems of this nature be prevented?

RESPONSE

Departure from approved procedures

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The Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy; section IV.C)¹ requires the IACUC of any institution where animal activities are carried out to assure that the approved research projects will be done in accordance with the Animal Welfare Act and Regulations (section 2.31)². The PHS Policy also requires research proposals to be consistent with the *Guide for the Care and Use of Laboratory Animals* (the *Guide*)³ unless a departure is justified and approved by the IACUC. The IACUC should also determine whether the research projects

conform to the institution's Assurance and meet various requirements, such as methods of euthanasia.

New Antigen Inc. has violated its agreement with Great Eastern University by not following the protocol approved by the Great Eastern IACUC, which indicated that the entire study would be done at Great Eastern University; this certainly would include disposition of the animals at the end of the study. New Antigen employees transported mice and used an external procedure location without the approval of the Great Eastern IACUC. Changing the disposition of animals at the protocol's conclusion constitutes a deviation from the approved protocol, regardless of any protocol approved by the New Antigen IACUC.

To determine whether this deviation is reportable to NIH/OLAW, I consulted the reporting requirements for OLAW under the PHS Policy (section IV.F.3.)¹.

The *Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals* (NOT-OD-05-034)⁴ includes both conduct of animal-related activities without appropriate IACUC review and approval and failure to adhere to IACUC-approved protocols as reportable situations. Therefore, I believe this deviation is reportable, although the situation is understandable and can be corrected. Because the deviation involved the Great Eastern University protocol, it is the responsibility of Great Eastern University's Institutional Official to report it to OLAW.

Preventing these types of communication errors related to the approved protocol between collaborating institutions can be challenging but it is certainly achievable. Both parties should understand and agree that the approved procedures outlined in the protocol