

appropriate scientific journal, that journal may require IACUC approval of the animal work. Also, Great Eastern oversight could serve as an indication of good science to MDL's customers; IACUC review provides an assessment of the animal work, which could suffice as peer review for scientific merit. In addition, seeking expert review of animal activities is evidence of good animal care, and such evidence could be useful in countering any negative attention from animal rights organizations. Finally, although MDL's animal use is not covered by specific US policies or regulations, it may be subject to the *International Guiding Principles for Biomedical Research Involving Animals*¹, which suggests that animal testing be approved by an ethical committee.

We think that Covelli has two choices. The first choice is to tell MDL to order and receive the animals itself, ending Great Eastern's involvement. The second choice is to continue the current situation with the additions of post-approval monitoring, a Memorandum of Understanding and, perhaps, inviting an MDL scientist to join the Great Eastern IACUC. We prefer the second choice, because even though MDL is not required by law or policy to have oversight of its animal use, it is the right thing to do.

1. Council for International Organizations of Medical Sciences. *International Guiding Principles for Biomedical Research Involving Animals* (Council For International Organizations of Medical Sciences, Geneva, Switzerland, 1985). <http://cioms.ch/publications/guidelines/1985_texts_of_guidelines.htm>

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RESPONSE

Clarify terms of agreement

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Assuming that Great Eastern University has a Public Health Service (PHS) Assurance and is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International, the university needs to abide by the *PHS Policy on Humane Care and*

*Use of Laboratory Animals*¹ (PHS Policy) and the *Guide for the Care and Use of Laboratory Animals*² (the *Guide*); the former requires "animal care committees at each entity which conducts biomedical and behavioral research"¹. Because the animals destined for MDL are ordered by and temporarily housed at Great Eastern University, Great Eastern is responsible for the oversight of these animals. Moreover, approval of the Great Eastern University IACUC is necessary for the current arrangement.

Great Eastern seems to treat MDL as a 'satellite' facility. Therefore, it was appropriate to have an IACUC-approved protocol for the procedures done at MDL and to include the facility in the semiannual IACUC inspections. However, Covelli's comments regarding the IACUC's oversight of the current situation suggest that Great Eastern may not be completing all required IACUC duties, including proper post-approval monitoring and adequate training. A formal written agreement between the collaborating institutions is necessary to define their respective responsibilities and ensure that MDL is following all federal laws and regulations.

Covelli's suggestion that Great Eastern order the animals and have them delivered directly to MDL is not a satisfactory solution. If the Great Eastern IACUC is trying to minimize its involvement with MDL, it should avoid all aspects of the arrangement. Because MDL does not receive federal funding or house any species covered by the USDA, the facility is not subject to the guidelines of the *PHS Policy*¹, the Animal Welfare Act and Regulations³ or the *Guide*². Consequently, if the current situation is altered so that all animals are ordered by and sent directly to MDL, without any connection to Great Eastern University, an IACUC protocol would not be necessary.

MDL should be able to obtain its own animals without substantially affecting its operations. Instead of having access to animals on an 'as needed' basis, as it does under the current arrangement with Great Eastern, MDL would need to plan about one week in advance to order its animals directly from a vendor. As there is currently no acclimation period to the new facility, having animals delivered directly to MDL should not present a problem.

The Great Eastern IACUC should thoroughly evaluate the situation when deciding whether to renew the protocol. The current arrangement may be a source of revenue for Great Eastern, and continuing it may preserve the neighborly relationship between the institutions. However, the Great Eastern IACUC must be certain that the relationship is clearly defined and that its post-approval monitoring is adequate.

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. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* (National Academies Press, Washington, DC, 1996).
3. Code of Federal Regulations. Title 9, Chapter 1, Subchapter A – Animal Welfare: Part 2 Regulations (§2.31).

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RESPONSE

Good neighbor or not?

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It seems that the working relationship between MDL and Great Eastern University has benefited both institutions. The scenario does not specify whether MDL pays Great Eastern for the mice or their care. I assume that Great Eastern owns the mice and has an Animal Welfare Assurance with the Public Health Service, but I cannot determine whether either facility is accredited by Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). Unfortunately, I also cannot evaluate the training and experience of the MDL personnel who carry out the animal procedures: are staff members aware of laboratory animal allergies and how to report any concerns regarding improper care or welfare of animals?

In the Spring 2003 edition of its newsletter *Connection*, AAALAC