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## Reviewing a ‘good neighbor’ policy

Mercurio Diagnostic Laboratory (MDL), a laboratory that carried out diagnostic tests on human and environmental samples, was located next to Great Eastern University. MDL was unaffiliated with the school and received no federal funding. The laboratory required laboratory mice for certain diagnostic tests. The mice were purchased for MDL by Great Eastern and housed at the school until they were needed. MDL had a protocol in place for the mice that was previously approved by the Great Eastern IACUC, but because the tests were acute (i.e., the animals were given an injection of a test substance and were euthanized or died soon afterwards), the mice used for testing were brought directly from the Great Eastern animal facility to MDL, where they were used within an hour of their arrival.

When the MDL protocol came up for renewal, Dr. Larry Covelli, the Great Eastern IACUC chair, wondered about the arrangement with the lab.

“What’s the big deal, Larry?” asked Betty Carruthers, the IACUC manager. “We’ve approved this protocol for years without any problems, so why are you concerned now?”

“I don’t know,” he responded, “it just seems like we’re playing with fire. We’re doing this to be good neighbors, but what if somebody at MDL violates the protocol? We would never know that. We would never know if they used the mice for a different test or never even used them and gave them to some kids for pets. We just don’t know.”

“I’m not sure about that,” said Carruthers. “We look at their records when we do the semiannual lab inspections, and they seem to do everything by the book. If they were trying to cheat on us, I don’t think they would be as open and cooperative as they are.”

“Maybe they don’t know any better,” said Covelli. “Maybe they just think they need an IACUC-approved protocol. Do you think it would be better if we just purchase

the animals when they need them and have them delivered directly to MDL by the vendor? That way, the mice wouldn’t ever be on campus and we wouldn’t have to review a protocol.”

“If you want to go that far,” Carruthers responded, “why not tell MDL to order the mice themselves directly from a mouse vendor? That way we don’t have to get involved at all.”

“Maybe you’re right,” said Covelli.

Covelli is becoming concerned that Great Eastern’s ‘good neighbor’ policy may not be so good for the school. Does MDL need IACUC approval from Great Eastern for its current arrangement with the school? Would it need an IACUC-approved protocol from Great Eastern if the school did as Covelli suggested, ordering the animals and having them delivered to MDL? What arrangement would you prefer to see between Great Eastern and MDL?

### RESPONSE

#### Two choices

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Covelli is concerned that the ongoing arrangement between Great Eastern and MDL is putting Great Eastern at risk for non-compliance. It is good practice for IACUCs to review previously accepted arrangements in light of increasing scrutiny from regulatory, accreditation and even animal rights organizations.

Although MDL is not required to have an IACUC-approved protocol, because it is not using a species of animal that is covered by the USDA or receiving government funding, it has enlisted the established oversight of the Great Eastern IACUC. As Covelli speculated, MDL may not understand that it does not

need a protocol; however, because MDL has negotiated the current arrangement with Great Eastern, we make the following assumptions. First, we assume that MDL needs Great Eastern because it does not have the resources to house mice for periods longer than their experiments. Second, we assume that MDL is paying Great Eastern to purchase, house and deliver the mice as well as to review the protocol, positioning Great Eastern as the owner of the mice. Third, we assume that Great Eastern has a Public Health Service (PHS) Animal Welfare Assurance Statement that covers all campus activities, such that even though MDL’s experiments are not federally funded, the mice are covered by Great Eastern’s Assurance.

The current arrangement does require an IACUC-approved protocol, but it is Great Eastern rather than MDL that needs the protocol, because of its PHS Assurance. The same principle would apply if Great

Eastern decided to order the mice and have them delivered directly to MDL, because Great Eastern would still be purchasing the animals.

If the current arrangement were to continue, Great Eastern could take certain actions to alleviate Covelli’s concerns. First, post-approval monitoring of MDL’s procedures could be instituted, including procedural observations as well as protocol discussions with MDL scientists to verify that the protocol is being followed as approved. Second, Great Eastern could invite an MDL scientist to become a member of its IACUC, allowing MDL to have a better awareness of IACUC concerns. Last, a Memorandum of Understanding could be written to specifically delineate the responsibilities of each institution.

We think that MDL is wise to seek Great Eastern oversight for several reasons. First, if MDL expects to publish its results in an