

Misunderstanding of an MOU?

Great Eastern University received an NIH-funded grant to perform a study with deer mice (*Peromyscus sp.*). Although most of the work would be performed at Great Eastern, the school contracted out a small component of the study to Little Eastern College. The Memorandum of Understanding (MOU) between the two institutions stated that both schools were responsible for reviewing and approving the protocol for the work to be approved at Little Eastern College.

As the study progressed at Little Eastern it became obvious that the ketamine/xylazine anesthetic being used was unsatisfactory and that isoflurane would be a better choice. The principal investigator (PI) at Little Eastern submitted a request to his IACUC office to change the anesthetic. The office had an IACUC-reviewed and

approved policy on anesthetic use for rodents; therefore, using the veterinary verification and consultation process (VVC), the PI's request was forwarded to the attending veterinarian at Little Eastern. The veterinarian verified that isoflurane at the dosage requested by the PI was within the boundaries of the IACUC's policy and would be an acceptable anesthetic for the study. The PI's request and the veterinarian's subsequent concurrence were documented in the IACUC's meeting minutes.

Some time later, at a routine USDA site inspection at Little Eastern College, the inspector read the IACUC minutes and the MOU between the two schools and saw that the anesthetic change was made without the concurrence of Great Eastern University. She asked why this happened,

as the MOU clearly stated that both schools had to review and approve the protocol. The explanation provided by Little Eastern was that the protocol was approved by both schools, but the anesthetic change was made by using VVC and there was nothing in the MOU stating that a VVC request had to be approved by both schools.

What is your opinion? Did the Little Eastern College's IACUC overstep its authority in one or more ways or was it compliant with the MOU? □

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The More ≠ the merrier

In this scenario, both institutions must have a properly constituted IACUC in order to approve research activities in accordance with the Animal Welfare Act and Regulations¹ and the Public Health Service Policy on Humane Care and Use of Laboratory Animals². We assumed that both institutions were registered with USDA APHIS and that both had Assurances with OLAW.

OLAW states that inter-institutional collaborations “have the potential to create ambiguities. Therefore it is imperative that institutions define their respective responsibilities³.” The *Guide for the Care and Use of Laboratory Animals* recommends that “the participating institutions... have a formal written understanding (e.g., a contract, memorandum of understanding, or agreement) that addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight⁴.” The formal written understanding between the two institutions in this scenario was a memorandum of understanding (MOU).

When Little Eastern College modified the protocol using the veterinary verification and consultation (VVC) process, it overstepped its authority with respect to the MOU. This is because, according to OLAW guidance, VVC is a review process for significant changes, though they are specific and may be handled administratively, with the veterinarian serving as a subject matter expert⁵, and

the MOU stated that both schools were responsible for reviewing and approving the protocol for the work to be performed at Little Eastern College. However, “OLAW and APHIS agree that review of a research project or evaluation of a program or facility by more than one recognized IACUC is not a federal requirement³.” Therefore, while Little Eastern College was incongruent with the MOU it established with Great Eastern University, no federal requirements or laws were violated.

The institutions may have been able to avoid this situation if the terms of their MOU had been different. “If both the awardee institution and the performance site institution have Domestic Assurances, they may exercise discretion in determining which IACUC reviews animal activities and under which institutional program the research will be performed. There is no requirement for dual review; IACUCs may choose which IACUC will review protocols for the animal activities being conducted,” according to OLAW guidance on inter-institutional collaboration³. Furthermore, “it is recommended that if an IACUC defers protocol review to another IACUC, documentation of the review should be maintained by both committees. Additionally, the IACUC conducting the review should notify the other IACUC of significant questions or issues raised during

a semiannual program inspection of a facility housing a research activity for which that IACUC bears some oversight responsibility³.”

We would advise both institutions to modify their MOU to delegate Little Eastern College as the IACUC responsible for reviewing protocols and animal activities at that institution, with the stipulation that Great Eastern University be provided a copy of all protocol documentation. Doing so would reduce regulatory burden as well as resolve such ambiguities as were observed by the USDA site inspector. □

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5. Office of Laboratory Animal Welfare, National Institutes of Health. Significant Changes to Animal Activities. <https://olaw.nih.gov/guidance/significant-changes.htm>