

VVC doesn't override MOU

Per the inter-institutional agreements, the requested change in anesthetic delivery and drug should have received approval by both colleges before a change

in ACUP (Animal Care and Use Protocol) procedure was made. Despite the fact that the veterinary verification and consultation (VVC) process was used for approval, the

memorandum of understanding (MOU) between the two colleges clearly states that both colleges must review and approve changes to the protocol.

Per the NIH NOT-OD-126, Significant Changes to Animal Activities Previously Approved by the IACUC, point 2.aA. "The specific significant changes described in 2.a-c, may be handled administratively according to IACUC-reviewed and approved policies with a veterinarian authorized by the IACUC.... This includes changes in: a. anesthesia, analgesia, sedation or experimental studies." The change in anesthetic delivery constitutes a significant change that is out of the scope of a VVC and not within the MOU between institutions.

As this is an NIH-funded study, appropriate external reporting of the incident should be determined by the institutions' IACUCs.

Additional considerations for the change from injectable anesthetic drug to inhalant gas anesthesia may include the need for updates and changes to an administrative appendices for the ACUP, occupational health and safety concerns and possible need for staff training. As the use of inhalant anesthetic gases by mask administration carries increased risk to those involved, additional consultation and/or enrollment of those in contact should include their enrollment in the institutions occupational health and safety program.

As there is ongoing collaboration of research studies being conducted by the two institutions, a method for flagging collaborative studies where an MOU exists should be developed or (if exists) reviewed to help prevent future recurrences. This oversight falls on the shoulders of the IACUC chair and/or administrator.

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A WORD FROM APHIS AND OLAW

In response to the issues posed in this scenario, the US Department of Agriculture- Animal and Plant Health Inspection Service (USDA-APHIS) and the National Institutes of Health- Office of Laboratory Animal Welfare (NIH-OLAW) provide the following clarifications:

In this scenario, two institutions are collaborating on research with deer mice under a Memorandum of Understanding (MOU). The MOU requires both Institutional Animal Care and Use Committees (IACUCs) to review and approve the protocol for the work. When a significant change is necessary, the IACUC where the work is conducted fails to inform the other institution's IACUC of the change made using veterinary verification and consultation (VVC).

USDA response

The review and approval of significant changes is an IACUC function^{1,2}. At least one IACUC that is party to the MOU must carry out the IACUC functions to meet the Animal Welfare Act regulatory requirements. Although USDA encourages research facilities that contract studies to determine and document which party is responsible for the functions of the IACUC, animal care and handling, and the reporting of animals on the Annual Report, there is no regulatory requirement that this occur. In the context of an animal welfare compliance inspection, USDA focuses on whether an IACUC carried out the necessary review and approval of the significant change as required by the regulations, not the division of

responsibilities described in the MOU. With that said, the implementation of the significant change by one IACUC without informing the other was not consistent with the MOU.

OLAW response

As noted by other reviewers, review of a research project by more than one recognized IACUC is not a federal requirement³. However, failing to inform the MOU partner of the significant change to the protocol is not in keeping with the MOU. OLAW does not consider the failure to follow the agreement in the MOU a reportable incident. Concerning the use of VVC in this scenario, if the IACUC's VVC policy allows changes in anesthetics which include inhalants and if the proper safety and training issues are considered, VVC is an acceptable option⁴.

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2. Title 9 Chapter 1 Subchapter A Section 2.31(e)(1-4).
3. Office of Laboratory Animal Welfare, National Institutes of Health. Frequently Asked Question D.8: PHS Policy on Humane Care and Use of Laboratory Animals. 2017. Found online at: <https://olaw.nih.gov/guidance/faqs#621>.
4. Office of Laboratory Animal Welfare, National Institutes of Health. Significant Changes to Animal Activities. 2018. Found online at: <https://olaw.nih.gov/guidance/significant-changes.htm>.

VVCs should be addressed in MOU

On its own accord, Little Eastern College appropriately applied the veterinary verification process (VVC) to change to a different anesthesia regimen that is supported in their approved IACUC

policy. OLAW and APHIS do not require that both institutions involved in the research perform an IACUC review of the project¹.

However, the Memorandum of Understanding (MOU) for this project states

that both schools must review and approve the protocol. Therefore, Little Eastern's decision to change the anesthetic protocol without notifying Great Eastern's IACUC of the action does not appear to align