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Who should decide when and how to contact OLAW?

The new vice-chair of the Great Eastern University IACUC was Dr. Misty Newland, a researcher with many years of laboratory and IACUC experience and who had a reputation for being a no nonsense administrator. Newland usually had very little to do as vice-chair because the committee chairman almost never missed an IACUC meeting. However, he missed the most recent meeting as he was away caring for an ailing family member. Newland chaired that meeting, during which there was a report concerning a research technician who intentionally did not administer the last scheduled dose of an analgesic to a rat. The technician had claimed that the animal was active, eating well, and showed no signs of pain from the placement two days earlier of a small intraperitoneal monitoring device. He saw no need to further stress the rat by giving it the final dose

of analgesia. All of the members present at the meeting considered this to be a deviation from the protocol but most felt that given the excellent condition of the rat, it likely had no significant impact on animal well-being and did not rise to the level of reporting it to the NIH's Office of Laboratory Animal Welfare (OLAW). The attending veterinarian said she could not be sure, but in her opinion the final dose would have been helpful yet not absolutely critical to the rat's well-being. Newland disagreed, but wanting to remain neutral, she said nothing. She called for a vote and the large majority of members voted that there would be sanctions (other than a suspension) and the incident was not to be reported.

Newland was convinced that not reporting the incident would be a regulatory violation, so she took the initiative, called OLAW, and reported what had happened to the rat.

When the regular chairman returned from his brief leave and found out what transpired, he turned on Newland, accusing her of betraying the committee's intent and violating the PHS Policy¹ because any such notification to OLAW requires the IACUC to do so through the Institutional Official. But Newland quickly replied that any person has a right to inform OLAW of a concern, even if that person is a member of the IACUC.

In your opinion, did the IACUC have the right to vote to withhold informing OLAW of the incident? Was Newland violating the PHS Policy by informing OLAW as she did? How would you have approached this situation?

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986, revised 2015).

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RESPONSE

Call me maybe

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OLAW's *Guidance on Prompt Reporting* states, "Institutions should use rational judgment in determining what situations meet the provisions of [PHS policy] IV.F.3,"¹ which outlines reporting criteria. Because of the impossibility of covering all scenarios, OLAW states that the institution, which we interpret as the IACUC in this case, should determine what is reported. Therefore, the IACUC does have the right to vote about whether to report this incident. However, the right to vote does not mean that the outcome of the vote is right. This is due to further statements in OLAW's *Guidance on Prompt Reporting* that list examples of reportable situations, including "failure to adhere to

IACUC-approved protocols" and "failure to monitor animals post-procedurally as necessary to ensure well-being."¹ We believe the withholding of post-procedural analgesics, contrary to what is described in the protocol, meets both of these criteria for reporting to OLAW.

In an effort to be succinct, we will not delve into the difficulty of sensitively identifying pain in rodents, but note that if the veterinarian and IACUC deemed a certain amount of analgesics necessary in the original protocol approval, the analgesic regimen must be followed. If researchers would like to change the analgesic regimen in the future, they should consult the veterinarian and amend their protocol.

We feel that it is clear that Newland did not violate the PHS policy and is well within her rights to contact OLAW directly. On OLAW's website about reporting noncompliance, it states "Relevant findings of the investigation are reported to OLAW by the IACUC through the Institutional Official (IO). However, concerns may be submitted

directly to OLAW from any source through any communication method, including telephone, fax or e-mail."² The scenario does state that Newland "reported" to OLAW, but we interpret that as equivalent to submitting a concern rather than a formal report, which should be done by the IACUC via the IO. After any concern is submitted, we presume OLAW would follow up with the IACUC and determine if a formal report is needed.

While we empathize with Newland's desire to remain impartial and extol her for ultimately correctly reporting the situation, we believe she could have handled the situation better. First, she could have brought up OLAW's list of reportable situations to be clear that animal well-being is not the only threshold for reporting to OLAW. Second, there will always be scenarios that are unclear if they should be reported to OLAW, and consultation with OLAW is always a good idea. In fact, OLAW's *Guidance on Prompt Reporting* states, "... consult with OLAW if in doubt. OLAW welcomes inquiries and discussion and will