

Jerald Silverman, DVM, Column Coordinator

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).

RESPONSE

Call me maybe

Derek Fong, VMD, DACLAM,
Christopher Manuel, DVM, PhD, DACLAM,
Jori Leszczynski, DVM, DACLAM &
Mark Douse, PhD

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

provide guidance with regard to specific situations.”¹ Newland could have broached the idea of consulting with OLAW during, or even after, the IACUC meeting so that there could be no perceptions that Newland was operating around the IACUC.

1. National Institutes of Health. NOT-OD-05-034: Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals. *National Institutes of Health Office of Extramural Research*. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html> (2013).
2. Office of Laboratory Animal Welfare. Reporting Noncompliance. *National Institutes of Health Office of Extramural Research*. http://grants.nih.gov/grants/olaw/reporting_noncompliance.htm (2014).

Fong and Manuel are Clinical Veterinarians, Leszczynski is the University Veterinarian and Director of the Office of Laboratory Animal Resources, Douse is the Director of the Office of Research Committee Support at University of Colorado Denver, Aurora, CO.

RESPONSE

Know your role and options

Carolyn A. Pelham, RLATG, CMAR

The synopsis fails to mention whether or not a quorum was present to properly vote on the sanctions to be taken, so we can assume that it was. Regardless, according to PHS Policy, all significant violations to an approved protocol must be reported to OLAW. Deviation by withholding or not following the approved analgesic regime becomes a significant change¹.

In her defense, Newland took what she felt was the correct action; she just took the wrong route. She is correct that anyone can report concerns, including members of an IACUC, but in this instance she isn't just anyone. She was the chair of the IACUC and should have behaved as such. Her duty was to make a full report to the IO explaining the actions and why the IACUC recommended sanctions. If the IO failed to follow through, then she could have taken further steps to report her concerns. The IO would hopefully not be willing to jeopardize PHS support for the institution over non-reporting of an issue.

Newland should have also used her position as the vice-chair to remind the other

A Word from OLAW

In response to the questions posed in this scenario, the Office of Laboratory Animal Welfare (OLAW) agrees with the commenters' concerns about the Institutional Animal Care and Use Committee's (IACUC) decision not to report the failure to follow the protocol. It is in the best interest of the institution, the IACUC, and the funding agency to be forthcoming when noncompliance occurs¹. OLAW recommends consulting OLAW guidance on prompt reporting that provides information to assist in determining what should be reported². As stated in the guidance, reporting serves two purposes: 1) it ensures that institutions address and correct situations that affect animal welfare, and 2) it enables OLAW to monitor the institution's oversight and assess the effectiveness of PHS policies and procedures². If a question about whether to report remains, a phone call to the OLAW office can alleviate concerns. The PHS Policy empowers the IACUC and the institution to self-evaluate within a cooperative framework of OLAW's guidance and support³.

1. National Institutes of Health, Office of Laboratory Animal Welfare Topic Index, Reporting Noncompliance (http://grants.nih.gov/grants/olaw/institutional_reporting.htm#reportingnoncompliance; accessed September 2016).
2. National Institutes of Health Guide for Grants and Contracts Notice NOT-OD-05-034. Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals. (released February 24, 2005; <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>).
3. Public Health Service. Policy on Humane Care and Use of Laboratory Animals, IV.F.3. (US Department of Health and Human Services, Bethesda, MD, 1986; revised 2015).

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IACUC members that their vote to withhold reporting of the incident could be overturned by the IO, thereby following the PHS requirement of having a program of self-reporting issues that arise. Not reporting protocol deviations can be an issue and the IACUC members need to all feel comfortable with the final decision. It appears that Newland—and some of her colleagues—did not agree with the decision, and Newland was being mindful of the importance of following all of OLAW's requirements in accordance with the institution's Assurance of Compliance. When Newland was given the vice-chair position, reporting structure should have been made clear to her. If the chair wasn't sure that she could handle any event that came up, then the meeting could have been postponed until he was able to return.

Going forward, the IACUC should have a defined mechanism in place for non-compliance: sanctions, re-training, reporting, and so forth. I would have reminded the other members that the IO was the final stop for reporting the event, so IACUC members would know that reporting the incident could still move forward. She could then have requested a meeting with the IO and chair, upon his return, and

voiced any concerns about the events from the meeting.

1. ARENA/OLAW. *Institutional Animal Care and Use Committee Guidebook* 2nd edn. (OLAW, Bethesda, MD, 2002).

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RESPONSE

Taking too many liberties can affect trust

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Denyse Levesque, DVM

Assuming that the post-operative analgesic regimen was written within the approved IACUC protocol, the research technician was in violation of the protocol when he decided to withhold the final dose of analgesia from the rat. The decision to withhold analgesics is considered a significant deviation from the protocol and, assuming this study was funded through PHS awards, this

event must be reported to OLAW.

The OLAW website has a section addressing Frequently Asked Questions, where it states in FAQ B13 that, "...conducting procedures that constitute a significant change in approved animal activities without prior IACUC approval is serious noncompliance that must be reported to OLAW"¹. In FAQ D9, OLAW states that, "examples of changes considered to be significant include, but are not limited to, changes...in anesthetic agents or the use or withholding of analgesics"¹. While skipping the last dose of the analgesic may not have significantly impacted the animal's well-being, the point is that the technician was not at liberty to make that decision.

The Great Eastern University IACUC was correct to vote for sanctions; however

Newland was also correct in her conviction that the event be reported to OLAW—though the manner in which she went about reporting the incident could have been handled better. As a member of the IACUC, Newland has a responsibility to speak up and make her opinion known, especially when there are potential animal welfare concerns; just because she is vice-chair does not mean she needs to remain neutral when there are disagreements. After the IACUC majority voted to not report the incident, Newland had alternate reporting options: specifically she could have spoken with the chairman about the issue upon his return or taken the matter directly to the IO. According to PHS policy, all reporting from the IACUC to OLAW takes place through the IO, so it appears Newland was in viola-

tion of said policy². She certainly betrayed the IACUC's trust and intent by not speaking up at the meeting and defending her position. Had she approached the issue with the IACUC chairman or the IO, the matter could have been revisited and immediately reported in the appropriate manner.

1. Office of Laboratory Animal Welfare. Frequently asked questions PHS policy on humane care and use of laboratory animals. *National Institutes of Health Office of Extramural Research*. <http://grants.nih.gov/grants/olaw/faqs.htm#630> (2016).
2. 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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