

What does “reporting to the IACUC” mean for PAM?

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Great Eastern University’s post-approval monitoring (PAM) program relied on IACUC members and the vivarium staff to supplement the IACUC’s semiannual inspections and program reviews. Over time it became obvious that a more robust and dedicated PAM program was required and, after much discussion about needs and reporting lines, two full-time PAM specialists were hired. Their job description gave them the authority to observe and evaluate all laboratory animal care and use activities to help assure that those activities were being performed in compliance with the appropriate IACUC approved protocols and federal laws and regulations. They reported to the IACUC and provided activity updates at the committee’s monthly meeting.

At the July meeting, Jodi Hall, one of the PAM specialists, reported that she had

visited a laboratory where a technician’s records revealed that mice had not been given any postoperative analgesia as was required by the investigator’s protocol. She said she informed the investigator who said he would speak to the technician and make sure the problem would not recur. When Hall reported the incident to the IACUC she fully expected that the committee would notify NIH/OLAW of the noncompliance, but to her surprise the chairman, Larry Covelli, thanked her for the information and moved on to the next topic on the agenda.

Hall waited two weeks to see if there would be an investigation or a report to OLAW, but neither occurred. She asked Covelli if he planned to notify OLAW and he said that in his mind the problem was resolved and no further action was needed. Knowing that the lack of notification was

contrary to federal policy, yet feeling insecure about how to proceed, she talked to Deb Fowler, the other PAM specialist, who suggested that Hall meet with the Institutional Official. But Hall balked at that idea, saying it was likely that Covelli would hear about it and then she would be in trouble with him. She said she needed and liked her job and was afraid to do anything that would put it in jeopardy.

When the PAM job description was approved, the university’s human resources department never considered the implications of “reporting to the IACUC.” In your opinion, is Larry Covelli Jodi Hall’s supervisor or is it the entire IACUC? If the IACUC, by not reporting the incident to OLAW, is noncompliant with federal policy, what do you think Hall can or should do to fulfill her job responsibilities without putting her job at risk?

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RESPONSE

Conflicts of interest

Samuel Baker

Firstly, the decision to develop an enhanced PAM program should be commended. While there are no regulations for a formal PAM program outside of the IACUC’s federally mandated continuing review requirements, the Guide, alongside my own experiences, suggest that this both enhances the wellbeing of animals, and provides opportunities to refine research procedures. With the PAM staff reporting to the IACUC, I feel that Covelli, as the Chair of the IACUC, is their supervisor. However, this is fraught with issues. The Chair likely does not have sufficient understanding of regulations governing IACUC

operations, or PAM programs, to be able to appropriately supervise them. In addition, there is a significant potential for a conflict of interest to arise. To avoid this, it would be preferable for the PAM personnel to report to a single person in the Office of IACUC, or equivalent department.

Having found and reported the non-compliance, PAM specialist Hall should feel that she has fulfilled her job responsibilities. This is because it is the responsibility of the IACUC, and not the PAM officers, to assess whether an activity is in accordance with all federal regulations and the institution’s Animal Welfare NIH/OLAW Assurance, and if not, to determine whether there is sufficient reason to investigate. While there is no mandate for the IACUC to investigate every allegation, I agree with Hall that not providing analgesia and compromising animal welfare

is a noncompliance that should warrant investigation. I also strongly believe that IACUC Chair Covelli should not be unilaterally deciding the outcome of that review, but rather the convened quorum of the IACUC as a whole should decide on how to proceed. In addition, the IACUC is required to use due diligence to determine if the noncompliant activity is being done on a PHS/NSF-supported project, and if prompt reporting to OLAW is necessary (PHS IV,F,3; NIH guidance document NOT-OD-05-034.). If this project was PHS/NSF-sponsored, or if it was written into the institution’s assurance that all investigations need to be reported, then the IACUC is noncompliant with federal policy in not investigating and reporting this noncompliance.

From here, Hall has options as to how she could proceed. Recognizing that Hall

is new to her role, I believe it's important that she talk more broadly with the Office of the IACUC, as there may be policies and procedures specific to this IACUC that she is not familiar with. Having been ignored by the Chair, Hall could bring her justifiable concerns to the IO; however, I feel an option that might be more comfortable for Hall is to reach out to the Institutional AV. Talking to the AV may both ameliorate Hall's concerns and strengthen her case for further IACUC review and, if necessary, the AV can act as a more appropriate conduit for reporting to the IO. Finally, it might be prudent for both Hall and Fowler to reach out to HR and raise concerns about the current reporting structure that the University HR is not aware of. This is also the appropriate forum for Hall to discuss any specific interpersonal issues that she may have with Covelli, and by involving HR ensure that there are no reprisals from Covelli for any appropriate action Hall may take.

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RESPONSE

PAM specialist: report without fear

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The central tenet of the practice of laboratory animal medicine is alleviation of pain in laboratory animals from research procedures. The most worrisome aspect of this protocol review scenario is that the mice experienced unrelieved pain after a surgical procedure and the failure in providing post-operative analgesia was not discovered until the semi-annual inspection of the laboratory. Unfortunately, such protocol non-compliance is not rare. However, such non-compliance usually gets rectified quickly because of the involvement of animal husbandry staff, veterinary technicians and facility veterinarians. The husbandry and veterinary staff can easily identify animals in pain, especially after a surgery. Then the veterinary staff can ensure that post-operative analgesics approved in the

protocol are promptly administered. More importantly, the procedures for ensuring compliance with post-operative care should be in place. IACUC can mandate placement of 'post-operative care cards' in the cage card holders of rodent cages that contain information on name and date of surgery, analgesics and frequency of monitoring following surgery. These cards need to be initialed by the research staff so that vivarium staff can know about the monitoring of animals after surgery. The aforementioned non-compliance also highlights deficiency in program of veterinary care. In fact, failure to provide analgesia after a painful surgical procedure to research animals rises to the level of animal welfare concern.

Hall is correct in her assessment that this protocol non-compliance is reportable to OLAW/NIH because failure to provide post-operative analgesia in an IACUC approved protocol is a serious deviation from the Guide¹, non-compliance with the PHS policy², violation of US Govt Principles IV and V², and breach of institutional Animal Welfare Assurance. Fowler has appropriately suggested that Ms. Hall convey her concerns to institutional official (IO) because the responsibility of reviewing and reporting animal welfare concerns rests with IO and IACUC^{1,2}, and Hall did not get appropriate response from the IACUC Chair. In our opinion, neither Covelli nor the entire IACUC are Hall's supervisors. Universities, as a norm, have an IACUC office with a Director and staff such as Ms. Hall, to carry out numerous administrative and regulatory functions of IACUC. Generally, IACUC Director and IACUC Chairperson are two different individuals. IACUC Chair is usually a faculty scientist engaged in research in the university. IACUC is a committee and not an employer. It is unrealistic to expect the entire IACUC to perform supervisory functions such as performance appraisals, for a university employee. The Human Resources department did not clearly specify an immediate supervisor for Hall. Hence it is appropriate for Hall to approach IO with her concerns because her job responsibilities fall within the purview of Office of Research. If she is hesitant to approach IO, she can reach out to IACUC Director and/or Attending Veterinarian (AV) and all of

them can meet with the IO in this regard. Hall does not need to fear about jeopardizing her employment because of the federal laws that protect 'whistle blowers' against any discrimination and reprisals from reporting animal welfare concerns or non-compliance of approved protocol³.

Few actions need to be taken to prevent reoccurrence of this scenario. The IO should delegate investigation of this animal welfare concern to a subcommittee because Covelli is not interested in pursuing this further. The IO can report this incident to OLAW based on the recommendations of the subcommittee. The Principal Investigator of the laboratory should provide a written explanation for the reasons for the non-compliance as well as corrective actions. The IO can assign members of IACUC to form a permanent subcommittee that is dedicated to investigating animal welfare concerns. The PAM specialist can present the recommendations of the subcommittee in the monthly IACUC meeting and the entire IACUC can vote to approve or disapprove self-reporting animal welfare concern to OLAW. IO should direct the IACUC to form policies on investigating animal welfare concerns as well as documentation for post-operative care and health monitoring. The AV should implement training for the husbandry and veterinary staff regarding signs of pain and distress in laboratory animals. The posters on grimace scales in mice, rat and rabbits from NC3R⁵ (National Centre for the Replacement Refinement and Reduction of Animals in Research, London, UK) can be posted in the vivarium. Lastly, HR needs to specify Director of IACUC office as the immediate supervisor for PAM specialists and then the IACUC Director needs to review the chain of command with both PAM specialists.

1. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
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).
3. *The IACUC Handbook* 3rd edn. (ed. Silverman, J., Suckow, M. & Murthy, S.) (CRC Press, Boca Raton, 2014).

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RESPONSE

Sharing is caring, but more clarity is needed

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This scenario demonstrates the challenges of creating a post-approval monitoring (PAM) program that best fits each institution’s animal program structure and research culture in the absence of clear and detailed regulatory requirements for PAM¹. In preparing this response, my PAM colleagues were convinced that the IACUC Chair is indeed the supervisor of the PAM specialists, whereas from my perspective as IACUC Administrator I am equally convinced the Chair is not.

Strictly speaking, the PAM specialists’ “reporting” to the IACUC is simply that: delivering information to the IACUC for its use in decision-making and determining next steps. It is frustrating when an IACUC fails to act as a supporting staff member believes is appropriate. However if Ms. Hall truly believes that the institution is at risk due to the inaction of the IACUC there are two other authorities she could approach: the Institutional Official (IO), and the Attending Veterinarian (AV).

Ms. Hall should do some investigating to find out if the incident really does need to be reported to NIH/OLAW by asking the following question: Is PHS or NSF funding used to conduct work on the protocol in question? If yes, Hall should meet with Dr. Covelli to express her concerns and explain that following federal policy² is in the best interest of the university. If Dr. Covelli still refuses to report the incident to NIH/OLAW, Hall should notify him that she will raise the issue for full discussion at the next IACUC meeting. Hall could also approach the AV and express her concern, because animals were put at increased risk of post-operative pain and distress due to the protocol violation. At the IACUC meeting when Hall raises the issue the combined opinions of both the AV and Hall will provide the full IACUC with a more complete set of information that

A Word from OLAW

In response to the questions posed in this scenario, the Office of Laboratory Animal Welfare (OLAW) provides the following clarifications.

The PHS Policy does not specifically address reporting channels for post-approval monitoring (PAM) personnel. OLAW recommends in previous guidance that direct, clear and straightforward lines of responsibility and corresponding authority allow organizations to respond quickly and effectively¹. The Institutional Official (IO) in the scenario should clearly define and assign responsibilities and reporting channels for monitoring animal care and use to safeguard animal welfare². While not required by the PHS Policy, a PAM program helps ensure the wellbeing of the animals and may also provide opportunities to refine research procedures³. If the study in question was PHS or NSF-supported, the incident qualifies as reportable to OLAW because it was a “failure to adhere to an IACUC-approved protocol”⁴. As such, the IACUC must be informed of the incident and through the IO promptly provide OLAW with an explanation of the circumstances and the actions taken to address the noncompliance.

1. Public Health Service. Policy on Humane Care and Use of Laboratory Animals – Frequently Asked Questions. Institutional Responsibilities, Question No. G.4. (US Department of Health and Human Services, Washington, DC, 2006, revised 2017). <https://grants.nih.gov/grants/olaw/faqs.htm#680>
2. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. pp. 23-24 (National Academies Press, Washington, DC, 2011).
3. Public Health Service. Policy on Humane Care and Use of Laboratory Animals – Frequently Asked Questions. Institutional Responsibilities, Question No. G.6. (US Department of Health and Human Services, Washington, DC, 2006, revised 2017). <https://grants.nih.gov/grants/olaw/faqs.htm#682>
4. National Institutes of Health. Notice NOT-OD-05-034, Guidance on Prompt Reporting to OLAW [online]. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html> (National Institutes of Health, Washington, DC, 24 February 2005).

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the IACUC can then act upon. If the IACUC still will not report the issue, Hall (and perhaps the AV) should express her concerns to the IO. At this point she has done her due diligence and it is up to the IO and IACUC to decide how to handle issues such as this. If Hall is a member of the IACUC, she could author a minority opinion regarding the decision if she is comfortable with her opinion being included in the semiannual program review report to the IO and OLAW (if the institution holds an Assurance)³.

Ms. Hall’s fear of reprisal if she approached the IO as her co-worker advised is a concern. This suggests a work environment that is not conducive to fulfilling the *Guide* and regulatory expectations for post-approval monitoring^{4,5}, and may violate rules (ref. 6; §2.32,c,4) on reprisals against employees who express concerns about research animals.

We recommend that the PAM specialists ask for clarification regarding workplace reporting lines and supervisory authority,

and to continue providing the IACUC with thoughtful, accurate reports about the animal program they oversee.

1. Banks, Ron E. 2014. Postapproval monitoring. In: *The IACUC Handbook* 3rd edn. (ed. Silverman, J., Suckow, M. & Murthy, S.) (CRC Press, Boca Raton, 2014).
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).
3. National Institutes of Health, Office of Laboratory Animal Welfare. FAQ C.6, *What are PHS requirements for recording and reporting minority views?* <https://grants.nih.gov/grants/olaw/faqs.htm#612>
4. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
5. United States Department of Agriculture. *Animal Welfare Inspection Guide* (US Department of Agriculture, Riverdale, MD, 2013).
6. United States Department of Agriculture. *Animal Welfare Act Regulations* (US Department of Agriculture, Riverdale, MD, 2013).

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