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 NC3R⁸ (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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