that cause pain or distress in human beings may cause pain or distress in other animals". In this situation, the fact that an animal may stand up and move postoperatively doesn't rule out the possibility of pain or distress and should not be used as a scientific justification to withhold analgesics. This may be viewed as a deficiency in the IACUC review process and veterinary care program at Great Eastern University. To prevent this deficiency, to meet the expectations of the *Guide*[4] and to ensure animal welfare, the institution should provide training for PIs and research staff on recognizing and treating pain and distress and should have a documented IACUC DMR process.

In summary, any IACUC member can refer a protocol for FCR during the DMR process. There is no statement in either the AWARs or PHS *Policy* to indicate otherwise.

1. Animal Welfare Act Regulations (§ 2.31, d, 2).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* IV, C, 2 (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. Office of Laboratory Animal Welfare. Guidance to IACUCs Regarding Use of Designated Member Review (DMR) for Animal Study Proposal Review Subsequent to Full Committee Review (FCR). Notice NOT-OD-09-035. (National Institutes of Health, Washington, DC, 8 January 2009). <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-035.html>
4. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 10–14,60–65 (National Academies Press, Washington, DC, 1996).
5. Public Health Service. *US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* (US Department of Health and Human Services, Washington, DC, 2002).

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A word from OLAW and USDA

In response to the questions posed in this scenario, the Office of Laboratory Animal Welfare (OLAW) and United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) offer the following clarification and guidance:

For animal activities funded by the Public Health Service (PHS), the PHS *Policy on Humane Care and Use of Laboratory Animals* (PHS *Policy*; section IV.B.4) states that the "IACUC shall review concerns involving the care and use of animals at the institution"[1]. Similarly, for species covered by the Animal Welfare Act, "The IACUC shall… review, and, if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees"[2]. Neither the PHS *Policy* nor the Animal Welfare Act Regulations limits how or when such concerns are considered. In this scenario, the IACUC member has a serious concern about the lack of analgesia for a proposed surgical procedure in a research protocol in the midst of review by a designated member of the committee. As mentioned by several of the respondents, OLAW's guidance on the use of Designated Member Review (DMR) subsequent to Full Committee Review (FCR) states that "any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol"[3]. OLAW's guidance is in accordance with USDA's regulation on designated member review[2]. The guidance can and should be interpreted broadly to apply to this particular scenario and to other circumstances where an IACUC member has concerns about a research protocol already approved by the committee or in the process of review and approval by either DMR or FCR. Administrative practices of the committee should not impede the appropriate and thorough review of concerns about proposed or ongoing animal activities. Critical to this issue is clear communication among the IACUC, the veterinarian and investigators to resolve questions and concerns about a protocol at the earliest point.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
2. Code of Federal Regulations. Title 9, Chapter 1, Subchapter A – Animal Welfare: Part 2 Regulations (§2.31).
3. Office of Laboratory Animal Welfare. Guidance to IACUCs Regarding Use of Designated Member Review (DMR) for Animal Study Proposal Review Subsequent to Full Committee Review (FCR). Notice NOT-OD-09-035. (National Institutes of Health, Washington, DC, 8 January 2009). <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-035.html>

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RESPONSE

Sean dropped the ball

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Designated Member Review (DMR) is one method of approving animal use proposals that is compliant with US Department of Agriculture and PHS guidelines[1,2]. The DMR process gives the designated reviewer full authority to approve the protocol but also requires that all committee members have the opportunity to look at the protocol and call for FCR prior to assignment for DMR. It appears that in this case, Sean Smith forfeited his right to call for FCR as an IACUC member during this specific pre-DMR review period. He wrongly assumed that the designated reviewer, who is also the AV, would require analgesia in this study. This case illustrates the responsibility of each committee member to play his or her role independently, irrespective of perceptions of how other members might make decisions.

The Office of Laboratory Animal Welfare guidance that Liz used to support her contention that any IACUC member could request FCR of a protocol was taken out of context. The guidance that Liz quoted is specific to the use of DMR subsequent to FCR[3] and does not apply in this scenario. The specific wording in the guidance refers to the situation that could arise if a committee had voted to allow use of the DMR process to review modifications required for approval that were stipulated by members during a convened meeting of the full committee. In that case, PHS allows for required modifications to be reviewed by the DMR process under two