

conditions: (i) all IACUC members agree in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use this method, and (ii) any member of the IACUC may, at any time, request to see the revised protocol or request FCR of the protocol. As stated previously, one required element of the DMR process is that all IACUC members must be given the opportunity to call for FCR. In our opinion, the provision presented in this guidance was stipulated specifically to allow members not present at the meeting the opportunity to call for FCR of any protocols sent for subsequent DMR during the FCR process. There is no provision in this guidance or in others that allows members more than one opportunity to call for FCR if they have second thoughts prior to approval. After approval, however, any member may request additional review of any protocol if he or she has concerns about animal welfare.

In summary, an IACUC member (Sean) cannot intervene during the DMR process once the process has begun (which happens only if no IACUC member calls for FCR). Sean now has two options: (i) contact the designated reviewer, mention his concerns and request that they be considered, with the full knowledge that the designated reviewer has the authority to reject the comments, or (ii) wait for approval of the protocol by DMR and then immediately request FCR of the protocol, citing his concerns.

1. Animal Welfare Act Regulations, 9 CFR (Chapter 1, Subchapter A, Part 2).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals – Frequently Asked Questions*. Protocol Review, Question No. D-19. (US Department of Health and Human Services, Washington, DC, 1986;

amended 2002). <<http://grants.nih.gov/grants/olaw/faqs.htm#d19>>

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## RESPONSE

### Talk to the veterinarian!

**Diane J. Gaertner, DVM, DACLAM**

In my opinion, Liz Smith is correct that, as an IACUC member, Sean Smith can ask for a FCR of the protocol until the protocol is approved through the normal DMR process. This does not require “special circumstances” as asserted by Sean Smith.

In addition, even after the IACUC DMR process has approved a protocol, the IACUC has the responsibility to review any concerns brought to it regarding the use of animals at the institution. If the PI’s protocol has already been approved by the IACUC DMR process, Sean Smith or any other member of the University community can bring his or her concern for the adequacy of analgesia for these sheep to the attention of the IACUC with the expectation that the concerns will be discussed at a convened IACUC meeting. Sean Smith’s concerns would not overrule the AV’s opinion during this discussion, but the IACUC members may be convinced that supplemental analgesia for these sheep is warranted and the IACUC discussion may require modification of the protocol. In general, when in doubt, most IACUCs will rule that postoperative analgesics shall be provided to research animals unless the PI can show scientific proof that the provision of these analgesics will alter the data to be obtained or endanger the animals’ recovery.

This scenario and the processes described above also illustrate how people’s convoluted efforts to avoid confrontation can waste time with political maneuvering. I question why the IACUC member, Sean Smith, didn’t simply express his concerns directly to the AV and discuss this issue. I am optimistic that an honest and respectful discussion regarding the need for analgesics to supplement anesthesia could allow for the best outcome for the sheep without the need for convoluted political maneuvering or a potentially heated IACUC discussion. If Sean Smith has useful references or personal experience that convince the AV that postoperative analgesics are needed, then this recommendation can be conveyed to the PI by the AV as the Designated Member Reviewer as part of the DMR process, without the need for a confrontational discussion at the IACUC meeting. If the AV has a solid basis for not requiring postoperative analgesics, then she or he can explain that basis; for example, some ‘balanced’ or ‘multimodal’ anesthetic protocols include drugs that provide substantial continued analgesic effects after animals awaken. If the AV continues to believe that postoperative analgesics are not needed, then Sean Smith can take the next step by requesting FCR (if the protocol is not yet approved) or by conveying his concerns as a member of the University community, resulting in a full discussion of the approved protocol by the IACUC at the next convened meeting.

In my opinion, Sean Smith should take the direct approach of discussing his concerns with the AV rather than expressing his distress to his wife Liz, other IACUC members or other colleagues!

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