

Committee’s deliberations, at which time Cotter, as Attending Veterinarian (AV), should have noted that four doses of an opioid for a minor implantation procedure might be excessive. The USDA’s Animal Care Policy No. 3 on Veterinary Care states that “the specific details of [postprocedural care] must be approved by the attending veterinarian or his/her designee.” Had a veterinarian been consulted before the protocol was approved by the IACUC, a more reasonable approach to postprocedural analgesia might have been included.

The citation for an infraction of the AWA is unnecessary, because this is not an issue of inhumane treatment or animal welfare. As required in AWA regulation §2.40(a)(5), adequate pre- and postprocedural care was provided in accordance with established veterinary medical and nursing procedures, which do not call for the use of drugs when they are not needed. It would be appropriate for Madela to request that a modification be submitted and approved by the IACUC before additional procedures are performed.

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## **Follow the Rules**

**Cathy Johnson-Delaney, DVM and Tena Petersen**

This conflict appears to be about an issue of regulatory compliance rather than one of animal welfare, because the appropriate documentation of a significant change to a protocol regimen (analgesic in this case) was not submitted or approved by the IACUC.

If the IACUC approved the administration of butorphanol every 4 h for the first 12 h, and then as needed, then that regimen should have been followed. The section §2.31(e) of the AWA regulations cited by Madela as an infraction addresses the documentation and IACUC review of significant changes in an ongoing activity involving animals. Neither Reiss nor Cotter had made an amendment to the protocol and submitted that to the IACUC before changing the

butorphanol dosing regimen. Altering the administration of an analgesic is a significant change to the protocol that should have been reported. Cotter cited a nonapplicable section of the AWA §2.40(a)(5), which applies to Dealers and Exhibitors. Because Reiss is a resident at Great Eastern, we assume he is working at a research facility, not at a Dealer or Exhibitor. In that case, a more applicable reference for Cotter is section §2.33 of the AWA, and more specifically, section §2.33(b)(5). Section §2.33(b)(5) is more applicable to the ‘as needed’ portion of the analgesic regimen and not to the preceding portion, which clearly outlines analgesic administration. Section §2.33(b)(5) is also applicable if unforeseen circumstances develop during the course of the study (e.g., additional administration of anesthesia or postoperative complications).

If, after assessing Toots postoperatively, Reiss felt that one administration of butorphanol provided adequate analgesia, then he should have contacted the PI on the study, explained his assessment, and requested that the PI consider submitting an amendment to the protocol to the IACUC. Taking into consideration that this may not be a unique instance, the amendment could reflect something to the effect that “animals will be given analgesics immediately postoperatively and will be reassessed by the clinical veterinarian every 4 h for the period of 12 h. Additional analgesics will be administered as per veterinary recommendation”. This instruction would allow the veterinarian to use his/her professional judgment regarding the provision of adequate veterinary care and appropriate analgesic administration to each patient. Until that amendment had been made and approved by the IACUC, Reiss had to administer the drug at the dosage and frequency stated in the protocol. Noncompliance would be a deviation from the protocol. As Madela stated, it was not a question of veterinary care so much as it was a deviation from the stated and IACUC-approved protocol.

Regarding Cotter’s reference to section 2.40(a)(5), which calls for adequate pre- and postprocedural care in accordance with established veterinary and nursing procedures, we again refer Cotter to section

§2.33(b)(5). Cotter’s assessment is correct in that established veterinary medical procedures do not call for the use of drugs when they are not needed. However, we refer Cotter to section §2.33(b)(4) and remind her that it is the veterinarian’s responsibility to ensure, during pre-study planning with the PI, that adequate veterinary care is described as part of the protocol before submission to the IACUC. The veterinarian should have assessed analgesic administration before and not after IACUC approval. The veterinarian must follow the approved protocol or have the documentation submitted to the IACUC requesting approval of the change.

Additionally, this project received approval from the IACUC as written. As per section 2.33(a)(3) of the AWA, the AV or other facility veterinarian with delegated program responsibility for activities involving animals at the research facility is required to be a participant on this Committee, and as such, should have approved the analgesic administration regimen. We would suggest that Reiss and Cotter familiarize themselves with the AWA, and if, in the clinical judgment of the veterinarian, the protocol should be amended to alter a medication regimen, that this then be done, submitted, and approved by the IACUC before the veterinarian changes the administration regimen.

Although the animals seem to be recovering nicely, we agree that there was a deviation from the approved protocol and support Madela’s position.

**Johnson-Delaney is the Attending Veterinarian and Petersen is the IACUC Administrator, for SNBL USA Ltd., Everett, WA.**

## **Don’t Take It Personally**

**M. Lynn Loney, MS, RLATG, RVT**

The central issue of this scenario concerns communications, interpretations and the personalities of the primary participants. AWA regulation §2.31(e)(3) does specify “a complete description of the proposed animals” as required documentation. Furthermore, there are many additional