

IACUCs can and frequently do permit some flexibility. Examples of how this commonly is done include giving a range instead of a specific dose of a drug or listing a maximum instead of a specific volume of blood to be collected. It also is achieved by giving alternative techniques for performing procedures. This same approach can be applied to a listing of anesthetics and analgesics too.

What the IACUC must do is to determine that each of the proposed anesthetic and analgesic protocols is appropriate for the species and surgical procedure. The committee should ask the investigator to limit the listing of drugs to those that they reasonably expect to use. This will prevent the extreme situation in which the investigator presents for review a whole formulary of agents, many of which will never be used.

The laboratory animal vets can address their concerns without insisting on an unnecessarily restrictive proposal. First, the veterinary staff should discuss the issue with the investigator prior to or in parallel with the IACUC review. These veterinary colleagues should be working cooperatively to agree on the menu of appropriate anesthetic and analgesic options that will be included in the IACUC proposal. If the veterinary staff and investigator are in agreement, the IACUC likely will be happy too. If there are residual concerns, the veterinary staff also can work out a plan with the investigator to monitor the outcomes from the surgeries and drugs used. They could then report back to the IACUC if any problems occur.

The end result is flexibility for the investigator and effective program oversight by the IACUC and attending vet.

1. Animal Welfare Act and Animal Welfare Regulations. 9 CFR.
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; reprinted 2002).
3. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* (National Academies Press, Washington, DC, 1996).

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## **RESPONSE**

### **Formalize SOPs**

**Karen R. Strait, DVM**

Under the Animal Welfare Act<sup>1</sup> and PHS Policy<sup>2</sup>, investigators are required to provide a description of the methods used to assess and alleviate pain for procedures that may cause more than slight pain or distress. A major surgical procedure would certainly fall within this category. There is nothing in the regulatory language, however, that precludes IACUC approval of several anesthetic and analgesic options in a single protocol, provided that the agents, doses and routes are appropriate for the procedures to be performed. Allowing flexibility in the choice of agents to be administered can be advantageous to both the research lab and the IACUC. Investigators are able to make quick changes between equally effective drugs should the need arise, and the IACUC reduces the number of modifications it must sort through while keeping investigators compliant with their protocol when quick changes are necessary.

Superficially, the IACUC appears to be doing everything right. It is reviewing all drugs and assuring that they are acceptable for the described procedures. Additionally, the labs are keeping nicely detailed surgical records and seem to be compliant. What is worrisome, however, is the underlying anxiety among the veterinarians and the other members of the IACUC. Is everyone just going through the motions? The laboratory animal veterinarians seem to be uncertain that they can fully assess the appropriateness of the drug regimen. If the veterinarians at Great Eastern University feel that they are unable to adequately review a protocol, then they have the authority and the obligation to request more information from the investigator. In this scenario, that may include the specific conditions under which each drug will be used. It is also unclear from the scenario whether or not the veterinarians are communicating at any point with the investigators. The veterinary consult is a required part of the protocol planning process for any

potentially painful procedure and is an excellent time for the veterinarian to make recommendations for the latest and greatest drug regimens. If the IACUC has not already implemented this policy at Great Eastern University, it must do so immediately. Ultimately, the responsibility falls upon the IACUC during the protocol review process to assure that methods used to alleviate pain and distress are appropriate and adequate. If it is unable to do so with the given information, it must not be shy about requesting more detail from the investigator.

The IACUC chairman is correct that IACUCs may approve standard operating procedures (SOPs) for routine aspects of research in order to simplify protocol preparation. Although the drug menu provided by the Department of Veterinary Surgery is not a true SOP, the IACUC may consider requesting a formalized version of the document for review. Alternatively, it can create its own anesthesia and analgesia SOPs. The SOP can indicate IACUC-approved drugs, doses, routes of administration, directions for preparation, criteria for which specific drugs are appropriate, etc. In this way, the Department of Veterinary Surgery has an approved list they can easily reference, and the IACUC can better control specifics regarding use.

1. Animal Welfare Act and Animal Welfare Regulations. 9 CFR.
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; reprinted 2002).

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## **RESPONSE**

### **A la carte is OK**

**Cheryl A. Cheney, CPIA**

It sounds as though the faculty in Great Eastern University's Department of Veterinary Surgery have prepared a veterinary formulary database that