Jerald Silverman, DVM, Column Coordinator

Training after protocol approval

If the IACUC, along with the Attending Veterinarian (AV), is responsible for assuring that personnel performing a surgical procedure are properly qualified and trained, then when should this training and qualification occur? This was the question facing the Great Eastern University IACUC when Dr. Larry Sturkie's protocol was being reviewed. Sturkie, an established researcher, proposed performing cardiac artery ligation on mice. He indicated on his protocol that, although his research team had no surgical experience, all members had taken and passed the vivarium-sponsored basic surgical training program and would be taught the artery ligation procedure by personnel from the Fitzgibbons lab, who were proficient with the technique and had IACUC-approved protocols that included performing that procedure. Further, the Fitzgibbons lab would train the Sturkie lab by having them practice on animals euthanized for other purposes, and then allow them to advance to non-recovery arterial ligation practice before having them perform the procedure on mice that would recover from anesthesia. During this time, other non-surgical aspects of the protocol would proceed.

With that information in hand, a full committee meeting of the Great Eastern IACUC was ready to discuss the protocol. Only one person, the AV, spoke up. He said that although the IACUC had often approved training in the manner described in the protocol, he was still uncomfortable approving a protocol when personnel were not yet proficient in a surgical technique. For example, he said, "what would the IACUC do if the Sturkie lab staff simply wasn't up to snuff with the procedure? How would you know this? Would you stop the study if you did know this?" Larry Covelli, the IACUC chair, quickly interrupted and said that the IACUC could always have a veterinarian do the training or watch the procedure being performed. But the AV said that the veterinarians did not have experience with the procedure, but that wasn't the intent of the question. The question was whether the IACUC should even approve a protocol when a major facet of the study (the arterial ligation training) had not happened. "Let me give you another example," said the AV. "Would you approve a biocontainment study before you had the approval from the biosafety committee or a radiation study before approval from the radiation safety committee? If you would not, then why is the IACUC ready to approve this study?"

What is your opinion? Is it necessary for surgical training and qualification to be completed before the IACUC approves a study with surgery as part of the protocol?

RESPONSE

Post-approval monitoring

Ruth Blauwiekel, DVM, PhD, DACLAM

The IACUC at Great Eastern previously has reviewed and approved protocols which utilize cardiac arterial ligation in mice. Even though the surgical expertise does not reside in the AV's office or in Sturkie's laboratory, skilled personnel willing to teach the technique are available within the institution. The proposed training scheme, to utilize cadaver animals first and then perform the procedure in living animals on a non-survival basis, is a logical way in which to instruct research personnel while minimizing pain and distress in the animals. If the AV himself were training researchers on the procedure, he would likely choose this same stepwise validation of the research surgeons' proficiency.

That said, the AV is justifiably cautious with regard to this technically complex procedure. He (or the IACUC chair) could suggest that the IACUC approve a portion of the animals for the study on a 'pilot' basis, allowing lab personnel to learn the procedure and demonstrate their proficiency. It would be valuable for the AV or his designee to observe portions of the training; even though he may not feel confident in teaching the procedures himself, he can observe the proficiency of both the trainer and the trainee and evaluate factors such as anesthesia, intra-operative support and appropriate clinical endpoints. To pursue his analogy of the hazardous agent or radiation studies, he essentially would be performing a risk assessment to assure that the lab personnel have taken appropriate measures to minimize the animals' pain and distress.

Once the lab has transitioned into routine performance of the procedure, the AV may wish to observe a survival procedure or at least follow up with research personnel regarding the record of success or failure. This is a protocol which exemplifies the importance of post-approval monitoring, since the technique is complex and still relatively new for the laboratory. Alternatively, the IACUC might stipulate that Sturkie report back to the committee after a limited number of surgeries with a summary of outcomes (e.g., experiments completed successfully versus procedures resulting in animal fatality).

The nature of research is such that investigators will need to develop and implement new methods in animal models. Although it is the IACUC's responsibility to assure that adequate training is provided to personnel performing surgery in laboratory animals, to do so by obstructing the adoption of new procedures would hinder progress in many important fields of research. Training (particularly surgical training) is an ongoing process, in which even experienced animal surgeons expand and improve their skills over time. It is incumbent on the IACUC, the AV and the investigators to develop systems for training personnel to use novel methods, for monitoring outcomes in those procedures