

and for adhering to appropriate endpoints to minimize animal pain and distress.

Blauwiekel is Attending Veterinarian at University of Vermont, Burlington, VT.

RESPONSE

Teamwork

Steven M. Kuhlman, VMD, DACLAM & Susan A. Iliff, DVM, DACLAM, CPIA

The Great Eastern University IACUC would benefit from establishing guidelines that address training before performance of study procedures, particularly those involving surgery. The AV's concern regarding the IACUC's approval of Sturkie's protocol to conduct cardiac artery ligation surgery on mice without his team having prior surgical experience is valid. The *Guide for the Care and Use of Laboratory Animals* (the *Guide*)¹ states that researchers must have appropriate training to perform surgery and that surgery training may have to be tailored to accommodate the breadth of educational backgrounds frequently encountered in research settings: "The IACUC, together with the AV, is responsible for determining that personnel performing surgical procedures are appropriately qualified and trained in the procedures." The *Guide* does not state that the AV must provide training on a specific procedure; in fact, it encourages a team approach to a surgery project. It is interesting that both the *Guide*¹ and the Animal Welfare Regulations² involve the AV in pre-surgery planning as well as post-surgical care, but neither places direct responsibility on the AV to review personnel qualifications and effectiveness of training. The *Guide* requires the AV (together with the IACUC) to ensure that training addresses good surgical technique (asepsis, gentle tissue handling, minimum tissue dissection, appropriate instrument use, effective hemostasis and proper use of suture materials and patterns)¹.

Key questions that need to be addressed include when and how the training should occur and whether the IACUC should approve the protocol, including the cardiac artery ligation procedure, before training has occurred. Training and qualification should occur before the surgery is performed on the

study protocol. There is concern regarding the Sturkie team's lack of surgical experience. Sturkie should pursue other options to generate the cardiac artery ligation mouse model. It is important to consider the science when evaluating these options. Besides the potential for animal pain and distress as his team gains experience with this surgery, there is the possibility of generating an inadequate model due to poor technique.

Other options should be explored to address the question of whether the IACUC should approve the surgical procedure before training has occurred. A team approach with the AV and the Fitzgibbons lab could be used. The Fitzgibbons lab could perform the ligation procedure and then transfer the animal model to Sturkie's study protocol. Alternatively, the Fitzgibbons lab could train the Sturkie team under AV oversight. A pilot study could be conducted under a protocol held by Sturkie that lists all personnel on his team as well as any Fitzgibbons lab personnel who will provide training. The approach might include starting with cadavers and moving to recovery procedures when the team is more skilled. Sturkie would report the results of the pilot study and training to the IACUC and, if results were satisfactory, request approval of the protocol. A teamwork approach to provision of training and ensuring proficiency would be in the best interest of the animals, the personnel and the science.

1. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
2. Animal Welfare Act and Animal Welfare Regulations. 9 CFR.

Kuhlman is Senior Principal Scientist at Merck Research Laboratories, Rahway, NJ and Iliff is Principal Scientist at Merck Research Laboratories, Kenilworth, NJ.

RESPONSE

Approve protocol

Sylvia Allen, RLAT, ILAM & Mary E. Martin, DVM, MPH, DACLAM

In this situation, we feel that the protocol can be approved with the understanding that the surgical training would occur as proposed and the Sturkie lab would not do

unsupervised surgery until the AV signed off on the training. Although the *Guide for the Care and Use of Laboratory Animals* (the *Guide*)¹ states, "The IACUC, together with the AV, is responsible for determining that personnel performing surgical procedures are appropriately qualified and trained in procedures," it does not specifically state that this must be done prior to protocol approval. If the protocol is approved, then the Sturkie lab can start working on other non-surgical aspects of the protocol. Meanwhile, the IACUC and the AV can work with the Sturkie lab to achieve the required proficiency in cardiac artery ligation.

As Sturkie wrote in his protocol, the AV could oversee the training of his lab by the Fitzgibbons lab members, who are proficient in the technique they will be using. The mice that had been euthanized for another purpose could be used to train the Sturkie lab in the cardiac artery ligation procedure. Once the AV was confident in their skill level, members of the Sturkie lab could then move on to the next step (which Sturkie outlined as non-survival surgery) and then finally to survival surgery. If the AV was uncomfortable with anyone's proficiency, he could prohibit that person from advancing to the next level.

With careful post-approval monitoring, the group could proceed with the study. The Sturkie lab should regularly report the results of their surgeries and perform necropsies on mice that did not survive. Knowledge gained from the necropsies will help them refine their techniques and increase survival rates. Periodically, the AV could observe their surgeries and help them fine-tune their technique and increase their survival rate.

We feel this protocol should be approved but that Sturkie must follow the steps outlined in the protocol for completing the required training, with the AV monitoring the progress to ensure proficiency in the technique. This will allow the research to proceed while the regulations governing animal welfare and personnel training are observed.

1. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).

Allen is Supervisor, Weill Hall Transgenic Mouse Facility, and Martin is Chief, Veterinary and Educational Services, Center for Animal Resources and Education, Cornell University, Ithaca, NY.