Jerald Silverman, DVM, Column Coordinator

Training and feasibility protocols: acceptable under current laws and standards?

The Great Eastern University IACUC worked conscientiously to assure compliance with the laws, regulations, and guidelines that apply to the use of animals in research. Nevertheless, the Committee was aware that the protocol review process, when not performed in a timely manner, could interfere with conduct of faculty research. The Committee also felt that writing a new protocol, or even amending an existing protocol, was a lot of work if the purpose of the study was only to learn a new procedure or explore a novel technique that was not already in an existing protocol. As one investigator said, "It just sucks the spontaneity right out of the research process."

In an attempt to address this problem while still assuring regulatory compliance, the IACUC developed a plan. The Attending Veterinarian (AV) developed a 'training and feasibility' protocol in his name. It allowed investigators to learn or attempt new procedures that were not included in their approved protocol. A university veterinarian was either to perform these procedures personally or directly supervise their performance. Some of these techniques were standard (e.g., subcutaneous injections), while others were more involved (e.g., a new surgical technique). In either case, the protocol

did not spell out the specific details of the procedures because they varied according to the specific research needs of the faculty. The IACUC insisted on several safeguards that they thought made this protocol acceptable. For example, the purpose of performing the procedures was either for training or to explore the feasibility of a new procedure, but not to collect data for publication. Also, this was not to be an end run around the protocol review process to conduct pilot studies, which required IACUC review. Animals were to receive analgesics, or better, general anesthesia before undergoing procedures that might cause pain or distress, even if the eventual experimental design was to involve no drugs. Surgical procedures would be nonsurvival unless recovery from anesthesia was essential to evaluate the success of the procedure. A veterinarian had to be physically present during the procedure. If in doubt about the appropriateness of a request, the AV would consult with the IACUC Chair. If the Chair had any reservations, the investigator would have to submit a protocol, or a decision would be put off until the full Committee could discuss it. Finally, the AV would report to the Committee each month on the procedures the veterinarians had performed.

The protocol was in effect when Dr. Wade Aminit, the new AV, joined Great Eastern. Aminit was uncomfortable with the protocol, feeling that the Great Eastern IACUC had gone too far in trying to accommodate researchers. There were two items on the agenda of the upcoming IACUC meeting that highlighted Aminit's concerns. In the first instance, an investigator wanted to explore new anesthesia methods for frogs. Working with a university veterinarian, the investigator tried several combinations of injectable anesthetics under the training and feasibility protocol. One combination seemed to work best, and the meeting agenda included an amendment from the investigator to include the new anesthetic regimen in his protocol. In the second instance, Aminit had been asked to use the training and feasibility protocol to try a new surgical procedure on five rats, but he first wanted the full Committee to discuss it. An investigator had performed the procedure on dogs under an IACUC-approved protocol, but with new technologies recently made available, he felt he could miniaturize the process and do the work in rats.

The IACUC Chair opened the discussion to the Committee's members. What would be your opinion of the training and feasibility protocol if you were on the Great Eastern IACUC?

RESPONSE

Details missing

Greg Stickrod, MS, LATG & Doug Miller, BS, LATG

Training and feasibility protocols make good sense for just the reasons this Committee has cited. It would be silly to create a new protocol or amendment every

time someone was going to be trained on subcutaneous injections. Moreover, such a protocol allows investigators a degree of scientific spontaneity; this is valuable, but it must also comply with regulations. The training and feasibility protocol at Great Eastern is basically sound. The safeguards are relatively well thought out and include: veterinarian in attendance, anesthesia and analgesia required, terminal procedures required (unless recovery was essential for evaluation), IACUC Chair involvement

with option for full Committee review, pilot studies generating publishable data not allowed, and a monthly report from the AV to the Committee.

There are, however, areas of vulnerability in this protocol that could lead to problems with regulatory compliance. The AWARs and PHS *Policy* require protocols to include the following: (1) identification of the species and the approximate number of animals to be used; (2) a rationale for involving animals,