Jerald Silverman, DVM, Column Coordinator

PI and Vet: Potential Conflict of Interest?

There was nothing particularly unusual about Dr. Ed McKeown's protocol. He was working with inbred Syrian golden hamsters, and his studies required repeated measurements of forced activity over the course of a month. The research involved placing the animals, all of which had cardiomyopathy and were being treated with investigational drugs, on treadmills and other apparatuses. This provided McKeown with a partial assessment of the value of those drugs in helping to ameliorate the hamsters' cardiac condition. If there was a problem, it was that McKeown was a veterinarian and he wanted to make all decisions about the health care of his animals. He told the IACUC that these were not ordinary hamsters, and with all of his years of experience working with them, he was the best person to assess and provide for their health care.

This position did not sit well with the lab animal veterinarians at Great Eastern University. They believed that through one of their own, the Attending Veterinarian (AV), they had the ultimate responsibility for the care of animals on campus. They were not about to cede responsibility for those research animals to an individual investigator, even if that person was a veterinarian. Their basic argument was that there was a conflict of interest that included, but also went beyond, basic medical care. For example, they told the IACUC that there were issues of proper husbandry that were intricately linked to animal health, and euthanasia decisions that would probably become necessary. Having the Principal Investigator (PI) unilaterally make those decisions was not, they contended, in the best interests of the animals. "Fine," said McKeown, trying to compromise. "Let the lab animal vets look after the animals' health and let the animal facility staff provide for their husbandry. If they have any concerns, they can come to me. But, when it comes to medical care, I am an acknowledged expert on cardiomyopathy in hamsters and I know which medications to use that will not interfere with my research. There will be an intricate combination of clinical and research decisions. If treating the hamsters will keep them alive a little longer, I want that decision, and the means to do it, to be mine and mine alone. I will be glad to tell the lab animal vets what I will probably do and what drugs I will probably use, but I cannot guarantee things. I have to see the animals and make decisions on the spur of the moment. The same holds for euthanasia. I know when these animals are starting down the road to no return, and that's when I will euthanize them. In fact, I'll even provide the IACUC with the criteria I plan on using to make some of my euthanasia decisions."

The IACUC had a difficult decision to make. Yes, it was true that McKeown was a veterinarian, an expert in hamster cardiomyopathy, and that he knew how to treat his animals. However, as the PI, would he have a skewed point of view? Would it be a conflict of interest for him to have the final say on their health care and euthanasia?

PI Can't Go It Alone

Stacy Pritt, DVM, MBA, J. Fred Nostrant, BS, and Barbara Smith, DVM, MS, PhD, DACVS, DACLAM

According to the *Guide for the Care and Use* of *Laboratory Animals* (*Guide*), an institution's AV needs to have direct or delegated authority to "...give research personnel advice that ensures that humane needs are met and are compatible with scientific requirements¹". The Animal Welfare Regulations (AWRs) stipulate that "Each research facility shall ensure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use². McKeown's statements indicate that this is not occurring in this scenario.

The American College of Laboratory Animal Medicine also provides the following comments: "The veterinarian must have the authority and responsibility for making determinations concerning animal well-being and assuring that animal wellbeing is adequately monitored and promoted. The veterinarian must exercise this responsibility in review of animal care and use protocols, and must have the authority to remove an animal from an experiment which is adversely affecting its well-being beyond a level reviewed and approved by the IACUC³".

Even though McKeown may have acknowledged expertise in the field of cardiomyopathy in hamsters, there are regulatory aspects to and IACUC oversight of the animal care and use program that come into play in which the AV is an integral link. Having the investigator tell the AV and other laboratory animal veterinarians what he "probably" will do does not fulfill the requirements of the applicable regulations, guidances, and laws. Additionally, the investigator is omitting the necessity of having "...timely and accurate information on problems of animal health, behavior, and well-being ... conveyed to the attending veterinarian" by being solely involved in the provision of veterinary care to these animals².

The investigator should have plans covering the care and treatment of the animals, what drugs will be used, and the criteria for