

Terminal procedures: Should an IACUC require a literature review for less painful alternatives?

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This was one of those times when Ken Bailey, the IACUC director at Great Eastern University, just wanted to put his hands to his face, cover his eyes, and say “you can’t possibly be serious.” But Dr. Seana Mann, the USDA veterinary medical officer, was totally serious. During a routine facility inspection Mann reviewed many IACUC-approved protocols, but only one was of concern to her. In that study dogs were placed under deep terminal anesthesia and the thorax was opened by a sternotomy. The investigator then placed electrical recording and pulsing leads on different parts of the heart and when that

part of the study was completed, the heart was removed for histologic examination.

Mann’s concern was that the protocol had no literature or related search for alternatives to the sternotomy. Confused, Bailey asked Mann if she meant that there should be a literature search for alternatives to using a live animal, but Mann replied that such a search was done. She said there should have been a search for an alternative less painful method of entering the thorax to perform the study. “Why does that matter?” said Bailey. “This was an acute procedure performed under general anesthesia. The dog never regained

consciousness. What difference does it make if the heart was visualized by a sternotomy, laparoscopy, spreading the ribs or some other means? It was a terminal procedure.”

Nevertheless, Great Eastern was issued a citation for a violation of the Animal Welfare Act regulations. Do you think the university should appeal the citation or teach investigators and protocol reviewers to include a literature search to help determine whether or not a terminal procedure performed under general anesthesia could be performed in a manner that would cause less pain or distress had it been a nonterminal procedure?

RESPONSE

Training and education

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First, in order to determine if the citation should be appealed, we should ask whether the Great Eastern University IACUC considered this procedure to be euthanasia or a non-survival surgery and what USDA pain category was identified in the protocol.

The intent of this procedure was to obtain readings on an animal’s heart and subsequently remove it for examination, from which the animal(s) will obviously not recover. The Great Eastern University IACUC should consider the definition of euthanasia, and whether a sternotomy performed under deep terminal anesthesia meets the intent of the definition. According to the Animal Welfare Act (§ 1.1; ref. 1), euthanasia is “accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress”. A prolonged surgical procedure that requires manipulation of an animal’s tissues under anesthesia prior to euthanasia does not meet this criteria and

should be classified as a non-survival surgery.

The question now becomes whether the pain category was appropriately assigned to these animals. Exposure of a major body cavity would be painful and require the use of anesthesia and should have been described as USDA pain category D. Next we need to ask, did the Principal Investigator (PI) consult with the Attending Veterinarian (AV) when planning the protocol? Procedures that have the potential to cause more than slight or momentary pain or distress require a veterinary consultation in the protocol planning stages and investigators are expected to provide documentation to the IACUC that alternatives were considered (§ 2.31,d,ii and § 2.31,d,iv,B; ref. 2). The IACUC, in turn, should have also confirmed that the research activities met the requirements for approval under the Animal Welfare Act, taking into consideration “procedures with animals will avoid or minimize discomfort, distress, and pain to the animals”³. Just because the dogs never regained consciousness does not mean the procedure itself was any less painful and alternatives should still have been considered.

Instead of appealing the citation, Great Eastern University should re-review their

institutional policies for training, education, and protocol review. As an example, the Great Eastern PI should have consulted with the AV who might have identified a refinement of technique with an alternative less-painful procedure. Moreover, consideration of alternatives, including refinement, reduction, and replacement⁴, is an important component of a well-functioning training program for investigators and IACUC members and goes beyond surgical proficiency and aseptic techniques. Equally important, IACUC members should be retrained on their oversight and responsibilities, including training on review of the “availability and appropriateness of the use of less invasive procedures” during protocol review⁴. Great Eastern University has a responsibility to ensure its investigators and IACUC members are provided with the resources to fulfill their roles in the animal care and use program.

1. Animal Welfare Act Regulations, 9 CFR, Part 1.
2. Animal Welfare Act Regulations, 9 CFR, Part 2, Subpart C.
3. Public Health Service. *Policy in Human Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).