

a sound research model, if the unaffected leg was previously considered the control? Can animals that underwent a single procedure still be compared with those that underwent a double procedure, even though they had different endpoints and clinical conditions? The IACUC should have considered these and other issues as well.

We believe that the IACUC made the right decision in this specific scenario; however, there may be instances in which reduction is rightfully prioritized over refinement (e.g., where comparison of variables in one animal serving as its own control would be more scientifically valid than using many more animals, creating more variables). Animal research is predicated on the concept of the 'greater good', with the goal of understanding pathogenesis and developing therapies to benefit "human or animal health, the advancement of knowledge, or the good of society"⁴. Using fewer animals to support those lofty goals may be a good thing, as long as those few animals are used in a way that is humane and scientifically sound. With vigorous management by veterinarians and appropriate oversight by the IACUC, pain or distress can be minimized or even eliminated.

1. Russell, W.M.S. & Burch, R. *The Principles of Humane Experimental Technique* (Methuen and Co., London, 1959).
2. Code of Federal Regulations. Title 9, Chapter 1, Subchapter A – Animal Welfare: Part 2 Regulations.
3. United States Department of Agriculture. *Animal Care Resource Guide Policies*. Policy #14: Major Survival Surgery. (United States Department of Agriculture, 25 March 2011).
4. Public Health Service. *US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* (US Department of Health and Human Services, Washington, DC, 2002).

Hallman is Director of Animal Welfare and Panchella is Compliance Manager in the Office of Regulatory Affairs, University of Pennsylvania, Philadelphia, PA.

RESPONSE

Too many problems

Christine Boehm, MEd, DVM, MS, DACLAM & Tanise Jackson, DVM

The Animal Welfare Act makes it clear that multiple surgical procedures included within

one protocol must be justified for scientific reasons and preapproved by the IACUC^{1,2}.

We feel that Wycoff has not adequately justified the scientific reasons. His argument about subjecting fewer animals to more pain is not scientific. Wycoff also proposed only "adequate" pain control. The definition of adequate is open to interpretation but may imply that there is room for improvement. One way that Wycoff could convince the IACUC that he is concerned about pain control would be to use a pain scoring sheet detailing the frequency of monitoring and any plans to increase administration of pain-relieving medications if indications of pain or discomfort are observed.

Wycoff has also not addressed the issue of appropriate controls for his study by consulting with a statistician. One might assume that un-elongated tibial tissue would be used as a control; in animals undergoing a single procedure, the unaffected leg would serve this purpose, allowing each dog to serve as its own control. It is not clear what the control would be in animals undergoing procedures on both hind limbs. A lack of appropriate controls could result in Wycoff needing to re-do his experiments, not only causing more pain and distress but also increasing the number of animals used on the protocol.

In addition, Wycoff needs to re-read the definition of a major operative procedure. Although his proposed procedures do not expose a body cavity, they do involve extensive tissue dissection or transection, which places them in the category of a major operative procedure³. These procedures must be justified adequately and scientifically in his protocol.

Were Wycoff able to adequately justify the procedures, he would still need to address the issue of the animals' welfare post-operatively. Stating that he will provide mobility carts does not assure that the animal's welfare is addressed. The dogs should be acclimated to the carts before the procedures to help identify which dogs are better surgical candidates than others. Dogs that do not acclimate, as determined by a veterinarian, should not be included in the study. An acclimation plan would perhaps give the IACUC more confidence in the investigator's research proposal. Wycoff also does not address how the dogs will be managed while they are sleeping (when most dogs prefer

a lateral position) or how dogs would be prevented from attempting to jump up from a sleeping position.

We feel the IACUC acted appropriately in denying the amendment until Wycoff has adequately addressed issues of pain control, multiple operative procedures, appropriate study controls and other welfare issues.

1. United States Department of Agriculture. *Animal Care Resource Guide Policies*. Policy #14: Major Survival Surgery. (United States Department of Agriculture, 25 March 2011).
2. Code of Federal Regulations. Title 9, Chapter 1, Subchapter A – Animal Welfare: Part 2 Regulations (§2.31).
3. Brown, M.J., Pearson, P.T. & Tomson, F.N. Guidelines for animal surgery in research and teaching. *Am. J. Vet. Res.* **54**, 1544–1559 (1993).

Boehm is Assistant Director, Laboratory Animal Resource Center, School of Medicine, Indiana University, Indianapolis, IN, and Jackson is Director, Animal Welfare and Research Integrity, Division of Research, Florida A&M University, Tallahassee, FL.

RESPONSE

Flawed reasoning

Regina Correa-Murphy, RLATG, CMAR, ILAM

Wycoff's contention that the surgeries proposed were not operative procedures because they do not penetrate and expose a body cavity or cause real permanent physical impairment is flawed. Although the most common definition of 'major surgical procedures' refers to those that penetrate and expose a body cavity, the *Guide for the Care and Use of Laboratory Animals*¹ also includes surgeries that produce substantial impairment of physical or physiological functions (e.g., joint replacement or limb amputation) in the definition of that term. Bilateral tibial bone elongation, as described in Wycoff's proposal, clearly falls into this category of a major surgical procedure. The designated IACUC reviewers also erred in the use of the term 'multiple' as applied to the operative procedures. The proposed operative procedures are not multiple major operative procedures, because the animals will not be anesthetized and subjected to additional surgical manipulation after a recovery period¹.

Wycoff's premise that fitting the animals with carts to aid their mobility means