

of objective and authoritative information. Reviews by SRGs certainly are both objective and authoritative. By ignoring the SRG's advice in this particular case, Great Eastern University's IACUC may have insisted on a study design that will produce flawed results, thereby needlessly wasting animal life and postponing the development of a valuable treatment for deafness.

1. 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).
2. Animal Welfare Regulations. Section 2.31, a.
3. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals—Frequently Asked Questions*. Protocol Review, Question D-12. (US Department of Health and Human Services, Washington, DC, 2006; revised 2010). <<http://grants.nih.gov/grants/olaw/faqs.htm>>
4. Office of Laboratory Animal Welfare. *Instructions for Completion and Peer Review of the Vertebrate Animal Section (VAS) in NIH Grant Applications and Cooperative Agreements*. Notice NOT-OD-10-027. (National Institutes of Health, Washington, DC; 17 March 2010).
5. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
6. Silverman, J., Suckow, M.A. & Murthy, S. *The IACUC Handbook* 2nd edn. (CRC Press, Boca Raton, FL, 2007).

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## RESPONSE

### IACUC overstepping its bounds

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Jocelyn D. Penner, DVM, Diplomat ACLAM**

We do not believe that the decision about the study design should be based on the fact that the concern was raised by an NIH review team, as implied by the narrative. Instead, the argument about appropriate study design should be based on technical merit, specifically the concern that the pharmacokinetics of the agent may result in both ears being exposed to the agent. The NIH raised

a legitimate concern regarding the validity of the study's results. Protocols should be reviewed as defined by OLAW's *Institutional Animal Care and Use Committee Guidebook*<sup>1</sup>, which includes the following statement (Principle II): "Procedures involving animals should be designed and performed with due consideration of their scientific relevance to human or animal health, the advancement of knowledge, or the good of society."

Because no IACUC can know everything, we hope every committee would welcome information from reliable sources. Although the IACUC may not be required to consider the opinions of peer review, it is acceptable and encouraged for the committee to use technical information from experts in the field. The Animal Welfare Act<sup>2</sup> states that "the IACUC may invite consultants to assist in the review of complex issues arising out of its review of proposed activities." Perhaps more to the point, however, earlier in the same section<sup>3</sup>, it also states, "Except as specifically authorized by law or these regulations, nothing in this part shall be deemed to permit the Committee or IACUC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility."

The IACUC is dictating Smith's study design. The committee can and certainly should ask why he needs the separate control group, but it has no right to require him to use each animal as its own control. The NIH reviewers brought up a legitimate concern regarding the use of a cat as its own control, and Smith prepared his protocol to address that concern. Although reduction of animal numbers is an appropriate goal when preparing a research protocol, using fewer animals at the cost of good science is senseless. If the proposed study results were invalid because animals were used as their own controls and the study had to be repeated using the proper controls, then the animals would have been used wastefully.

The question of appropriate controls is a valid technical concern, and it should be judged on that basis alone, regardless of who raised the issue. The IACUC does need to embrace the three Rs (reduction, replacement and refinement), and how it does so is very much influenced by the limitations imposed by technology and state of the science. A number of experimental

approaches and possible side studies could be proposed to determine what sort of controls are appropriate for the study (e.g., monitoring the agent in the blood after administration), some of which could require even more animals than presently requested. The IACUC should not dictate to Smith how to do his research and should approve the protocol as originally submitted. We side with Smith on this issue, unless the IACUC can show that no benefit can be gained by the use of a control group of cats.

1. Office of Laboratory Animal Welfare. Appendix F. *Institutional Animal Care and Use Committee Guidebook* 2nd edn. (US Department of Health and Human Services, Washington, DC, 2008).
2. Animal Welfare Regulations. Ch.1, Subpart C, 2.31, d (3).
3. Animal Welfare Regulations. Ch.1, Subpart C, 2.31, a.

Poston is the Institutional Official; Thrall is the IACUC Chair; and Penner is the Attending Veterinarian for the Animal Welfare program at Battelle Memorial Institute's operations in Richland, WA.

## RESPONSE

### Help IACUC understand the science

**Stephen I. Levin, DVM, PhD, DACLAM,  
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CPIA & Diana M. Palila Berger, DVM, MS**

This scenario raises the issue of an IACUC's authority to carry out scientific and technical reviews of animal research projects. The Animal Welfare Act and Regulations (AWARs)<sup>1</sup> and Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*<sup>2</sup> provide only limited guidance on this subject. The AWARs indicate that "except as specifically authorized by law or these regulations, nothing in this part shall be deemed to permit the Committee or IACUC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility."<sup>1</sup> Although the IACUC should evaluate the "rationale for involving animals, and for the appropriateness of the species and the numbers of animals to be used,"<sup>1</sup> the IACUC does not have the authority to dictate a reduction in animal numbers, especially if Smith has provided a valid scientific