

funding agency. That decision could affect the institution's compliance with the AWA and the PHS *Policy*, which will in turn impinge on many investigators' funding.

#### References

1. Van Sluyters, R.C., Simpson, J.E. & Dell, R.B. in *The IACUC Handbook* (eds. Silverman, J., Suckow, M.A. & Murthy, S.) 2.4 (CRC Press, Boca Raton, FL, 2000).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals III.B* (US Department of Health and Human Services, Washington, DC, 1986).

**Santiago is Animal Subject Compliance Coordinator, DLAR, New York University, New York, NY.**

## IACUC Should "Get Tough"

**Sylvia Kondo, BS, DVM and James Stevens, DVM, PhD**

One can infer the requirement that the IACUC inspect an animal holding site before its occupancy from the various guidelines pertaining to NIH-funded research. The *Guide* states clearly that "a strategy for achieving desired housing should be developed by animal-care personnel with review and approval by the IACUC<sup>1</sup>." According to the *PHS Policy*, the IACUC is charged to inspect, at least once every six months, all of the institution's animal facilities (including satellite facilities) using the *Guide* as the basis for evaluations. And according to the *PHS Policy*, the definition of an animal facility is "[a]ny and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours<sup>2</sup>." In this case, Foulke chose to house his animals in microbarrier cages inside of a Class II biosafety cabinet in his laboratory. That clearly makes the laboratory a satellite facility, under the definition, and it comes under the jurisdiction of the IACUC.

Neither the animal-care personnel nor the IACUC had an opportunity to develop a housing strategy independent of the Department of Animal Resources for the animals in question.

According to *PHS Policy*, the IACUC must also "review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing studies<sup>3</sup>." As such, the IACUC is charged by the *Policy* to "determine that the living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and non-medical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained<sup>4</sup>." Although Foulke had an IACUC-approved protocol, he failed to seek the necessary approval from the IACUC or modifications before beginning activities with animals. These modifications included housing his animals in a new "animal facility" (a Class II biosafety cabinet in his laboratory), using his laboratory technician to care for the animals (there is no information regarding whether the technician is trained in animal-care procedures), having no mechanism for proper veterinary care, transporting his own animals in a nonapproved vehicle (his car), and, presumably, using procedures that had not been approved for his protocol for care and handling of these animals. In addition, Foulke's actions posed potential health and safety issues for those in the laboratory where the mice were temporarily housed. Because he did not follow proper quarantine procedures that were written and established at the institution, he could potentially have adversely affected the other animals housed in the animal facility at Great Eastern had he been successful in placing them there when space became available. These modifications had the potential to compromise severely the health of the animals as well as the animal care and use program at both institutions. The incident should have resulted in a report to the OLAW as a substantial breach of *PHS Policy*.

The Great Eastern IACUC was in principle correct in its actions, but it should have focused on the broader picture regarding Foulke's noncompliance. They allowed him to exploit one aspect of his noncompliance—his failure to have the IACUC inspect and approve an animal housing area before occupancy. Although this is a very important point, the main issue here is Foulke's total disregard for attaining approval for the numerous modifications that resulted in his attempt to usurp the system. The IACUC should instruct Foulke to notify the Animal Resources Department immediately and request housing of the animals in quarantine according to established policy. This would place additional stress on the department because quarantine space was already at a premium. To prevent future misunderstandings, the institution should have a clearly written internal policy that summarizes the guidelines, which support the obligation of the IACUC to inspect and approve an animal facility before occupancy. That policy should also set criteria and guidelines for establishing and operating a satellite animal facility. Foulke should receive clear written notification of the policy in its entirety. Because the university dean is the IO, he or she must be involved in these communications and should listen to the IACUC with the ear opposite to the one that Foulke has.

#### References

1. Institute for Laboratory Animal Resources, National Research Council. *Guide for the Care and Use of Laboratory Animals 22* (National Academy Press, Washington, DC, 1996).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals III.B* (US Department of Health and Human Services, Washington, DC, 1986).
3. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals IV.B* (US Department of Health and Human Services, Washington, DC, 1986).
4. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals IV.C* (US Department of Health and Human Services, Washington, DC, 1986).

**Kondo is Director, Laboratory Animal Service, University of Hawaii, Honolulu, HI; Stevens is Professor of Pathology, University of Colorado School of Medicine, and Consulting Veterinarian, Denver VAMC, Denver, Colorado.**