We feel that pushing noncompliance under the rug is the wrong thing to do. Minor issues can build up quickly and become larger problems. All noncompliant events need to be handled the same way. The sanctions should be understood, and investigators should know what will happen if they choose not to comply. A culture of compliance should be built on trust between the investigators, the IACUC and the regulatory agencies. As laboratory animal professionals, we must promote animal welfare, not hide it.

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

Coan is Director, Hill is the Assistant Director and Adams is Clinical Veterinarian, Office of Laboratory Animal Care, University of Tennessee, Knoxville, TN.

RESPONSE

Retraining required

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Covelli should be proud of the swift action the IACUC took in this instance, but he overreacted to the situation. His statement about hiding animal welfare or noncompliance issues “under the rug” from regulatory agencies is a path to the ‘dark side’. Regulations exist to protect the animals and the research they represent, as well as the institution. Concealing the issue is counterproductive and harmful. If noncompliance issues or other problems are covered up and then discovered at a later date, it can be devastating. This is the fodder that activist extremists live for.

One of the IACUC’s mandates is to ensure that research is done in accordance with regulations and with the utmost concern for the care and well-being of the animals involved. Open discussion is vital in these sessions, so that concerns can be brought forth and acted upon, and a record should be kept of all discussions in case a problem arises at a later date. Anything said at an IACUC meeting is subject to review, and occasionally, the IACUC may find that it

A word from OLAW and USDA

In response to the questions posed in this scenario, the Office of Laboratory Animal Welfare (OLAW) and United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) offer the following clarification and guidance:

In making these comments, we assume that the PHS *Policy on Humane Care and Use of Laboratory Animals*¹ (PHS *Policy*) applies in the given scenario, either because the research is PHS-supported or because the institution’s Assurance includes a commitment to apply a uniform standard to all animal activities. As required by the PHS *Policy* (section IV.F.3), the IACUC, through the Institutional Official, is required to promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to serious noncompliance with the PHS *Policy*¹. This incident is a serious noncompliance, despite full recovery of the sheep, because an animal activity was conducted without IACUC approval. Great Eastern must report this incident to OLAW. If in doubt about a particular circumstance, a preliminary phone call to OLAW can help to clarify expectations and to address reporting parameters. As detailed in previous OLAW guidance on reporting noncompliance, “Reporting promptly to OLAW serves dual purposes. Foremost, it ensures that institutions deliberately address and correct situations that affect animal welfare, PHS-supported research, and compliance with the *Policy*. In addition, it enables OLAW to monitor the institution’s animal care and use program oversight under the *Policy*, evaluate allegations of noncompliance, and assess the effectiveness of PHS policies and procedures”². OLAW views such reporting as evidence that the institution’s system of oversight is effective. OLAW expects an institutional climate that promotes compliance, relevant internal policies, adequate training, effective checks and balances and open communication channels within the institution and with NIH. Reporting noncompliance is a cooperative process in which OLAW provides assistance and guidance to the institution.

Conducting an animal activity without IACUC approval is also a serious noncompliance with the Animal Welfare Act and Regulations (AWARs)³. When an IACUC has already taken action with regard to such a noncompliance, inspectors may use their own judgment as to whether to issue a citation, depending on whether or not the action taken is deemed appropriate. In this case, the inspector apparently considered the IACUC’s action to be insufficient, because he cited the facility for inadequate training as well as for conducting an activity without approval. The fact that two of the facility’s investigators did not recognize that their actions were noncompliant does raise questions about the adequacy of the overall training of Great Eastern’s investigators, which does not seem to be an area discussed by the IACUC. There is insufficient information in this short scenario to determine whether or not the citation was appropriate, but the inspector and Covelli should have discussed their apparent disagreement about the facts of the citations and attempted to address such issues at the time of the inspection. If they were unable to resolve any concerns, Covelli could have appealed the citations⁴. USDA/APHIS/Animal Care realizes that disagreements are a natural part of regulatory oversight and has established the appeal process to address such situations. We consider compliance with the AWARs to be a cooperative process and hope that regulated facilities see the process in this same light.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
2. Office of Laboratory Animal Welfare. *Guidance on Prompt Reporting to OLAW. NOT OD-05-034*. (National Institutes of Health, Washington, DC; 24 February 2005; updated 15 April 2010).
3. Code of Federal Regulations. Title 9, Chapter 1, Subchapter A – Animal Welfare: Part 2 Regulations (§2.31).
4. United States Department of Agriculture. *Research Facility Inspection Guide*. Section 7.8 Inspection Appeals Process. (United States Department of Agriculture, Washington, DC, 2001). <http://www.aphis.usda.gov/animal_welfare/downloads/manuals/rig/section/7.8_rig.pdf>

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