

has not been given all of the information that it needed. But upon discovery of such gaps, the IACUC has the opportunity to remedy the situation and self-report. Given the opportunity, most investigators will comply with rules and regulations.

Simple protocol revisions or amendments, such as the biopsy in this scenario, can be submitted to the IACUC and quickly acted upon for approval. Even though the sheep in this scenario recovered without incident, the biopsy does represent noncompliance with an animal use protocol. Therefore, NIH/OLAW¹ and the funding agency should have been notified, if only to ask for guidance in the matter and the measures taken by the IACUC. Although this is not required specifically, USDA should have been notified as a courtesy. The Institutional Official, of course, would receive a written report of the incident.

In this instance, the protocol deviation did not result in animal suffering or harm, and the PI suspended the activity. At issue is whether the IACUC's letter of reprimand and Covelli's notification of protocol noncompliance (retraining) was adequate, or whether the initial IACUC protocol compliance training received by the investigator was insufficient, thus creating the conditions underlying the noncompliance of this instance. In this light, the IACUC may have considered undertaking a review of the adequacy of training received by investigators, as well as the IACUC², to assure compliance with regulations of the IACUC, the Animal Welfare Act³ and the PHS. The IACUC should also have reviewed the institution's PHS Assurance Statement, which should also clearly delineate reportable actions and the agencies that should be notified.

The USDA inspector was within his or her jurisdiction to cite the IACUC for a training issue³, but it may have been more appropriate to address this concern informally at the exit interview. From the information given in this scenario, it is not possible to form an informed opinion on the

overall quality of the institution's training program. In consideration of the swift, though possibly incomplete, action taken by Covelli and the IACUC upon discovery of the incident, the citation may well have been modified or at least presented along with an explanation that action by the IACUC was taken in a timely manner, even though it failed to include retraining. Covelli could have registered a protest of the finding as well. Although receiving a citation was not wonderful, Covelli has been given an opportunity to revisit the existing training program for investigators and IACUC members to ensure that this type of problem does not recur in the future.

1. Office of Laboratory Animal Welfare. *Guidance on Prompt Reporting to OLAW. NOT 00-05-034*. (National Institutes of Health, Washington, DC; 24 February 2005; updated 15 April 2010).
2. ARENA/OLAW. *Institutional Animal Care and Use Committee Guidebook* 2nd edn. 27 (Office of Laboratory Animal Welfare, Bethesda, MD, 2002).
3. Animal Welfare Act Regulations, 9 CFR (Section 2.32).

Croxford is Training Facilitator and Smiley is Senior Veterinarian in the Division of Laboratory Animal Resources, University of Kentucky, Lexington, KY.

RESPONSE

Reasonable and right

Richard C. Simmonds, DVM, MS

Given the information presented in the scenario, the initial responses of Great Eastern University's IACUC and veterinarian were completely in accordance with the concept of self-regulation that forms the basis of the PHS *Policy on Humane Care and Use of Laboratory Animals*¹ and the original intent of the Animal Welfare Act². I also agree with the stated position of the IACUC, that the noncompliance "was not serious enough to inform NIH/OLAW of the incident and its resolution." Further, the fact

that the IACUC's discussion of the incident was well-documented in the Committee's minutes is evidence that the University was not attempting to hide the incident.

In responding specifically to the two questions posed at the end of the scenario, I make three assumptions about facts not presented in the scenario: (i) the two investigators involved were both in good standing with the IACUC, (ii) the University had not been previously cited for investigator training deficiencies (iii) and the USDA inspector had not discovered other alleged noncompliance aspects of the institution's training program on this site visit. Given these assumptions, I believe that Covelli had not only a "reasonable" complaint, but a fully justified one! The inspector's unreasonable, overzealous decision to cite the University for "inadequate training of research personnel and for not having an appropriate proposal to conduct an animal activity" indicates a serious lack of professional judgment, probably fostered by APHIS' preposterous emphasis on 'gotcha' inspections, with inspectors being evaluated on the basis of how many citations they issue. Rather than being cited, Great Eastern should have been complimented (at least orally by the inspector, if not in writing on the inspection report!)

Secondly, I believe this kind of overzealousness on the part of any regulatory inspector serves to stifle open and full discussion about any regulatory issues, if the discussion is going to be recorded in official minutes available to regulatory inspections. It is only reasonable to expect humans to avoid potential negative repercussions from any such open discussion.

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. Animal Welfare Act Regulations, 9 CFR.

Simmonds is Emeritus Director, Laboratory Animal Medicine, Nevada System of Higher Education, and Emeritus Professor of Physiology, School of Medicine, University of Nevada, Reno, NV.