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## Citation for a discussion of noncompliance

Dr. Larry Covelli was proud of the IACUC he chaired at Great Eastern University. There was a culture of thorough but reasonable protocol reviews, open discussions at meetings and an honest effort to balance animal welfare with research requirements. Why, then, was he morose and bitter after talking to the IACUC Administrator?

Unknown to the IACUC, an investigator without an IACUC protocol was given a single-needle biopsy sample taken from the liver of a sheep that was being used in a survival abdominal surgical procedure for an unrelated purpose. The sheep study did have IACUC approval, but the approval did not include the biopsy. The Principal Investigator (PI) of the sheep study thought he was just doing a favor for a colleague who needed a small sample of liver tissue. In fact, as was later learned, the PI thought he was reducing animal usage because his colleague would not have to use an entirely separate animal for the biopsy. As for the sheep, she recovered uneventfully.

All of this occurred on a Monday, and by the next morning, Covelli knew of the incident. He quickly contacted both investigators, told them why they were noncompliant with NIH/OLAW policy and USDA/Animal Care regulations, and stated that no further biopsies were to be done without an approved protocol amendment or a new protocol. Coincidentally, the monthly IACUC meeting took place that Wednesday, and at the meeting, Covelli dutifully reported what had transpired. After a discussion, the committee concluded that the actions taken by Covelli were appropriate and voted to send a letter of explanation and reprimand to both investigators. Although the incident was a protocol noncompliance, the discussion and vote indicated it was not serious enough to inform NIH/OLAW of the incident and its resolution.

Some months later, during a routine USDA/Animal Care inspection, the inspecting veterinarian read the minutes of the IACUC meeting during which the sheep

incident was discussed. He then cited Great Eastern for inadequate training of research personnel and for not having an appropriate proposal to conduct an animal activity. Covelli was mortified. “My God,” he said, “if there was ever a reason to hide animal welfare problems under the rug, this is it. There was no requirement for us to report anything to the USDA but we got slammed nevertheless for just discussing it. And now it’s going to be publically posted and blown out of proportion. Why not just cite us for every repair order that’s submitted or every time the vets ask a PI to change an anesthetic dosage. This is ridiculous and untenable!”

Now we know why Covelli was morose and bitter. But did he have a reasonable complaint, or was he just angry that Great Eastern received an IACUC-focused USDA citation while under his watch? Do you think Covelli was right when he implied that less will be said at future IACUC meetings about protocol noncompliance with USDA-covered species?

### RESPONSE

#### Don’t hide it

**Patricia N. Coan, DVM, PhD, DACLAM,**  
**William A. Hill, DVM, MPH, DACLAM, CPIA**  
**& Joleen K. Adams, DVM**

Although the investigators thought they were being mindful in reducing animal numbers, the fact remains that animal procedures were carried out without IACUC approval.

Should the USDA have been notified? The institution was not required to report to the USDA, as the IACUC did not suspend the protocol (9 CFR 2.31.d.7)<sup>1</sup>. According to the PHS *Policy on Humane Care and Use of Laboratory Animals* (IV.F.3.a)<sup>2</sup>, however, OLAW could have been notified: “The IACUC, through the Institutional Official,

shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to: any serious or continuing noncompliance with this Policy.” Could the institution report a noncompliant event to OLAW? Yes; carrying out animal procedures without IACUC approval is a serious noncompliance. This can be considered a reportable offense, depending on the institution’s IACUC procedures and policies.

Should the USDA cite noncompliant incidents that have already been identified and resolved? The liver biopsy was not a part of the original protocol, and so it was carried out without IACUC approval. The USDA can cite noncompliant incidents that happened previously. Perhaps the USDA did not think that the institution took appropriate corrective action by just sending a letter of reprimand to the

investigators. Was additional training required? What procedures did the IACUC put into place to prevent future occurrences? Was the current investigator training program adequate? Was there post-approval monitoring in place? Did the minutes reflect the discussion of the IACUC regarding compliance issues?

We understand Covelli’s frustration at being cited for something that he thought the IACUC had discovered and handled. The citation was for the noncompliant event, not for the IACUC’s response. The investigators who were involved in the noncompliance obviously needed more training. Covelli must realize that there are many different viewpoints and interpretations by IACUC members and regulatory personnel.

Was Covelli right when he implied that less would be said about noncompliance?

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).

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## RESPONSE

### Retraining required

**Ellen J. Croxford, AA, RLatg, CPIA & Jeffrey R. Smiley DVM, PhD**

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*<sup>1</sup> (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*<sup>1</sup>. 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”<sup>2</sup>. 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)<sup>3</sup>. 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 citations<sup>4</sup>. 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](http://www.aphis.usda.gov/animal_welfare/downloads/manuals/rig/section/7.8_rig.pdf)>

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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/OLAW<sup>1</sup> 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 IACUC<sup>2</sup>, to assure compliance with regulations of the IACUC, the Animal Welfare Act<sup>3</sup> 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 issue<sup>3</sup>, 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).

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## 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*<sup>1</sup> and the original intent of the Animal Welfare Act<sup>2</sup>. 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.

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