

Whether this incident should be reported to Office of Laboratory Animal Welfare (OLAW) depends on whether the study was funded through the Public Health Service, unless Great Eastern's OLAW Assurance Statement indicates that it will report all animal-related incidents regardless of funding sources<sup>1</sup>. The scenario does not specify which species was being used, but this incident may be reportable to the United States Department of Agriculture if it involved a species covered by the Animal Welfare Act or the use in biomedical research of an animal species typically used for food or fiber.

Great Eastern's surgical training program seems to have been approved by its IACUC, as it is covered by a protocol. If the approved surgical training protocol defines the parameters of acceptable aseptic surgical technique, it may not be necessary to further specify those accepted and approved practices in an individual protocol or IACUC policy, unless the technique is an exception to that standard of aseptic surgery that must be approved by the IACUC.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals – Frequently Asked Questions*. Applicability of the PHS Policy, Question A-1. (US Department of Health and Human Services, Washington, DC, 2006; revised 2010). <<http://grants.nih.gov/grants/olaw/faqs.htm>>

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**RESPONSE**

**Report to OLAW**

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Institutions are mandated by the IACUC and through the Institutional Official to report any sanctions or interruptions in protocol activity imposed by the IACUC due to noncompliance or serious deviations from the *Guide for the Care and Use of Laboratory Animals*<sup>1</sup> to the Office of Laboratory Animal Welfare (OLAW) in accordance with federal guidelines such as the Public Health Service

**A word from OLAW and USDA**

*In response to the issues raised 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:*

This commentary assumes that the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*<sup>1</sup> is applicable to this scenario because the research was supported by the Public Health Service or because of the Institution's commitment in its Assurance to apply a uniform standard to all animal activities. It also assumes that the species of animals involved in the research activities are covered under the Animal Welfare Act, regulations and standards.

A review of reportable incidents to OLAW over the last 10 years showed that almost 30% of the cases involved animal study protocol issues, and more than 40% of those involved failure to follow the protocol. The decision as to whether this requires a suspension is up to the IACUC. A suspension must be reported to OLAW, and if species covered by the USDA are involved, it also must be reported to USDA<sup>1,2</sup>. The IACUC has discretion in determining the best remedy for each incident of noncompliance with the protocol. Other corrective actions to consider include retraining and counseling of personnel involved with the infraction, enhanced oversight of the individual or the research activity by the attending veterinarian or other IACUC members and assignment of a mentor for a probationary period.

Great Eastern should not hesitate to report this incident. OLAW and USDA consider this a reportable case because poor surgical technique jeopardizes the health and well-being of animals. This constitutes a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*<sup>3</sup> (the *Guide*). The *Guide* states that persons are to have appropriate training to ensure that good surgical technique is practiced, including asepsis, gentle tissue handling, minimal dissection of tissue, appropriate use of instruments, effective hemostasis and correct use of suture materials and patterns<sup>3</sup>. USDA considers this a violation of sections 2.31(d) (viii) and (ix) of the Animal Welfare Act<sup>2</sup>.

For anyone in doubt about reporting, a phone call to OLAW or USDA can help to clarify expectations and alleviate apprehensions. We encourage institutions to contact us early during the process of dealing with reportable incidents. OLAW's compliance officers and USDA's Veterinary Medical Officers welcome the opportunity to have a preliminary discussion about an incident and to provide guidance on approaches to consider. OLAW regards reporting as evidence that the system of IACUC oversight is working<sup>4</sup>. Conversely, not reporting a noncompliance may result in loss of confidence in the institutional animal program. OLAW's and USDA's acceptance of institutional corrections of reported incidents are based on the effectiveness of those corrections and preventive measures. Although the USDA inspector may still cite the noncompliant item(s) involved, adverse actions against institutions are normally not considered when institutions themselves identify, report and correct noncompliance. Compliance actions affecting an award are rare because institutions are usually able to address incidents successfully and to take appropriate actions to prevent recurrence. The consequences are more serious if an incident is not reported promptly and OLAW or USDA finds out about it through other sources.

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. Code of Federal Regulations, Title 9, Chapter 1, Subchapter A - Animal Welfare: Part 2 Regulations. (§2.31).  
 3. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* (National Academies Press, Washington, DC, 1996).  
 4. Notice NOT-0D-05-034, Guidance on Prompt Reporting to OLAW [online]. <<http://grants.nih.gov/grants/guide/notice-files/NOT-0D-05-034.html>>

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