

(PHS) *Policy on Humane Care and Use of Laboratory Animals*² (Policy). Guidance to PHS awardee institutions and IACUCs on PHS Policy requirements for prompt reporting of noncompliance is provided in the National Institutes of Health Guide and Contracts notice number NOT-OD-05-034 (ref. 3). This guidance is intended to assist IACUCs and Institutional Officials in determining when and how noncompliance should be reported and to promote greater uniformity in reporting.

According to the PHS Policy², conditions that jeopardize the health or well-being of animals, resulting in actual harm or death to animals, should be reported. In this scenario, Linda Girard reasoned that she was overwhelmed with lab work and admitted taking shortcuts in aseptic and surgical technique, contrary to her IACUC training, which led to wound dehiscence and infections. This is definitely an issue of noncompliance and a reportable incident to OLAW. Because of the noncompliance, the Principal Investigator (PI)'s protocol should be temporarily halted until Girard and all personnel listed on the IACUC-approved protocol are retrained in the survival surgical procedures described in this project. All the animals that underwent survival surgeries by Girard may need to be euthanized owing to the possibility of infections. The PI should be advised of his or her responsibility for all aspects of the approved project, including assurance that all research staff involved in handling animals in this project are qualified and appropriately trained in animal procedures, and should closely monitor personnel working with animals on this protocol to avoid the same mistake in the future. Girard and the PI should be clearly informed of the consequences of protocol noncompliance, irrespective of any reasons for the noncompliance, such as overwhelming workload. We agree that additional IACUC monitoring of Girard's work should be mandated, and we advise the IACUC to monitor procedures carried out by other personnel listed in the protocol as well.

Although we appreciate and commend Great Eastern University on an excellent surgical training program, there appear to be some deficiencies in requiring surgical details to be described in protocols and a lack of written IACUC policies on aseptic

surgical techniques and survival surgeries. These deficiencies should be addressed and resolved by Great Eastern's IACUC. We disagree with those IACUC members who believed that Girard could not be tightly bound to nonexistent policies or protocol detail, as there is a fundamental responsibility to assure animal welfare (animal health and well-being) that is shared by all who are involved in an institutional animal care and use program.

1. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* (National Academies Press, Washington, DC, 1996).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals*. IV.F.3 (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. Notice NOT-OD-05-034, Guidance on Prompt Reporting to OLAW [online]. <<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>>

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RESPONSE

Voluntary suspension

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The Great Eastern IACUC acted promptly and appropriately when notified of the noncompliant activity involving wound dehiscence and infection in post-surgical animals. Given the scale of the animal welfare concern created by this incident, it is likely the IACUC will vote to report the incident to the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health. The lack of aseptic technique and shoddy surgical practices jeopardized the health and well-being of the animals and led to the subsequent euthanasia of the animals involved (Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals, NOT-OD-05-034; ref. 1). The Great Eastern IACUC's decision to report this incident to OLAW would require a majority vote of the IACUC members in attendance.

Suspension of an animal activity initiated by the IACUC is a severe action reserved for the most serious situations. The IACUC

is more likely to temporarily suspend the activity until the infractions are corrected. The most favorable situation is for the Principal Investigator (PI) to voluntarily suspend any animal-related activities until IACUC-directed retraining and corrective actions are completed.

Given the assurances of Girard and the PI that future surgical manipulations would be done as expected and the IACUC's mandate for further oversight, the committee would likely accept voluntary suspension of the activities approved under the PI's animal protocol. Possible corrective actions would be for Girard and the PI to meet with the Chair of the IACUC to receive counseling. During this meeting, the Great Eastern IACUC chair could stress the seriousness of the deviations, remind the PI and Girard that using animals is a privilege and not a right and also notify them of their required attendance at another survival surgical training session.

Even though Girard attended surgical training sessions and was well aware of the expected techniques and practices involved in survival surgery in animals, the Great Eastern IACUC does not seem to have policies in place outlining survival surgery and aseptic technique to which they can refer in this situation. The *Guide for the Care and Use of Laboratory Animals*² addresses the subject of survival surgery and aseptic technique. Great Eastern can refer to this document as the basis for the proposed IACUC policy on aseptic technique and survival surgery. The Great Eastern IACUC protocol form should be reworked either to outline required practices in survival surgery or to refer to accepted aseptic technique and required survival surgery practices in the survival surgical portion of the form. The resulting IACUC-approved policies and guidelines would serve as a resource to all animal users regarding the IACUC's expectations.

1. Notice NOT-OD-05-034, Guidance on Prompt Reporting to OLAW [online]. <<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>>
2. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* (National Academies Press, Washington, DC, 1996).

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