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Noncompliance in survival surgery technique

Great Eastern University's surgical training program covered everybody who performed major survival surgery for research purposes, including board-certified surgeons, veterinarians, technicians and others. People who claimed to have basic surgical competency were thoroughly tested in aseptic technique and basic surgical skills by a surgical trainer, using a simulated animal. Basic skill training was provided by a surgical trainer for those who required it. Advanced training for specialized techniques was provided by the surgical trainer or the research laboratory, using previously euthanized animals and progressing to non-survival surgery, as specified in the IACUC protocol. A veterinarian or training specialist always observed the first one or two survival procedures; if there were perceived problems, the trainer was required to immediately inform the Attending Veterinarian or IACUC chairperson.

The training and testing program worked almost flawlessly, until the veterinarians received a report from a veterinary technician that animals on which Linda Girard, a postdoctoral fellow, had operated

two days earlier had a high incidence of wound dehiscence and infection. Some had to be euthanized. Necropsies revealed that the surgical procedure had not been carried out well. When confronted, Girard admitted that she took protocol 'shortcuts' because she was overwhelmed with lab work. The shortcuts included wiping instruments with alcohol rather than sterilizing them between procedures on different animals when multiple animals were operated on during the same surgical session. She disinfected but did not change her surgical gloves between procedures on different animals. She used a continuous suture pattern to close the abdominal wound when individual sutures were specified. Lastly, she sutured the peritoneum, muscle and skin as a unit, rather than closing the skin incision independently from the other layers. All of these shortcuts were contrary to her IACUC training. The findings were promptly transmitted to the IACUC, and the committee immediately convened an emergency meeting with Girard and the Principal Investigator (PI) in attendance. After a discussion, the committee found itself in a quandary. Girard had been

properly trained, and her surgical technique had been observed and approved. The current problem had been quickly identified. When Girard and the PI were told by the IACUC what was required to bring the study back into compliance, they immediately agreed to do it. Additional IACUC monitoring of Girard's work was mandated. But was the infraction of sufficient magnitude for Girard to be suspended? Even if she were not suspended, should this incident be reported to the Office of Laboratory Animal Welfare at the National Institutes of Health? Some IACUC members said yes to the suspension and report, while others disagreed. Those that disagreed said that in order for the committee to suspend Girard or report the incident, the details of the committee's expectations (e.g., changing surgical gloves between animals) should have been specified in the approved protocol or at least be part of a written IACUC policy. Because neither of these conditions was met, they believed that Girard could not be tightly bound to a nonexistent policy or nonexistent protocol details.

What do you think the Great Eastern IACUC should do?

RESPONSE

Academic misconduct

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We congratulate Great Eastern University on its surgical training program. The fact that this case is an exception to an otherwise flawless record is a testament to the quality of the training that its faculty and staff receive.

There are two main issues in Girard's case: workload and academic (dis)honesty. There is no excuse for taking shortcuts because of other lab work; it is incumbent upon Girard, as a postdoctoral fellow, to discuss her workload with the Principal Investigator (PI) and to

determine what measures could be taken to prioritize or even reassign some of her duties to allow her adequate time to carry out the surgical procedures in accordance with the protocol and Great Eastern's accepted aseptic surgery standards. The PI, who presumably signed some form of an assurance statement attesting to the training, competence and performance of individuals who carry out animal activities on his or her protocol, also bears responsibility to mentor and oversee the activities of everyone who is assigned animal activities under his or her protocol and to assist the graduate and postdoctoral trainees in becoming responsible PIs themselves.

There has been a substantial uptick in the numbers of cases of academic misconduct in many universities. Some may not see Girard's shortcuts as academic dishonesty,

but these actions are really no different from falsifying scientific data or plagiarizing information, just less public. In this case, Girard should be temporarily suspended and should undergo re-training in aseptic surgical technique. Moreover, she should also be mandated to take further training or re-training on research ethics and compliance, so that she gains a better understanding of her responsibilities, her role in the bigger picture and her future as an independent investigator. She should carry out any surgical procedures under direct supervision of a qualified individual until the IACUC and veterinary staff are satisfied that she is capable of carrying out aseptic surgery properly when unsupervised. If a second similar incident is reported, Girard's surgical privileges should be permanently revoked at Great Eastern.

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 sources¹. 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*¹ 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*¹ 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^{1,2}. 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*³ (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 patterns³. USDA considers this a violation of sections 2.31(d) (viii) and (ix) of the Animal Welfare Act².

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 working⁴. 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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(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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