

Documentation on personnel training

While Dr. Jerry Silverman was overjoyed to learn that his postdoctoral fellow, Dr. Abigail, successfully obtained a junior faculty position at another institution, he

was concerned about the continuity of operations after her departure from Great Eastern University (GEU). A primary aspect of Jerry's research includes an innovative rodent model involving a

series of complex surgical procedures to essentially connect the spinal cords of two animals. Abigail spent three years perfecting this procedure and is one of only a few in the nation that could successfully create the model. Accordingly, Jerry asked Abigail to train his lab's junior postdoc, Dr. Yin, so they could continue performing the procedures after her departure.

GEU has a robust training program with dedicated staff, but it also relies on the PIs to train their own animal users on lab-specific and highly specialized procedures, such as those performed in Jerry's lab. Although GEU's IACUC requires mandatory online and in-person training prior to IACUC approval, the PI, through an assurance statement on the protocol, assumes the responsibility for performing specialized training and ensures staff will be trained prior to performing specialized procedures.

A few months after Abigail left GEU, the IACUC asked Mr. Cooper, the GEU Post-Approval Monitor, to perform a series of unannounced post-approval monitoring visits. When Cooper found Yin in the middle of surgically connecting two mouse spinal cords, he asked to be shown the lab's log of documented training. When such a log could not be furnished, Cooper alleged Yin hadn't received the proper approvals and training to perform the surgery.

Jerry was brought before the IACUC to discuss the allegation of noncompliance, which included permitting staff to perform animal activities for which they were not properly trained, thereby jeopardizing animal welfare, and failing to provide documentation of training when requested. Jerry contested that Yin was, indeed, properly trained; the assurance statement combined with Yin's observing and assisting with the surgery, as documented in the surgery records, was validation.

Who is ultimately responsible for training animal users? □

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COMPLIANCE CONSIDERATIONS

The Protocol Review coordinators offer the following compliance considerations:

Does GEU meet the regulatory requirements?

GEU meets the regulatory requirements: it has a robust training program with dedicated staff and developed a minimum set of training requirements that must be completed prior to personnel being added to a protocol and/or conducting animal activities independently. In addition, GEU relies on the PIs to train their own animal users on lab-specific and highly specialized procedures.

As one of many mechanisms utilized to validate that individuals are appropriately trained, and that the training is truly effective, GEU's IACUC employed Mr. Cooper, a post-approval monitor. Cooper's primary role is to ensure animal activities are conducted in accordance with the IACUC's expectations, which includes that users received the required training and that the training truly qualified individuals to perform animal activities independently.

Who is ultimately responsible for training animal users?

GEU established methods to ensure personnel are adequately educated and trained before they are permitted to conduct IACUC-approved animal activities independently, the IACUC communicated these expectations to the PIs, and it employs mechanisms to appropriately document the training.

Since GEU relies on PIs to perform specialized animal procedure training and validate individual competency before individuals perform independent procedures, it must trust the effectiveness of the process. Cooper's heavy-handed approach to the PAM visit suggests GEU's IACUC lacks confidence in its approach of trusting PIs to train and subsequently authorize technicians to perform animal procedures independently. In fact, their approach may imply there is a lack of trust and partnership between the PIs and

the IACUC (which includes the PAM, veterinarians, and the compliance office).

Is GEU's training adequately documented?

In this particular case, Cooper's report to the IACUC indicated Dr. Jerry Silverman was deficient in maintaining training records. Rather than using the "policing" approach, Cooper and Silverman could have identified other strategies that validated the animal handlers' training. For example, Cooper could have reviewed the surgery records and noted that each prospective surgeon participated in trainings for three months before being permitted to perform survival surgery independently. In this particular case, the surgery records could have also served as the training records. Furthermore, evaluating procedural outcomes (e.g., lack of dehiscence, infection, and mortality) is a method of evaluating the effectiveness of the training and/or that training occurred.

The inherent flexibility of the regulations permits institutions to develop mechanisms that meet their specific needs and address their particular research and institutional culture. The most successful programs will develop strategies through a collegial process involving all stakeholders of animal care and use programs. Regardless of which method an institution employs to ascertain documentation of training, there is an undocumented presumption that institutions ensure the expectations are clear to all constituents.

GEU is a vehicle for addressing everyday challenges that we all experience. If your institution is challenged with an issue, send us a scenario or an idea and we may include it as part of an upcoming column. □

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A more collegial process that facilitates compliance

Assuming GEU is a PHS Assured institution, they must base the program of animal care off *the Guide*.¹ *The Guide* states that “institutions are responsible for providing appropriate resources to support personnel training (Anderson 2007), and the IACUC is responsible for providing oversight and for

evaluating the effectiveness of the training program (Foshay and Tinkey 2007).² *The Guide* adds that “all Program personnel training should be documented.” It should be noted that similar language exists in the Animal Welfare Regulations.³

The regulatory language cited above highlights three elements: who provides

training; who validates and ensures training; and documentation of training. However, the language does not prescribe how any of these should be done. Institutions have the flexibility to establish requirements for training, evaluation, and documentation to best meet their needs for the program of animal care. The institution may elect to utilize various resources in the animal care program such as IACUC staff, veterinary staff, skilled research staff, or subject matter experts/consultants to provide the training. Oversight and evaluation of training is charged to the IACUC. Examples for accomplishing that include: IACUC review of the Animal Protocol (e.g. description of personnel experience/qualifications), post-approval monitoring (PAM), formal training program/staff, or other relevant metrics.

We note that the language regarding documentation is a “should” statement - not a “must.” If the IACUC requires documentation of training, it could occur through: IACUC office records, within the Animal Protocol form, PAM site visit records, records from formal training staff observations, online training scores, or records of training within the laboratory. If required, the IACUC should ensure that all parties involved in the training program understand the institution’s expectations on how to document training.

Due to the lack of details regarding GEU’s requirements for documentation of training, and due to a lack of information from Mr. Cooper’s report of non-compliance, it is difficult to assess if Dr. Yin was properly trained for the procedure or if there was an actual animal welfare concern. If GEU had a formal process that required labs to document training, then that would be the only noncompliance to address in the scenario presented. We base this on no specific evidence being provided as to a lack of training. Additionally, no animal welfare issue was noted as having been observed.

We are of the opinion that both Cooper and the IACUC could have navigated the situation differently. Since the institution has the flexibility to evaluate and document training, the PAM person can observe the procedure ensuring it is in accordance with the approved protocol. Additionally, the PAM person can review surgical records, surgical outcomes, and any veterinary medical records that may have been

A WORD FROM THE USDA AND OLAW

In this scenario a Principal investigator (PI) develops an innovative rodent model that involves the surgical connection of spinal cords of two animals. The PI indicates in his protocol that he would be the responsible party for training others on the specialized procedure. During a post approval monitoring inspection, a lab member is found performing the surgery on a mouse with no documentation of training from the PI. An allegation that animal welfare was jeopardized in this instance was brought before the IACUC.

The animal undergoing the procedure is not a covered species under the AWA regulations. Under the definition of ‘animal’, mice of the genus *Mus* bred for research are excluded¹. As a result, the AWA regulatory requirements regarding personnel training cannot be applied².

The hallmark requirements defined in the U.S. Government Principles VII and VIII, the Health Research Extension Act of 1985, and the PHS Policy are for appropriately trained, qualified, and experienced personnel, and the availability of instruction and training to ensure animal welfare³⁻⁵. The institution is responsible for the training, but the size and nature of the research program will determine the type of instruction and by whom it is presented⁶. *The Guide* requires institutions to ensure that those performing experimental manipulation, including surgery, are qualified to conduct procedures and that the training is documented⁷. Who should provide the training is left to the institution’s animal program to determine. The oversight of the training’s effectiveness is the responsibility of the IACUC through post-approval monitoring^{7,8}. In the case of Dr. Silverman, the IACUC should consider, as the *Guide* suggests, “a culture of care focusing on the animals’ well-being” and “an educational

partnership with investigators” in carrying out post-approval monitoring⁷. Unless adverse outcomes have occurred, the training from experienced lab members, if documented through surgical records, meets the requirements highlighted above. Improved communication by the IACUC on how training is documented would be a reasonable solution going forward. □

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generated for animals that underwent the procedure. The PAM person should report site visit activity to the IACUC, who can then evaluate the effectiveness of training. The IACUC would then be better able to communicate any necessary refinements to the PI. This would be a more collegial process that facilitates compliance. □

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Improved animal welfare is elementary

The scenario at GEU prompts the reader to consider who is responsible for training animal users. We propose a short answer based on regulation and policy: The institution! But that might not be the main question that arises from this scenario (continue on, Gentle Reader...).

The Animal Welfare Act gives the research facility responsibility for training personnel involved in animal care and use¹. This assignment of responsibility to the institution is reinforced in the *Guide for the Care and Use of Laboratory Animals*² and, as we all know (or should know), the Public Health Service Policy requires that Assured institutions comply with the *Guide*. The *Guide* further tells us that “personnel training should be documented” (the *Guide*, p. 15), which aligns with that favorite saying of administrators and clinicians alike: if it’s not written down, it didn’t happen.

We’re told that GEU has a robust training program, but that it also relies on PIs to train their personnel on lab-specific procedures. It is considered good practice for labs to document when such training takes place, and surely a written training record of some kind would serve as evidence that GEU’s expectations have been met. After Dr. Abigail announced her imminent departure from Jerry Silverman’s lab, the PI asked her to train Dr. Yin on the lab’s complex surgeries. We are unable to deduce from the facts we are given whether GEU has a requirement for how lab-based training is documented. But let’s look past the absence of training records and consider what led to our beloved PI defending himself

against allegations of noncompliance before the GEU IACUC.

The IACUC instructed Mr. Cooper, the GEU post-approval monitoring (PAM) specialist, to conduct a series of visits to the Silverman lab, but asked that these visits be unannounced. When Cooper showed up during the most complicated of surgeries, he proceeded to demand documentation of Yin’s training to perform the procedure he had just walked in on. It is unclear how much time elapsed before Cooper made the determination that proper training had not been provided, and made a bee-line to the IACUC to inform them that noncompliance had occurred.

We wonder if Cooper had an axe to grind with Silverman’s lab, as his visit and follow-up appear to be lacking in the collegiality and partnership we strive for in our own program. But several facts are missing from the narrative. Did Cooper have reason to believe Yin was untrained? Did he observe inadequate surgical technique when he materialized mid-surgery? Did Yin’s mice have a poor post-operative recovery? Has there been a decrease in the quality of overall animal health for the lab since Abigail’s departure? Was there any attempt by Cooper to discuss his findings with the PI before he took his allegations to the IACUC?

In the absence of an SOP or policy that establishes clear expectations for how lab-based training is conducted and documented, we can’t help but side with the PI in this case. We encourage the GEU IACUC to call off the dogs (so to speak) and look at their own processes and policies. If

they believe that written documentation of lab-based training is necessary, then codify that and ensure the research community is aware of this expectation. Providing template forms for busy PIs would also be helpful and streamline the PAM process. Announced lab visits to oversee planned surgeries could help prevent interrupted procedures, and reduce the risk to animals undergoing them.

Relationships between researchers and the IACUC can be tough when the IACUC is perceived to be adversarial and just plain unhelpful. This scenario in the Silverman lab doesn’t help the GEU IACUC’s image and doesn’t appear to be doing much for animal welfare, either. As Sherlock Holmes might say if tackling this case, improved animal welfare is elementary, and the true foundation of this scenario. □

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