

Customer Inconvenience for Regulatory Convenience

Great Eastern University (GEU)'s IACUC takes the training of their animal users very seriously. The IACUC performed a detailed review of several different training programs and chose those that best meet their needs. Consequently, the GEU training program involved a combination of online modules and in-person sessions, and covered topics such as:

Online:

- The ethical obligations in animal care and use

- General laboratory safety
- Vivarium procedures

In-Person:

- Basic lab animal handling techniques
- Surgical techniques including peri- and post-operative monitoring and care

All training was mandatory, and as refresher training, some courses were required to be repeated on an annual or triennial basis. Given that the GEU training team was comprised of only two trainers who performed the in-person

training sessions, the IACUC agreed that the trainings would be offered at least monthly. The committee also concurred that the research team members (animal users) would need to complete the training before conducting any animal activities. Further, if refresher training wasn't completed on time, personnel would be suspended from performing animal activities until it was completed.

Although the training staff made every effort to accommodate the training needs of personnel (e.g., permitting course registration the day before the session), Principal Investigators (PIs) frequently interjected during IACUC meetings that the frequency of course offerings was inadequate. Much to their dismay, a highly virulent virus began circulating and many of the vivarium staff were out sick for upwards of two weeks. Both IACUC trainers inevitably fell ill, but not at the same time. The absences not only left many new animal users without training but created a backlog of personnel requiring new and refresher training.

To address the matter, the IACUC voted to permit the animal users requiring refresher training to be able to continue performing animal activities until the training backlog was resolved (i.e., temporarily remove the requirement of completing the refresher training). Approximately seven months later, the trainers were caught up and the IACUC agreed to reinstate the process of suspending animal users who didn't complete refresher training by the due date.

GEU's most famous PI, Dr. Jerry Silverman, was first in line at the IACUC Chair's door to inquire: if the refresher training is important enough to suspend those not completing it, then why can the requirement be postponed due to trainer shortages? Further, perhaps the training is simply unnecessary regulatory burden placed on researchers and it should be reconsidered.

What do you think:

1. Can or should IACUCs "flex" training requirements or deadlines to address resource shortages?
2. What type of evaluation could IACUCs conduct to determine the need and/or content of continuing education?

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A WORD FROM OLAW AND USDA

Response from OLAW

In this scenario questions are raised about the flexibilities allowed for training programs in how requirements are adjusted. The essential requirements for training are echoed throughout the federal laws and standards in the Health Research Extension Act of 1985, U.S. Government Principle VIII, and the PHS Policy¹⁻⁴. The *Guide* discusses in more detail the specifics for proper training of the research team, animal care staff, and IACUC members⁵. Because the size and nature of institutional research programs varies, the scope and depth of instructional programs and the frequency at which they are offered may vary⁴. It is the IACUC's responsibility in its oversight of the animal program to evaluate whether the training provided is meeting the federal and *Guide* standards resulting in proper care and preventing potential animal welfare incidents³.

Response from USDA

Qualifications for scientists, research technicians, animal technicians and other personnel involved in animal care and use at research facilities is addressed in § 2.32 of the Animal Welfare Regulations. Research facilities are responsible for ensuring that personnel are qualified to perform their duties, and the regulations stipulate five areas in which training must be provided: 1) humane methods of animal maintenance and experimentation; 2) the concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress; 3) proper use of anesthetics, analgesics and tranquilizers for any species of animals used by the facility; 4) methods by which deficiencies in animal care and treatment are reported; and, 5) utilization of services available to provide information on appropriate methods,


alternatives to animal use, unnecessary duplication, and the Animal Welfare Act⁶.

Furthermore, training and instruction must be made available and qualifications of personnel reviewed "with sufficient frequency to fulfill the research facility's responsibilities^{6,7}". The Regulations do not mandate a specific training frequency or format. Each research facility may determine its own training program and alter that program as needed, so long as the performance outcome (personnel are qualified to perform their duties) is maintained and reviewed at a sufficiently regular interval to identify deficiencies.

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4. Public Health Service Policy on Humane Care and Use of Laboratory Animals – Frequently Asked Questions. Institutional Responsibilities, Question No. G.1. *What kind of training is necessary to comply with the PHS Policy, and how frequently should it be provided?* (US Department of Health and Human Services, Bethesda, MD, USA). <https://olaw.nih.gov/faqs#guidance/faqs?anchor=50376>
5. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals*. 8th edn., 16-17. (National Academies Press, Washington DC, 2011).
6. Animal Welfare Act Regulations, Part 2, Subpart C, 2.32

How Fresh is Your Refresher Training?

It is within the IACUC's purview to decide how to best meet the needs of the institution in terms of the method of delivery and frequency of training, and to adjust training requirements in response to extreme external factors provided the decisions are made in accordance with regulatory requirements. *The Guide* (pg. 15) states that personnel involved in animal use must be adequately trained and that the IACUC is responsible for providing oversight and evaluating the effectiveness of the training program¹. The AWA also places the responsibility of personnel training on the IACUC and outlines several essential topics that must be included².

In this scenario, Great Eastern University's IACUC made the decision to adjust training expectations during extenuating circumstances. The assessment of risk led them to prioritize new personnel training

and pause refresher training. Changing a program in response to unexpected circumstances is not ideal, but in reality programs must remain flexible to changes that may impact the animal care program. An immediate solution is necessary until a long-term solution is attainable. Holding a vote to adjust training expectations for a set time period shows proactivity on the part of the IACUC and avoids potentially allowing the training program to fall out of compliance with its OLAW Assurance if trainers are unable to meet demand. That being said, a training program that is disrupted due to the absence of one of the two trainers at any given time is likely unable to meet the needs of the institution consistently, and the IACUC should consider further long-term solutions to ensure the training program is fully supported. This could include involving veterinary staff or

other qualified research staff as "back-up" trainers, hiring an additional position or moving some less critical training to a more accessible online format.

Great Eastern University should conduct a re-evaluation of the training needs of the institution. While the IACUC implemented a training program that met the needs of the institution at the time, feedback from Principal Investigators (PIs) has not been positive and circumstances have shown any staffing challenges renders the program unsustainable. Programs must be flexible and adaptable over time as external and internal factors are rarely constant and new challenges reveal weaknesses previously unidentified.

The IACUC has several evaluation tools they could utilize in this scenario. Surveys may be used to gather participant feedback on the training program at regular intervals. The trainers could also assess which portions of the program are most essential based on individual proficiency during refresher training. The trainers could then provide an update to the IACUC with an overview of their findings. The IACUC could also compile program metrics related to Post-Approval Monitoring to identify areas of non-compliance where further training may be needed. Collectively, multiple evaluation tools may facilitate better communication and inform the IACUC's decision on the content of the training program. Open communication between researchers, the IACUC and training personnel regarding the strengths and weaknesses of the training program is needed in this situation to accomplish an effective collaboration that benefits the animal care program. □

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COMPLIANCE CONSIDERATION

The Protocol Review coordinators offer the following compliance considerations:

1. Is continuing education (a.k.a. refresher training) a regulatory requirement?

In short, yes. The *Guide* specifies that "The institution should provide appropriate education and training... to ensure that they have the necessary knowledge and expertise for the specific animal procedures proposed and the species used¹" and "Continuing education programs should be offered to reinforce training and provide updates that reflect changes in technology, legislation, and other relevant areas¹."

However, OLAW does not prescribe the method(s) or content of continuing education; a printed handout or leaflet could constitute continuing education, as could an in-depth discussion during an IACUC meeting or a detailed, online training module. Many institutions chose to tailor continued education to recent trends of non-compliance, findings from semi-annual inspections, and/or programmatic changes.

2. Can changes in an institution's Animal Care and Use Program Training Policy be made at the IACUC's discretion?

In accordance with the *Guide*, the IACUC is charged with ensuring each animal user is appropriately trained to conduct proposed animal activities before the activity can be initiated. As part of the semi-annual program review, the IACUC is regulatorily required to evaluate the effectiveness of the training program. Providing the committee is confident that the program is effectively achieving the required goals, the IACUC can change the individual training requirements at its discretion. □

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Are the Complaints Telling Us Something?

Before discussing whether the GEU IACUC can “flex” training requirements, it is helpful to remember what the responsibilities of the IACUC are regarding training and resources. First, Public Health Service (PHS) Policy¹ and the Animal Welfare Act and Regulations (AWAR)² hold the *institution* responsible for ensuring that personnel who are “involved in animal care, treatment, and use”³ are qualified to do so, and for providing appropriate training. The method and frequency of training are not established in the regulations.

The GEU IACUC voted to deviate from their internal training requirements under extenuating circumstances (illness impacting the in-person trainers’ ability to deliver training at the established frequency). The deviation only applied to continuing/refresher training, allowing the initial training to take priority and thus fulfill the requirement to ensure personnel were qualified to work with animals. While this enabled personnel to be approved to start work, the IACUC should determine whether allowing this vote of suspension was appropriate without first notifying the Institutional Official (IO), since the “flex” sends a message of lesser value for continuing education in the context of the overall training program.

In accordance with PHS Policy and the *Guide*³, the IACUC is responsible for

providing oversight and evaluating the effectiveness of the training program and providing recommendations to the IO regarding training^{1,3}. The GEU IACUC has been presented with an opportunity to do exactly that. In this case, the GEU IACUC has already been receiving ongoing feedback on the current training program — through frequent complaints during IACUC meetings. Dr. Silverman’s appeal to the IACUC Chair after the suspension of delinquent trainees was reinstated suggests the current investment in refresher training is not yielding any perceived effectiveness.

In light of this feedback, the IACUC should consider whether the current requirement remains appropriate for the size and scope of the program. If GEU has an established Post-Approval Monitoring program that assesses training effectiveness, the IACUC could utilize feedback from these assessments. They could employ a formal or informal survey of personnel who recently completed the refresher training (or were suspended) for input on the content and delivery of the training. In addition, the IACUC could conduct an internal review of what topics are currently included in the refresher training, whether this content remains current with and relevant to GEU’s animal care program, whether the delivery method for each topic is appropriate, what resources are needed for delivery, and how

to assess the effectiveness of the training for future review.

The next semi-annual program review provides a formal reason for the IACUC to review these data in the context of evaluating the training program and identifying recommendations to the IO¹. The report to the IO would be the appropriate time to present their assessment of training program, what changes are recommended, and the resources needed to conduct an effective ongoing training program. This conversation may have been better served before the training backlog caused a crisis, but better late than never. □

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