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*Note: Text has been edited for clarity.*

## Training Issues

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*Moderator:* Susan Silk, MS, OLAW, NIH

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### Slide 1 (Training Issues)

>> *Silk:* Hello, today is June 20, 2013. Welcome to the [OLAW Online Webinar](#): Training Issues. I am very pleased to welcome our guest speaker, Sara Maloney, who will present best practices in training from an operations perspective. Ms. Maloney began her career in veterinary medicine working as a clinical vet tech in animal clinics and hospitals. She did undergraduate work at Worcester Polytechnic Institute, with a focus in biotechnology. She joined the Boston Children's Hospital family in 2007. At Children's, Sara is an IACUC Coordinator in the Office of Animal Protocol Support and Assurance. In that capacity she supports the IACUC and all other staff involved in the care and use of research animals. Some of her many duties include conducting investigator orientation classes, performing pre-reviews of animal protocols, processing protocol actions resulting from IACUC review, organizing, leading and participating in semiannual facility inspections and drafting reports, performing grant to protocol congruency reviews, managing the internal office website, and also she is a part of the "Research Administrator On-Call" team. I feel lucky she is able to take time from all that to join us today. She is a member of the Massachusetts Society for Medical Research, the American Association for Laboratory Animal Science, and the IACUC Administrators Association.

I met Sara in November 2012 at an IACUC Administrators Best Practice Meeting where she gave a talk on evaluating animal care and use programs. It was a wonderful talk and I'm delighted that OLAW has the opportunity to share her expertise with you today.

### Slide 2 (PHS Policy on the *Guide* and AWAR)

The PHS [Public Health Service] Policy [[Policy on Humane Care and Use of Laboratory Animals](#)] requires that Assured institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* [[Guide](#)] and that they comply with the applicable regulations issued by the USDA under the Animal Welfare Act. [IV.A.1. Footnote 2] OLAW's expectation is that Assured institutions base their training on the PHS Policy, the *Guide*, and the AWARs [[Animal Welfare Act and Regulations](#)].

### Slide 3 (OLAW Training Guidance)

OLAW Frequently Asked Question [[FAQ G1](#)] G1 asks, “What kind of training is necessary to comply with the PHS Policy and how frequently should it be provided?” The Policy refers to appropriately trained, qualified and experienced personnel and the availability of instruction and training. It is the institution’s responsibility to train its staff. The size and nature of institutional training programs vary significantly. Variation in programs is a natural outcome of diversity of programs.

### Slide 4 (FAQ G1 con’t.)

At a minimum, OLAW expects PHS-Assured institutions to meet the following expectations of the *Guide*: ensuring that individuals are trained and qualified in species-specific procedures, that research staff are trained to accomplish procedures in a way that is both humane and produces scientifically valid data, that personnel are trained to use the minimum number of animals that will provide valid data with minimum distress to the animals, that personnel are trained in the use of hazardous agents, and that personnel fulfill local training and licensing requirements.

I have condensed this material so that it sort of almost fits on the slide. But you can read the full text of [FAQ G1](#) on the OLAW website at the URL which squeezed onto the bottom of the slide [[http://grants.nih.gov/grants/olaw/faqs.htm#instresp\\_1](http://grants.nih.gov/grants/olaw/faqs.htm#instresp_1)].

### Slide 5 (USDA Training Requirements)

The Animal Welfare Act and Regulations [AWARs] say about training: “Training of scientists, animal technicians, and other personnel involved with animal care and treatment at research facilities... Each research facility shall provide for the training of scientists, animal technicians, and other personnel involved with animal care and treatment in such facility...” [Sec. 2143 (d)]

### Slide 6 (What is a Best Practice?)

What is a best practice? OLAW defines a best practice as a method that has been shown to achieve superior results and is used as a benchmark. PHS-Assured institutions are not required to follow best practices. Unless specific statutory or regulatory requirements are cited, the information that we provide today should be viewed as recommendations. A recommendation may not be suitable or applicable to every institution. An Assured institution may use an alternative approach if the approach satisfies the requirements of the PHS Policy.

### Slide 7 (Guidance Regarding Best Practices)

What Sara presents to you today are the current best practices being used at Boston Children’s. Boston Children’s is a large research institution that is part of an even larger system. They have developed these best practices through experience and education, through sharing with colleagues, and responding to the needs of investigators and their research animals. We have a large diverse audience with us today. OLAW invites you to consider Sara’s best practice information as it relates to the animal care and use program at

your own institution. Some practices may apply to your program; some may not. It is up to you, using your experience and education, to apply this information as appropriate at your institution.

And now, I am pleased to present Sara Maloney.

Slide 8 (Training Issues)

>> *Maloney*: Thanks, Susan. And thanks for that introduction and for inviting me to speak today. And good afternoon to everyone out there and thank you for joining us.

As Susan discussed, there are requirements for training personnel in PHS-Assured animal care programs. And regardless of the type or size of the program, institutions often encounter issues when developing their training regimens. And when Susan asked me to speak about training issues, 6 basic topics associated with the development and implementation of a training program came to mind.

Slide 9 (Training Issues)

So, during this webinar, we'll review: which personnel to include in training, what topics and practices to cover, the appropriate frequency of training personnel, methods for how training and education can be obtained, the documenting of training activities, and finally – how those responsible for the program can evaluate the effectiveness of personnel training.

Slide 10 (Why Training is Important)

But before we get started, I think it's important to recognize that no two animal programs are the same – and therefore training programs can and will vary widely based on the individual needs of the institution and the personnel involved.

Proper training and experience are necessary for a successful animal program. To quote the *Guide*: "Laboratory animal science and medicine are rapidly changing and evolving disciplines." So, adequate training helps to ensure high quality science is conducted and animal well-being is prioritized. And education of personnel can also facilitate compliance with the institution's program.

Slide 11 (Considerations for Training Programs)

When developing a training curriculum, program coordinators should consider the personnel qualifications required to conduct and support their specific animal program. These needs may depend on various factors like: the type and size of the institution, the administrative structure – that is both available and needed – to provide adequate care to animals, the characteristics of the physical plant, the number and species of animals that will be maintained, the nature of the research, testing, teaching, and production activities.

And in the following slides, we will review minimum requirements as well as best practices for each training issue. Best practices should be considered as examples, and some may be more suitable for institutions than others.

So let's go ahead and get started...

Slide 12 (Personnel to Include in the Training Program)

The first training issue addresses *who* to include in training, and this may be the leading question program coordinators choose to answer during the planning process. Minimum requirements under the PHS Policy indicate those who are responsible for housing, feeding and care of the animals used, as well as those who will be conducting procedures on live animals, all require training. The Policy also discusses proper constitution of the [Institutional] Animal Care and Use Committee and the general training and experience required for each type of member.

Facilities that are registered with the USDA should be aware of the specific training requirements in the Animal Welfare Act and Regulations, which closely reverberate the requirements of the PHS Policy. The *Guide for the Care and Use of Laboratory Animals* generalizes these requirements by indicating "All personnel involved with the care and use of animals" must be trained. But who specifically does this mean?

Slide 13 (Personnel Categories in the *Guide*)

Well, Chapter 2 of the *Guide*, in the Personnel Training and Education section, breaks down specific personnel training requirements by grouping staff into 4 main categories.

This includes: the veterinarians and other professional staff such as pathology, imaging, and behavioral professionals; animal care personnel such as technicians and husbandry staff; the research team including principal investigators, study directors, technicians, post-doctoral fellows, students, and visiting scientists; and last but not least, the Institutional Animal Care and Use Committee itself.

But, depending on the organization of the institution, all personnel involved in the program may not necessarily fall under these 4 categories.

Slide 14 (Other Personnel to Include in Training)

Other key personnel, such as the Institutional Official and occupational health and safety professionals, may require training in order to succeed in their roles. Numerous other types of personnel may be involved as well – either directly or indirectly – in the animal program and it would be best practice to ensure these people receive appropriate training.

Other personnel may include: administrative staff such as the IACUC support team; those involved in animal transportation both at the shipping and receiving ends; facilities personnel including those responsible for design and renovation of animal facilities; engineering staff; maintenance and custodial staff; and security personnel. And when considering the requirement for a contingency or disaster plan, institutions may find it beneficial to include emergency management personnel in the training program – and this may involve both institutional and local fire and law enforcement officials. And finally,

program administrators might consider including their institutional human resources management and legal professionals in the training roster.

Personnel to include in the training program should not be limited to the list here though, as all aspects of animal care and use and maintenance should be evaluated to ensure all relevant staff receives adequate training.

Slide 15 (Training Topics: Considerations)

After selecting who needs to be included in the [training] program, institutions will then need to determine *what* practices, procedures, and topics each person must be trained and educated in. The PHS Policy itself discusses general requirements for personnel training. And those who must comply with the Animal Welfare Act and Regulations should be aware that these documents indicate similar requirements to the PHS Policy – but also specify some topics of training and instruction in greater detail. The *Guide* provides more extensive parameters, indicating who “must” and “should” be educated in specific subjects.

So what – specifically – must or should be included on the training program syllabus?

Slide 16 (Personnel Training Topics)

Well, the table here, and on the next 2 slides, depicts various training topics, the documents they’re included in, and which personnel must or should receive training in those areas of study.

So first and foremost, the PHS Policy, Animal Welfare Act and Regulations, and the *Guide* all indicate that each person involved in the care and use of animals must be adequately trained, educated, or experienced to conduct such activities. Therefore training needs must be assessed on a person-by-person basis.

According to both statute and guidance, all relevant personnel must also be trained in the basic principles and ethics of laboratory animal science and the humane and proper practice of animal care, use, and maintenance.

Numerous roles require education in the concept of the “Three Rs” which refer to: alternatives to the use of animals, methods that limit pain and distress, and methods that minimize the number of animals required to obtain scientific information.

And all personnel handling animals must be trained in the specific procedures they will be performing. This includes everything from animal handling methods to good surgical technique, the use of anesthetics, analgesics and tranquilizers, methods of euthanasia – both primary and secondary – and everything in between, as it applies to their responsibilities.

Slide 17 (Personnel Training Topics)

The veterinarian, both as an IACUC member and in a role of program direction, must be

formally educated in laboratory animal medicine for the species being maintained. And the housing, feeding, and non-medical care of animals, including behavioral biology and enrichment, must be directed by a veterinarian or other trained scientist and is often administered by animal care personnel, all of whom require adequate training and experience. Others, if participating in or evaluating these activities, such as the research team and the IACUC, may also be included in these trainings. All relevant personnel involved in the care, use, and maintenance of animals must undergo training in the recognition of signs of animal pain and distress. This includes individual clinical, behavioral, physiological, and biochemical indicators and the appropriate responses to such signs including humane endpoints – both planned and early. And the reporting of concerns about animal care and use, including why this is important and how to do it, is an essential area of study for all program personnel.

#### Slide 18 (Personnel Training Topics)

Other training topics for various personnel should include – but is not limited to – education in institutional contingency or disaster plans, as required by USDA regulation and discussed in the *Guide*. Animal facilities and access, with additional consideration that the veterinary staff may benefit from training in animal facility administration and management.

Occupational health and safety concerns, such as the identification of hazards, medical evaluation, risk assessment, preventative medicine, safe practices including personal hygiene and the use of PPE, and established standard operating procedures like the use of equipment and proper waste disposal. And finally, education in the institution's animal care and use program including the IACUC function and protocol and program review processes – and in relevant animal care and use legislation, regulations, guidelines and policies – should be provided to both the IACUC and the research team – and may be useful for other program personnel. While some basic topics are required for all staff involved, the syllabus for training should be tailored to the needs of individual roles and program coordinators will need to look beyond the regulations and the *Guide* to assess specific personnel needs.

#### Slide 19 (Frequency of Training)

With consideration of the personnel, their roles and necessary topics of training, institutions must also determine the appropriate *frequency* of training. The PHS Policy requires the IACUC to ensure personnel are appropriately qualified and trained, but does not mention specific frequency. The *Guide* indicates which personnel should participate in ongoing education activities. And the Animal Welfare Regulations mention review of qualifications with “sufficient frequency” to fulfill necessary responsibilities. Formal education requirements and state and local laws must also be taken into consideration whenever applicable. And outside of this, it's really up to the institution to determine the necessary frequency of their personnel training.

#### Slide 20 (Frequency of Training)

Overall frequency of training and education can be sorted into 3 categories. First would be initial training and education to ensure personnel are appropriately qualified to begin animal activities. The second involves continuing education activities to ensure staff are

knowledgeable about the latest practices and procedures. And lastly, mechanisms for interim or timely notifications should always be considered in case personnel need to be educated or updated in emergency or unexpected situations.

The *Guide* specifically discusses the ongoing training of 4 categories of personnel. These categories include: the veterinarians and other professional staff, animal care personnel, the research team, and the IACUC. It would, however, be best practice to perform a risk assessments of all categories of personnel to determine the necessary frequency of training for individual roles, and this should largely be based on performance standards.

Slide 21 (Training Methods: Considerations)

Now that we have considered, *who* to train, *what* topics to include, and *how often* – we need to assess *how* training can be provided or verified. Both the PHS Policy and the Animal Welfare Act and Regulations require that training be provided, but how to go about doing this – beyond formal education and local and state requirements – is really left up to the individual facilities to determine. The *Guide* provides suggestions for how some personnel should be educated including veterinary and animal care staff, the research team, and the IACUC.

A one-size fits all training curriculum may not be best practice for an institution if the individual personnel involved have varying roles and responsibilities. Best practice would be to first define what training and education is necessary, and then assess how that can be accomplished. And a collaborative approach, including training by those with expertise in various fields, should always be considered.

Slide 22 (Methods of Initial and Continuing Training and Education)

So what are some ways institutions can provide training or ensure education is obtained? Well first – completion of a formal education and degree training is an appropriate way of assessing qualification and is required for certain personnel, such as the veterinarians, and encouraged for others, like the animal care staff. On-the-job training should be provided to animal care staff and it would be best practice to ensure all personnel have on-the-job training available to them – like hands-on training in specific procedures for both the veterinary and research teams.

Employee orientation programs should be developed for personnel such as the IACUC members to help them understand their role and educate them in all aspects of the institution's program including relevant regulations, principles, and practices. An orientation program may also be used for the research team, and some institutions employ a collective teaching approach for this – using expertise from various personnel such as the IACUC support staff, experienced researchers, veterinary staff, and the occupational health and safety team. And some institutions that collaborate with each other frequently, and have similar training programs, may wish to employ the use of Memoranda of Understanding in order to verify that adequate training and experience was received at one institution and therefore does not need to be duplicated at the other facility.

#### Slide 23 (Methods of Initial and Continuing Training and Education)

Continuing education activities should be encouraged for all personnel. And in some cases, such as for the animal care staff and IACUC members, this should be accomplished – in part – by participating in local or national laboratory animal science meetings or other relevant organizations and workshops. Institution-sponsored seminars, such as talks from field experts or vendors, should be encouraged for some staff, like the animal care team. For example, institutions may request that the research groups give talks about their studies to the animal care staff. Such practices may help them to understand parameters beyond the care and maintenance of the animals, such as the reasons for their existence in the program and the importance of their inclusion in the study.

Webinars such as those provided by OLAW and the USDA and other organizations are also convenient ways of obtaining continuing education. And hopefully you're all agreeing with that so far! And finally, practices in self-guided study should be encouraged for personnel like the animal care staff. This may also be useful for IACUC members, the research team, and other relevant roles. There are commercially available reference materials for this type of training, and institutions may find it beneficial to develop and make available manuals for common practices and standard operating procedures.

#### Slide 24 (Methods of Timely Notification)

As I mentioned earlier, methods for timely education of personnel are important to consider. For example, situations such as drug shortages or changes to the layout of the facility may require time-sensitive reporting to relevant staff. Some mechanisms for early notifications could include: posted signage such as in the event of equipment failures; email alerts considering the use of pre-populated distribution lists; text message notifications are also being used more often now; and institutional websites are useful if they're maintained and accessible to staff during such events.

#### Slide 25 (Documenting Training: Animal Welfare Assurance and Animal Use Protocol)

So after working through the *who*, *what*, *when*, and *how* aspects of training, institutions will want to ensure that *documenting* requirements are met. And what are those documenting requirements? Well, the PHS Policy requires that the "the qualifications" of the veterinarian, and "a synopsis of training" of personnel be included in the written Animal Welfare Assurance. The *Guide* then states that the animal use protocol should describe the "adequacy of training and experience of personnel in the procedures used" as well as the "roles and responsibilities of the personnel involved."

#### Slide 26 (Other Documenting Considerations)

The *Guide* also specifically states that "all Program personnel training should be documented," and based on issues discussed in earlier slides, we know that there is much training that occurs – which may not be captured in the animal use protocol. For example, the training of personnel outside of the research team like the veterinary and animal care staff, occupational health and safety professionals, the IACUC themselves, and other staff

not directly involved in the research study. If the animal protocol restricts descriptions of training and experience to study-specific procedures, then mechanisms for documenting other training activities will also need to be developed.

For example, education in topics such as animal care and use legislation, regulations and principles, contingency or disaster plan training, education in occupational health and safety practices, training that occurs during post-approval monitoring, and any other continuing education activities that may not make it into the protocol should be considered when planning what will be documented and how.

Slide 27 (Documenting: Methods and Maintenance)

Regarding methods, there are a few options for how training can be documented outside of the animal protocol. For example, facilities may develop paper-based systems or decide to utilize electronic systems. With electronic systems, there are several commercially available products out there and some facilities choose to develop their own home-grown software.

But regardless of the methods used, documenting of training activities should be appropriately maintained. It's important to know who in the institution will be responsible for maintaining such records and this may be delegated to multiple different parties. For example, the research team may take responsibility for maintaining records of lab-based trainings and the IACUC support staff may be responsible for retaining records of participation in employee orientation programs. It's also important to ensure documentation is stored in such a way that it can be made available for periodic review, if required, such as during facility inspections. And as far as the length of time records should be retained goes, OLAW requires this be done for 3 years, and this may also be affected by state or city laws – and program administrators should be aware of their local requirements.

Slide 28 (Evaluating the Effectiveness of Training)

And finally, for our last topic, we'll discuss *evaluating* the training program. In order to ensure the training curriculum and methods are working appropriately and effectively, institutions should perform ongoing evaluation of their programs. The PHS Policy itself discusses the continuing review of ongoing activities at appropriate intervals.

The *Guide* then indicates that the IACUC themselves is responsible for providing oversight and for evaluating the effectiveness of the training program. And the Animal Welfare Regulations state that one of the Committee's functions is to make recommendations to the Institutional Official regarding any aspect of personnel training.

Slide 29 (Methods of Evaluating the Effectiveness of Personnel Training)

So how can we evaluate the effectiveness of our chosen methods? Well, the IACUC can evaluate the training program, such as who is being included, what's being trained, and methods that are used during semiannual program review activities. Inspections and site visits can also be effective ways of evaluating the training of program personnel, since issues may be observed during the inspections and also while reviewing the results of those

inspections. With regard to animal care personnel, consideration of the number of certified people on staff may lend to the general level of education amongst the team. However one must keep in mind that English as a second language and funding availability can preclude some staff and facilities from taking advantage of programs like these. And staff meetings that involve question and answer segments can be an easy way to schedule in regular assessments and can also serve as a way to educate staff at the same time.

On a more individual level, employee performance evaluations and audits can be useful tools in judging the effectiveness of the training and education program. For example, audits of animal care staff by supervisors are helpful methods for ensuring specific procedures, such as cage changes and sampling from sentinels, are being performed correctly. Review of issues with animal morbidity and mortality can elucidate indicators of training and education issues amongst the veterinary, animal care, and research personnel and should be reviewed regularly. And the training of the research team is often evaluated during post-approval monitoring activities.

Slide 30 (Methods of Evaluating the Effectiveness of Personnel Training)

Review of noncompliant incidents are a helpful way of determining whether the underlying cause of those events can be related back to inadequate education. Also, the use of quizzes – either formal or informal – following employee orientation programs can be used to gage how well the information presented is being absorbed. And the IACUC members themselves should undergo ongoing evaluation by Committee leadership and the Institutional Official.

Other helpful methods of evaluating the effectiveness of the training program could include: review of specific feedback obtained from various program personnel, review of responses to unexpected events and practice drills (such as practice fire alarms), and review of occupational health and safety-related incidents – as again – these issues may relate back to inadequate training in such subjects.

Slide 31 (Resources)

So hopefully after reviewing all of these issues associated with training, you'll have a clear understanding of the requirements and best practices associated with developing a new training program or for evaluating and optimizing an existing one. Program coordinators may wish to review the content of the PHS Policy and *Guide* more closely, as well as the Animal Welfare Act and Regulations if the facility is registered with the USDA.

Other helpful resources that are linked to the [OLAW website](#) include:

- the [Animal Welfare Information Center](#) (AWIC)
- the [Laboratory Animal Welfare and Training Exchange](#) (LAWTE)
- the [American Association for Laboratory Animal Science](#) (AALAS)
- the [Institute for Laboratory Animal Research](#) (ILAR)
- and, if collaborating abroad, guidelines from other countries may need to be considered.

So before we get to the question and answers – and we will try to get to as many questions as possible – I'd first like to just say a quick thank you to both Susan and Lori from OLAW – as well as my colleagues here in Boston – all of whom have taken time out of their busy schedules to sit through some of my practice runs and provide their invaluable feedback. So, thank you again. And back to you, Susan.

>> *Silk*: You're welcome. It's a pleasure to work with you, Sara. And now on to our questions. First we will answer the questions that were sent to us before the webinar.

Slide 32 (Question 1)

Question 1: **Many institutions depend on their PI's to conduct some procedures regarding specific training since at times they are the experts. Regarding documenting the PI conducted training; is it adequate for the PI to include in a protocol that "personnel" will be trained on a procedure before beginning a procedure, or is there an expectation that the PI will keep a separate training log that specifically identifies (date, and sign-off by the trainer for example) when each technician was adequately trained?**

I'll answer this one. This is an institutional decision to be based on what works best for the IACUC to be assured that staff are qualified prior to conducting animal activities. The institution is free to use whatever method works to ensure that [Principle VIII](#) of the U.S. Government Principles can be met. And so now I'll read you Principle VIII: "Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals."

Slide 33 (Question 2)

Question 2: **The intensity of trainings can vary significantly from institution to institution. How would you suggest evaluating the effectiveness of a training program? Any suggestions on evaluation standards?** I think this is one for you, Sara.

>> *Maloney*: The effectiveness of training can be evaluated by assessing the ability of staff to appropriately conduct procedures and abide by relevant policies, practices, and regulations. The failure of training is reflected in identified noncompliance that occurs due to staff not being informed or proficient. Many institutions have staff take tests following training or observe individuals conduct procedures appropriately before allowing independent work to proceed.

Slide 34 (Question 3)

>> *Silk*: The third question, I think, is one for you, Sara: **Relating to establishing comprehensive training programs, any suggestions for small institutions with limited resources?**

>> *Maloney*: These institutions should avail themselves to the many on-line resources from OLAW, AAALAS, USDA, FBR, etc. There are free journals such as [Lab Animal](#) and as online access to many other publications. Perhaps send one individual to a national meeting and have the individual share information with others back at home.

Slide 35 (Question 4)

>> *Silk*: Let's see, this next one is for OLAW so I'll take it. Question 4: **One common sanction for noncompliant events is for the IACUC to require a PI to retake, for example, an online training course. If OLAW sees this sanction time after time from the same institution, would OLAW question the effectiveness of the training?**

When the OLAW Division of Compliance Oversight sees a repeat of the same noncompliance for the same individual or laboratory, the institution is directed to use additional methods or escalating sanctions to ensure prevention. If OLAW sees training as the first response to different problems with different laboratories – various laboratories, we would not necessarily question the effectiveness of the training. OLAW's response would be on a case-by-case basis.

Slide 36 (Question 5)

And, here's one for you, Sara. Question 5: **Must all training be documented?**

>> *Maloney*: Yes, formal training should be documented. But informal discussions or ongoing mentoring in laboratories does not need to be documented.

Slide 37 (Question 6)

>> *Silk*: Question 6, for Sara: **Is it OK for the PI or a member of his staff to do some of the training?**

>> *Maloney*: I'd say, yes. Often the PI or experienced lab staff are the best qualified for teaching specific procedures and you would want the best qualified to be doing that.

Slide 38 (Question 7)

>> *Silk*: Question 7, for Sara: **Should the IACUC look at training records during every semiannual inspection and program review?**

>> *Maloney*: The OLAW [sample semiannual checklist](#) lists training of staff, including the IACUC, as an item that needs to be reviewed every 6 months. Review of training records is one of the methods for the IACUC to assess this aspect of the program.

Slide 39 (Question 8)

>> *Silk*: I'll answer Question 8: **What if someone hasn't completed the specific species training and starts to work with animals? Is this reportable to OLAW?**

Yes, it is. Staff must complete the IACUC-required training before starting animal activities.

The guidance on prompt reporting to OLAW lists as reportable “participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as [required] by IV.C.1.f.” [[NOT-OD-05-034](#)] “Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.” [PHS Policy [IV.C.1.f.](#)]

Slide 40 (Question 9)

>> *Silk*: Question 9, another one for me: **A collaborating surgeon whose specialty is human cardiology will be conducting an experiment using sheep at our institution. He claims he does not need training as he works on human subjects daily. Should we allow him to proceed without additional training?**

OLAW's answer is no. A sheep is different from a human and a human surgeon should be trained by the veterinarian on animal-specific requirements and institutional policies regarding the use of animals. It may not be necessary to conduct remedial training on asepsis and tissue handling, but the surgeon should be apprised of unique physiological aspects of the species such as the rumen, thermoregulation, anesthetic support, post-op monitoring, and so forth.

Slide 41 (Upcoming OLAW Online Seminars)

- September 19, 2013 – Topic: TBD
- December 12, 2013 – Topic: TBD

>> *Silk*: And now we'll move into the live real-time portion of the questions. Always more challenging for us. So we encourage you to get those questions in beforehand. Question A, and Sara I'm going to take this one.

>> *Maloney*: All right.

>> *Silk*: But Jerry [Collins] and Pat [Brown] are on the line with us, of course we invite them to participate, too. [Question 10] **As a post doc I developed a new surgical technique for attachment of devices to skulls of nonhuman primates. I have just accepted my first junior faculty position but the IACUC at my new institution will not allow me to perform the procedure without someone here training me. Since I developed the technique and no one here has any experience with it, how will they train me?** And here's our answer:

You should work closely with the institutional trainer or trainers in compliance with the institutional requirements. It may be necessary to demonstrate your particular technique so the IACUC can understand this unique situation and opportunities for refinement that they can see. It's also to confirm that your proposed procedure meets the institution's standards for procedures conducted at their facility, such as aseptic technique. In summary, OLAW suggests that you engage in a give-and-take process with the trainer and the IACUC that we think would result in the betterment of both animal welfare and your research.

Next: [Question 11] **Do investigators need to undergo regular training?**

And the answer, I'll take this one, Sara, is yes. On Page 17, the *Guide* discusses training of the research team. It says, "Continuing education programs should be offered to reinforce training and provide updates that reflect changes in technology, legislation, and other relevant areas."

Here's another one for me. [Question 12] **If we have never documented training but only accepted written assurance of it from the PI, how should we proceed to document adequate training of our investigators?**

Well, the Policy, in [Section IV.C.1.f.](#), requires that personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures. In IV.C.1., the Policy goes on to add that the IACUC shall determine that the research project conforms to this requirement. And finally, the *Guide* stipulates, on Page 15, that all program personnel training should be documented. So OLAW says that it's up to the institution to determine the best method of documentation. Sara, could you speak on how you might do this sort of documentation at Boston Children's?

>> *Maloney*: Documenting of lab-based trainings?

>> *Silk*: Yes. When the PI teaches his own staff.

>> *Maloney*: We would request that the PI keep their own records of staff training. And then the qualifications of those personnel should be also included in the animal use protocol, that would be the main area where that would be kept. We can also request to see the lab-based training documentation during semiannual inspections.

>> *Silk*: And so that would be a good method and – but other methods might be possible, too. But that sounds just fine.

>> *Collins*: Susan, if I could jump in for a second.

>> *Silk*: Yes, please.

>> *Collins*: It strikes me that the question in part was talking about a situation where people have been doing it forever and now there's a need for documentation. It strikes me that one of the additional pieces here is a performance based standard in the sense that assuming that the veterinarians and folks working with the vets have been monitoring animals over a long period of time, certainly that would give the institution an opportunity to have a sense of how things have been going and perhaps give them an opportunity to say there were 3 or 4 labs where we know over the last couple of years there have been some problems, maybe we need to be focusing on them first as far as their documentation is concerned.

>> *Silk*: Good point.

Sara, this one I think is a good one for you. [Question 13] **What procedures need training documentation?**

>> *Maloney*: All formal training activities should be documented. And the activities – the activities that need to be trained would be based on the individual roles of the personnel. So you would have to review the roles of the personnel, identify what they need to be trained in, and then any formal training that goes from there should be adequately documented.

>> *Silk*: I'll add to that and say that we discussed this issue in detail in [OLAW FAQ G1](#). In that FAQ we have collected the requirements that are stated in the *Guide*. And you can read those in FAQ G1.

>> *Maloney*: And I might refer them back to the tables that were provided in the slides that indicated which personnel needed to be trained on what topics as well.

>> *Silk*: Absolutely. And then here's one for Sara, and you mentioned this I think in your talk: [Question 14] **How do you document training that occurred at another institution?** How do you do that at Children's?

>> *Maloney*: I think it would be helpful to have a Memoranda of Understanding between institutions if your plan is to accept training from other institutions. If not, if you are not comfortable with accepting the training from another institution, it would probably be best to have the investigator or whichever personnel trained at your institution as well. But there should be adequate documenting and agreement for that type of understanding.

>> *Silk*: Now, here's one where the questioner would like to ask Sara what she does at her institution regarding if the technical staff is working only with tissue, do you require inclusion in the occupational health program and if so what training do you require? [Question 15] Oh, I see, it is 2 questions: **If the technical staff is only working with tissue, are they included in the occupational health program? And also what training do you require of them?**

>> *Maloney*: Staff that are working here, all of them are included in our occupational health program. If they're working with tissues, not live animals, they may not necessarily be working under my program. But they would be part of an occupational health program.

>> *Silk*: Do you require other training for them if they just work with tissues?

>> *Maloney*: I would have to defer to my health and safety professionals here and can certainly answer that in more detail later.

>> *Silk*: That's a good point; that we work as teams. And so I think that was a really great

answer. We depend on the expertise of various roles and responsibilities.

>> *Maloney*: My role focuses on those that are using the live animals, as opposed to the tissues. Though, we do want to know what's coming in and being used and it is pertinent to the occupational health program.

>> *Silk*: Very good. Let's see now. This one we'll put it out here for everybody. It's probably going to come to you first, Sara, if you want to comment on the effectiveness of online training. [Question 16] This person asks: **If we are using online training, they are using CITI, the Collaborative Institutional Training Initiative, for investigators, staff and students, how often would you recommend the training be updated or retaken? Also, how would we evaluate the effectiveness of that kind of training as it is not hands-on or related to a particular procedure necessarily?** So Sara, do you want to comment on CITI and online.

>> *Maloney*: I don't have a lot of experience with CITI and online training. We do much person-to-person training here. But I think as far as online training goes and evaluating how effective it might be, it might be helpful to employ the use of a quiz at the end of it, to see how well that information is really being absorbed during that method of training.

>> *Silk*: I know the CITI modules do have a quiz at the end. Jerry, do you have any experience with those modules?

>> *Collins*: I do not.

>> *Silk*: Okay.

>> *Maloney*: I've heard good things, but I don't have personal experience of that.

>> *Silk*: All right. We'll move on.

>> *Collins*: If I could just make a brief comment, and I think it's been alluded to before. I think one of the issues, too, especially with the online training, it seems to me that it is a good practice to have an individual who is doing something new for the first time, to make sure that there's some oversight of that procedure. Just to make sure that in fact they fully understand all of the things they should be doing, irrespective of how that training has occurred, especially when it's a particularly invasive procedure.

>> *Silk*: I do some work with the CITI Program, and I know they are releasing new modules all of the time. So it's something that whatever was true a year ago maybe now has been expanded into more modules.

[Comment submitted by CITI: Didactic online programs, such as the CITI Program, can provide in-depth regulatory and species-specific training with the advantages of easy online

access and compliance database inter-connectivity, which is a valuable supplement to hands-on wet lab and person-to-person training.]

[Question 17] But now we'll move on to another one: **Do you have suggestions for evaluating the effectiveness of project-specific training, provided by the PI?** Sara?

>> *Maloney*: Evaluating project-specific training – so the training is being provided by the PI?

>> *Silk*: Yes.

>> *Maloney*: I would say probably post-approval monitoring activities would be a very effective way of evaluating how well the researchers are performing those procedures after being trained by the PI.

>> *Silk*: I agree. Jerry, do you have any comment on that?

>> *Collins*: I'm in agreement.

>> *Silk*: Okay. Me, too. It's unanimous.

[Question 18] **We have had the case where someone is going to a remote location and will have local people helping with the research when they arrive. These individuals may not speak English or even have computer access, so they could not take our online training, nor would they be able to come to our institution for a classroom training. What should be done in this case?**

My wonderful team of OLAW people behind me have made some notes here. They say that for PHS-funded research, OLAW would expect the IACUC to ensure equivalent training to that that the onsite researchers receive. A paper-based [or online] training and onsite training are possible options. Jerry, have you ever had that situation?

>> *Collins*: It is an interesting challenge. And frequently for us it arose not for projects that were funded by PHS. And one of our concerns would be typically field studies that I'm thinking of right now. It's not even so much training to make sure that in fact the interactions with the animals are okay. But also to make sure that the individuals that are having those interactions are adequately trained so they themselves are safe – so they aren't transporting inappropriate materials with them to a foreign country. So there are a lot of issues that are outside of IACUC issues, but are institutional concerns that should be considered.

>> *Silk*: Sara, have you run into such a situation?

>> *Maloney*: I can't say that I have personally run into a situation like this, but as far as - we're talking about those that have English as a second language really.

>> *Silk*: Yes.

>> *Maloney*: There are many resources out there, too, that can help institutions accommodate their investigators that struggle with English as a second language. And I probably would advise them to review those resources.

>> *Silk*: And this question gives me the opportunity to say that when you come upon unusual, unique, specific situations like this, you are always welcome to call us [OLAW] and we'll help you figure out on a case-by-case basis what's the most appropriate solution.

[Question19] **Please comment on training online versus live lecture format.** And this goes on to say: **Find better response to online classes.** I don't know what that means. Would either of you, Jerry or Sara, like to respond to this request to comment on online training versus live lecture format?

>> *Maloney*: I don't mind jumping in. I do live training. I like the person-to-person interaction. You can create a dynamic presentation for them. And try to work with your audience and keep their attention to elicit the best results possible. I think that online trainings don't always necessarily have mechanisms for doing that. So I really do prefer the person-to-person trainings.

>> *Collins*: Another comment, Susan, I think we need to separate training in the sense of training in working directly with animals versus training in all of the other areas that individuals need to be aware of. It seems to me that the hands-on approach, the wet lab approach, I think is the best way to provide individuals with that kind of interaction. Recognizing there are useful tools that do not involve direct access to the animals as well. But I think ultimately you need to be able to watch a person's hands, see how they are handling the animals to make sure that they have internalized what they have seen on a video screen or piece of paper, or quite frankly from somebody that is speaking to them. I agree that the interaction, the personal interaction is very, very important in being there.

[technical difficulties with screen sharing]

>> *Silk*: [Question 20] **Could you provide guidance for members when evaluating the training as it is described in the protocol? Respective to the proposed procedures.** Could you provide guidance for IACUC members when they are trying to evaluate training as described in the protocol – respective to the proposed procedures? This is wet lab training they're asking about, I bet.

>> *Maloney*: I don't mind speaking to that.

>> *Silk*: Okay.

>> *Maloney*: I think that it's important to verify that all of the procedures listed in the protocol are accounted for in the personnel experience description; that not one particular procedure has been left out of the list of experience associated with each person. And I think that it's helpful to glean the experience of the room as far as whether or not that individual investigator – the description of their experience is adequate.

>> *Silk*: We have just a few more minutes and we have just a few more questions. So I think that we can make this work. We have a comment from someone that says CITI grades and you must receive at least 80% correct to pass the module.

[Question 21] Here's someone who would like to know: **How you train your short-term summer students.**

>> *Maloney*: Oh, we have our short-term summer students go through our standard orientation process, just like any other investigator. Sometimes we have to make special accommodations as far as – you know our scheduled orientations not falling in a timeframe for them to be able to get their work done. So we do at times offer individual one-on-one trainings for those who have their scheduling conflicts. But they receive all of the necessary materials just like any other person handling animals at the institution.

>> *Silk*: [Question 22] **What about IACUC members? Is their service on the IACUC and the different things they encounter as members enough or should there be a defined continuing education program for IACUC members? Certainly there're discussions during IACUC meetings and materials provided for continuing education, but I was thinking more in terms of should there be a yearly classroom or online training for IACUC members?**

>> *Collins*: Susan, I'll jump in on this one. I think certainly additional training makes an awful lot of sense. My sense is that service on an IACUC really involves a lot of on-the-job training. I believe a valuable way of providing that training is when an unusual circumstance occurs, when new guidance comes out, that during a committee meeting a few minutes are spent discussing it so that the committee itself works as a committee to generate its sense of what the meaning of this new thing is and how it's viewed by that committee and how they think they can best apply it at their home institution.

>> *Silk*: Someone handed me a message here. The *Guide*, on Page 17, states that the IACUC should have ongoing opportunities to enhance their understanding. So it should be offered to them. This is in addition to formal orientation and training of new members.

[Question 23] **Just a comment. When looking at various departments that might undergo certain training within an institution, this person suggests including PR and media relations.** Sara, Jerry, what do you think about that? Including the media and public relations in the training?

>> *Maloney*: I think it would be helpful. It just depends on the organization of the institution and whether or not it's applicable to them. But it could be helpful for those personnel to be aware of some of the aspects of animal care and use at their own institution.

>> *Collins*: I would second that. I think it's very important for those offices at an institution to, number one, be aware of the kind of work that's being done within the institution. And also to know at least some of the leadership involved in that work, so that should the need arise for them to provide information outside of the institution, they are well prepared to gather relevant information. I would also encourage them to recognize that unfortunately there may be a circumstance in which there is the need to respond to an urgent matter and that they should be well prepared to do that as well.

>> *Silk*: I see that we're out of time, we do have more questions coming in. So I'll wait another day or two and allow time for all of you to send any additional questions that you want to ask. You can just send them to the [OLAW DPE](#), Division of Policy and Education, mailbox or send them to my mailbox or to Lori's and we'll work with Sara and we'll answer these questions and post them for you.

Before we say goodbye, I want to express our sadness at the recent, unexpected death of Dr. Harry Rozmiarek. Harry was a friend and mentor to many of us in the IACUC community. He was a wonderful man and we will miss him greatly.

Thank you, Sara, for a wonderful webinar. I appreciate all of your work on the webinar and in service of humane animal care and use and good science. Thanks to all of our participants, all of you in every part of the United States and those of you who got up at crazy hours to join us today in this webinar. Please come back and join us for our next webinar which will be held on September 19, 2013. Goodbye.