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**Contents:**                    **Transcript**  
   **Additional Questions**

## **Semiannual Program Review**

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Slide 1 (Semiannual Program Review)

>>*Neera:* Hello. Today is Thursday, December 13, 2018. I am Neera Gopee, Veterinary Medical Officer in the Division of Compliance Oversight at OLAW, and today it is my pleasure to welcome our speakers, Dawn O'Connor and Bill Greer, to the [OLAW Online Seminars](#) to present **Semiannual Program Review**. As part of the semiannual program evaluation, this webinar is a companion piece to Bill and Dawn's June 28, 2018, OLAW webinar on [Facility Inspections](#). Please be sure to review the slides and transcript of this webinar on OLAW's website.

Slide 2 (Semiannual Program Review)

Dawn serves as the Assistant Director, Regulatory Compliance for the Animal Care and Use Office, ACUO, at the University of Michigan. She began her career in 1988 at the University of Michigan. She has 20 years of regulatory experience, with a Certification as a Professional IACUC Administrator, CPIA, and 10 years of experience as a veterinary technician in the Laboratory Animal Medicine Unit. She also served for seven years as an AAALAC *ad hoc* specialist. Dawn has extensive expertise in regulatory compliance with an emphasis on interpretation and implementation of the policies, procedures, and standards at the University of Michigan. She provides leadership and management to a compliance staff and oversees IACUC functions such as facility inspections, IACUC meetings, and follow up, protocol review processes. Dawn also serves as a board member for the IACUC Administrators Association, IAA.

Our other speaker, Bill Greer, serves as Assistant Vice President for Research Compliance Oversight at the University of Michigan where he provides leadership to and oversees the University's Animal Care and Use, Institutional Biosafety, Controlled Substance, Laboratory Safety, and Autonomous Systems Compliance programs. In partnership with

the attending veterinarian and the IACUC, Bill leads the Animal Care and Use Office in fostering an environment of engagement, support, and service to the research community.

Bill works with the animal care and use committee to ensure all animal research is reviewed, approved, and conducted in accordance with all appropriate international, federal, and state regulations and guidelines, as well as with specific guidelines from funding agencies, institutional policies, and appropriate accreditation standards. Bill joined the University of Michigan in May of 2016 after serving for 15 years as Associate Director in the Office of Research Protection at Pennsylvania State University. He also serves as the executive director and president of the IACUC Administrators Association, IAA, and is the co-director of the IAA Best Practice Meetings.

It's my pleasure to welcome both of you once again to the OLAW Online Seminar and now to hand the microphone over to Bill.

Slide 3 (Throughout the Webinar)

>>*Bill*: Thank you very much, Neera. It's our pleasure to be here and our pleasure to participate. So, throughout the webinar, Dawn and I will be discussing semiannual program reviews and how they are conducted. So Dawn will look at the program review process used here at the University of Michigan, and my goal is to briefly review the regulatory requirements and discuss some of the alternative methods that may have been used by other institutions to conduct their reviews. But for your convenience, we have color coded the slides. Dawn's will have a white background and they will be reflecting the practices employed here at the University of Michigan. And my slides have a gray background and will summarize the regulatory requirements and offer other ideas for conducting program reviews.

Slide 4 (Why do we Conduct Semiannual Program Reviews?)

>>*Dawn*: We are required by law, both the Animal Welfare Act and the Health Research Extension Act, to conduct reviews of our institutional programs on a semiannual basis. Both the Animal Welfare Act and the Health Research Extension Act have specific requirements on how to conduct and what to include in the reports to the Institutional Official (IO). In my next few slides we will do a comparison of these requirements. In order to receive federal funds, institutions must comply with both of these documents.

Slide 5 (Yes, Federal Law and Policy, but...)

>>*Bill*: So, while performing a program review is a federal expectation, the requirement in itself also provides the institution opportunities. For example, many programs are memorialized through written documents. These documents are often a collection of policies, guidelines, and SOPs, or may even include points as simple as an IACUC's position statement.

Since robust programs continue to evolve based on new discoveries in, for example, the field of veterinary medicine, the review can be used as an opportunity to ensure the program continues to reflect current best practices. It gives institutions the opportunity to update written documents after IACUC discussions; and once the documents are reviewed by the committee, these reviews can be documented and maintained through the compliance office. In addition, the opportunity allows committee members to reconsider past decisions and enhance practices that ultimately may improve the overall quality and efficiency of the program.

Another opportunity is to use the program review as a source of ongoing training for committee members. During program reviews, members have the opportunity to ask specific questions about various components of the program, which ultimately improves their understanding of the overall animal care and use program and more importantly their role as a committee member.

Slide 6 (Ensure the Program is Consistent with the Standards)

So when conducting the program review, the federal expectation is to ensure program practices are consistent with governing standards. So OLAW recognizes the *Guide* [*Guide for the Care and Use of Laboratory Animals*] as the primary regulatory document, and the USDA recognizes the Animal Welfare Act [and Animal Welfare] Regulations. The *Guide*, referenced in the PHS Policy [Public Health Service Policy on Humane Care and Use of Laboratory Animals], and the Animal Welfare Act Regulations specifically list, for example, the roles and responsibilities of the IACUC, the prescribed living conditions of the laboratory animals, and the components of the veterinary care program.

In addition to the primary standards institutions may also use other resources when conducting their review. It is important to recognize that institutions performing a program review must ensure comparisons are being made to the appropriate documents. For example, institutions that use swine in studies that are intended to improve overall food animal production process, i.e., food and fiber, would apply the Ag Guide [*Guide for the Care and Use of Agricultural Animals in Research and Teaching*]. Importantly, institutions using swine in biomedical studies would apply the principles of the *Guide* and the Animal Welfare Act Regulations. In fact, if an institution uses some swine in biomedical research and some in food and fiber studies, that institution would need to apply the Ag Guide to the food and fiber study and the *Guide*, as well as the Animal Welfare Act Regulations, to the activities involving the biomedical swine.

Slide 7 (What Other Resource Documents may be Helpful?)

In certain circumstances, the primary guidance documents may not include the relevant information as it relates to some specific animal activities. As a result, and depending on the institution's research portfolio, other standards may be used to compliment the program review. For example, institutions that conduct a significant number of wildlife studies may find the Mammalogist [*Guidelines of the American Society of Mammalogists for the Use of Wild Mammals in Research and Education*] or Ornithological [*Guidelines to*

the Use of Wild Birds in Research] guidelines useful during their program review. Although not regulatory requirements, institutions with accredited programs may also take this opportunity to compare their programmatic practices to AAALAC's position statements.

So in addition, some institutions may have practices within their programs that departs from the regulatory standards based on internally established performance standards. So, during the program review, the IACUC could recognize the departures and validate the performance standards continue to justify the program departures.

#### Slide 8 (NIH Guide Notices and OLAW FAQs)

In certain circumstances, regulatory guidance may be provided to organizations through an NIH announcement. Consequently, institutions, when performing its program review, may also need to use these resources. In some cases, the NIH announcements may be cited in an OLAW FAQ. As a result, ensuring program expectations are consistent with FAQs and NIH announcements may also be part of the overall program review.

For example, the FAQ in Section D on Protocol Review, [Question 9](#), references the OLAW NIH announcement on significant change. Consequently, an institution validating its practices may only be able to find the relevant details in a NOT [NIH Guide Notice] announcement which perhaps an OLAW FAQ could be providing the reference. It is worth emphasizing that in some cases the only information on an expectation may be in an NIH announcement or described as part of a regulatory clarification through OLAW in an FAQ.

#### Slide 9 (What are the Components of an Animal Care and Use Program (ACUP)?)

So, let's quickly generalize the primary components of an animal care and use program. Based on the *Guide*, the IACUC should ensure compliant methods for program oversight and support have been established. They should also verify that the husbandry practices meet the *Guide* expectations, and that the veterinary care program and the physical plant conditions meet and also satisfy the expectations.

#### Slide 10 (Resources that may be Representative of the Program)

So, what documents may characterize an institution's program? Many institutions use the [OLAW checklist](#) as a resource to ensure it reviews each and every component of the program. So, I'm sure institutions are familiar with the checklist, but briefly it breaks down a program into relevant sections. It also provides the specifics of each section with citations to the *Guide for the Care and Use of Laboratory Animals*. In addition, and based on an institution's program, a customized version of the OLAW checklist may be developed and used satisfactorily to meet the needs of the institution. It is also worth noting that many other documents represent an institution's program and its status.

For example, AAALAC International has developed an animal care and use Program Description, PD, template that can be used to comprehensively describe the details of an institution's program. Traditionally this document, after completion, is provided to AAALAC International in preparation for an institution's accreditation visit. Since the PD thoroughly

describes the institution's program, upon review and discussion during an accreditation visit, AAALAC frequently then accredits that institution's program. In other words, their Program Description. So it is worth mentioning that the PD template provided through AAALAC could be used by any institution to organize the details of its program whether it is interested in earning accreditation status or not.

So, as we are aware, OLAW also gathers the details relative to an institution's program using the PHS Assurance template. Consequently, an OLAW approved Animal Welfare Assurance also includes the details of an institution's program and could be specifically re-evaluated on a regular basis which could serve as the program review. It is also worth noting that program performance can also be used to and also can be quantified through metrics which could be used to look at various components of the institution's program. For example, the number of annual noncompliant events and related animal incidents may reflect how effective an institution's training program is.

Slide 11 (Does your Institution Conduct the Review by Just Checking the Boxes?)

So, how does your IACUC perform its program review? Do you include a copy of the OLAW checklist as part of the IACUC meeting packet? Then during the meeting, go through the checklist point by point and simply ask the IACUC members to agree that the list – the listed requirements – are satisfactory as it relates to your program and then finally record in the minutes that the committee discussed each listed item in the checklist. Then provide a brief summary of that review to the IO as part of the IO report and repeat the process six months later.

Slide 12 (What's the Dialogue during your Program Review? Option 1)

Let's talk about the dialogue during your program review or the program review at your institution. So, looking at option 1, does your IACUC administrator or Chair say perhaps "Does anyone have any concerns regarding section 1 on the OLAW checklist?" Hearing no comments from the IACUC, they move on and the IACUC administrator or the Chair says "Any questions on section 2?"

Slide 13 (What's the Dialogue during your Program Review? This (Option 2)?)

Or, if we take a look at option 2, does your IACUC administrator or Chair say something like this, "Referencing the checklist, there's a specific question that says does the IO have the authority to allocate needed resources to the program," for example, the IACUC Chair goes on to say "The IO has a portion of the budget dedicated specifically to animal care and use and has and will continue to ensure the program has necessary fiscal resources to function."

With that the IACUC may ask questions and engage in a discussion and someone on the committee may say, "So how much is allocated, and could we cover major capital expenses such as replacing a cage washer?" In addition, a committee member may ask for examples of allocations that have been made over the years. So once completed, the

IACUC Chair then continues on through providing additional relevant information about each section and prompting folks to ask questions.

#### Slide 14 (Benefits of Checking the Box)

If we take a look and we consider option 2, we see that it's a much, much better process that satisfies the requirement beyond the bare minimum and that particular process meets and somewhat exceeds the minimum requirement. If your process is to follow option 1, then I use the word to say it barely meets the requirement. If your program review has become so routine that it's possible for the Institutional Animal Care and Use Committee members to go through the process and not even look at the checklist, then you may want to look to see if there are ways to enhance your process. At a minimum option 2 provides the administrator the opportunity to make callouts on each section and that in itself will help to facilitate conversations between committee members.

#### Slide 15 (Optimal Comprehensive Program Review)

So, if we turn the requirement into an opportunity, how can we do that? If the review is conducted as perhaps a mini retreat, maybe at least once a year, for IACUC members, the committee members will become more familiar with the expectations and more likely to learn and understand why they are in place as committee members and why the IACUC is there and its function. Not to mention that the institution just satisfied a regulatory requirement, and that is to conduct ongoing continuing education for committee members.

If the program review is performed by reviewing, for example, the Assurance or the Program Description, this process will and help institutions to ensure the documents remain current. And consequently, if Assurance changes need to be reported to OLAW during the annual report period, they would be readily available and at your fingertips. In addition, as you know the PD is sent to AAALAC every three years, and when we prepare the Program Description for AAALAC review, it is a very daunting process. If perhaps we kept it current, it would make it as much easier for us to satisfy this requirement and provide it to AAALAC on a timely basis.

#### Slide 16 (What do we do at the University of Michigan (U-M)?)

>>*Dawn*: Thank you, Bill. So, let's talk about the U of M model.

#### Slide 17 (Old U-M Program Review Model: Check the Boxes)

Previously at the University of Michigan, we used to review the OLAW checklist in a manner that was not effective or provided learning opportunities for the committee. The Animal Care and Use Office in cooperation with the Laboratory Animal Medicine Unit would provide the necessary updates to policies, guidelines, and veterinary care within the OLAW checklist request. Then we would present this to the IACUC at a designated meeting. If further updates were suggested by the committee, then the Animal Care and Use Office would note that during the meeting and revise the documents as necessary. Conducting the program review in this manner only made the committee feel

overwhelmed with lengthy conversations. Does this sound familiar to anyone? By just checking the boxes.

#### Slide 18 (New U-M Program Review Model: Enhancement)

We proposed a new method of program review that would require their full participation and they would be leading the actual review during an IACUC meeting. The key was to present the plan, communicate the strategy, ensure they were educated in their role and that they would have full support of the Animal Care and Use Office staff, however the decision and the work was completely the IACUC's responsibility. Listed here are the steps that I will discuss in the following slides.

#### Slide 19 (Step 1: Communicate the Strategy for Conducting Program Review)

The key again is to communicate and provide instructions on how to accomplish the task. We send out an announcement each spring and fall with member assignments. Each member and subcommittee Chair will be rotated each six months to give every member an experience at leading and learning about the program in depth. All necessary review documents are provided electronically to each member with a deadline for completion.

#### Slide 20 (Step 2: Select Standard Document for Program Review)

Each fall we use the OLAW checklist modified for our program, followed by each spring using the Program Description to conduct the program review.

#### Slide 21 (Step 3: Review the Program)

For the sections of the checklist, we assign multiple committee members to work as a team and provide any resources upon request. Our compliance and quality assurance staff are assigned a subcommittee as support and to gather any needed documents for the IACUC. We also assign a subcommittee Chair to keep the team on task and complete the work by the deadline. It is the subcommittee Chair's responsibility to decide how best to accomplish the task of reviewing their section. For example, they may meet formally, they can converse via email, or they could have teleconference calls to get the job done.

To provide knowledge of a particular section, individuals with expertise are assigned for each subcommittee. For example, an Environmental Health and Safety specialist may be assigned to the Occupational Health and Safety section. Just prior to an IACUC meeting, presentations are collected in the Animal Care and Use Office from the members. Any one of the members from each of the teams can present their section and provide any recommendations to the full committee.

#### Slide 22 (The Enhancement Program Review Model Provides IACUC Member Training Opportunities)

Each subcommittee member receives their section of the AAALAC Program Description electronically. The subcommittee conducts a thorough review and comparison of what we say we do is actually what is happening in the research community. Any inconsistencies or suggestions for improvements are noted in the IACUC meeting minutes and then the

Animal Care and Use Office staff ensures that the updates are reflected within the PD. Performing an AAALAC program review once a year proves to be very helpful and efficient as changes are identified as you find them rather than waiting to update the PD twelve months prior to the submission deadline.

During the review of the checklist, the members use all their resources to gather the data, ensure that it matches what is performed at the institution, and then shares it with the team to make an assessment of the program section. If the team identify deviations, it is noted during the meeting and the Animal Care and Use Office will work with various units to determine the best method for correction according to the plans laid out by the committee. If the deviations will cost additional funds, then the IO is apprised of the need. Suggestions for improvements are reviewed and determined the best way to implement, along with input for all applicable units; and again, if the unit feels that resources are needed, then the IO is made aware.

#### Slide 23 (New vs. Old U-M Program Review Model)

The University of Michigan is a very large biomedical research program that spans across three campuses, with two field stations and more than 30 plus buildings on the main campus alone. By rotating members between sections of the Program Description or the checklist each six months, they will continue to learn about different areas each time which expands their knowledge of the entire University of Michigan program. Not only are the members engaged about the program, they are also aware of the requirements and the regulations needed to effectively update and manage the program efficiently.

#### Slide 24 (Enhancements Through Program Review)

Engagement of the committee is key to really learn more about the program in depth. Over the past two years, our committee has been engaged and we have improved processes such as methods for better tracking of pilot studies, improvement of tracking minor deficiencies, and identified improved methods for sterilizing procedures of instruments. In the euthanasia section of the OLAW checklist, it asks the question "Training is provided on appropriate methods for each species and considers psychological stress to personnel." The result of this was a compassion fatigue committee to address staff needs. In addition, the committee suggested that training be expanded to cover the psychological stressors that are a result of staff performing euthanasia.

As we all well know that our AAALAC PD accumulates many changes over the years, but doing an annual review of your Program Description, you can make the necessary changes as they occur and not have that rushed feeling just prior to submission. By providing continuing education to the committee, this also helps them to understand what needs to be part of the review process each six months. As a result of rotating each of the committee members, each of them sees through a different perspective and that keeps us on our toes and constantly reviewing our practices to ensure they are effective and have value. This model of review has also helped us to better refine not only procedures and practices but to help with the redesign of our animal protocol template.



#### Slide 25 (Results of the Enhancement Model)

As a result, through a program review it was recognized that there is an increased awareness of how compassion fatigue can impact anyone involved in the laboratory animal science and that U-of-M has a program to help our animal care staff and soon the program will be expanded to the research community.

#### Slide 26 (Are We Done Yet?)

>>*Bill*: Okay. Are we done yet? Are we done yet? Anyway, so during the June 28th, 2018 webinar, we discussed facility inspections, and today we talked about the program review process. So, anything else?

#### Slide 27 (Let's Tell the Institutional Official (IO))

Let's close the loop. So, the attending veterinarian and the IACUC Chair and administrator handle the daily details associated with an animal care and use program. The IO is frequently in a senior leadership position and must be given a program status update at least [semiannually].

#### Slide 28 (Reporting to the IO)

As you can see, the regulatory references are consistent from standard to standard. The expectation is that each IACUC submits a report on the program status to the IO at least [semiannually]. The Animal Welfare Act Regulations, the PHS Policy, and the *Guide* all indicate the report must be prepared and issued to the IO from the IACUC.

#### Slide 29 (What Must the IO Report Include?)

Generally speaking, the IO report typically includes the details associated with the semiannual facility inspections and the details identified during the program review.

#### Slide 30 (What Must the IO Report Include?)

If we speak more specifically, the regulations require us to include in each IO report, a description of the nature and the extent of the institution's adherence to the *Guide*, the PHS Policy, and the Animal Welfare Act Regulations. It asks that we list the departures from the provisions of the *Guide*, the [PHS] Policy, and the [Animal] Welfare Act with a [reason] for the departure.

In addition, if any deficiencies are identified, the deficiencies should be listed, and it should be categorized as either being a significant deficiency or a minor deficiency. Associated with each deficiency, the report must also include a reasonable and specific plan with a schedule for the correction of the problem. In addition, and finally, the report [must] include a list of any minority views expressed by the committee members.

#### Slide 31 (How about Some Definitions?)

So, for simplicity and just to bring it out on the table so we understand, we threw a few definitions on a slide for you to take a look at. A significant deficiency is defined both in

the PHS Policy and the Animal Welfare Act. It is basically anything that may be a threat to the health and/or safety of an animal. Departures would be an activity related to animal care and use that is not necessarily consistent with the *Guide* or the Animal Welfare Act expectations. And finally, the minority view is a written opinion expressed by an IACUC member that may not be consistent with the majority opinion of the committee.

Slide 32 (What Else do we Need to Know about the IO Report?)

What else do we need to know about the IO report? The IO report needs to be prepared and/or updated, then provided to the IO at least semiannually. That report needs to be signed by a majority of the IACUC members and it must be maintained as an official document of committee activities and be made available to OLAW or USDA upon request.

Slide 33 (What Should the Report Look Like?)

What should the report look like? Institutions have the discretion to make the IO report as comprehensive as they wish, providing the report includes the required details that were previously discussed. For example, some IOs prefer to have that comprehensive collection of materials, so lots of materials, lots of data, matrix and everything associated with the program. While others in a senior leadership role simply want to have a summary of the activities, obviously it needs to include all the points that we mentioned previously, and accompany that with a discussion between the IO, the IACUC Chair, the AV [attending veterinarian] and perhaps the compliance director.

Slide 34 (Questions)

>>Neera: Thank you, Bill and Dawn. Now we will answer several questions that we received before the webinar. We also welcome live questions from the audience. Please type them into the questions pane on your control panel now.

Slide 35 (Question 1)

Question one, how much flexibility does OLAW allow in the conduct of semiannual program review? For example, if my institution performed its program review on January 15<sup>th</sup>, when does OLAW expect the next program review to occur? And I am going to answer this one.

Slide 36 (Answer 1)

I've put the answer up on the screen so that everyone could see it. OLAW expects the subsequent semiannual program review to be conducted approximately every six months and which means six months later from the previous inspection and no later than 30 days after July 15<sup>th</sup>.

Slide 37 (Question 2)

Question 2, can institutions use the AAALAC site visit to satisfy their semiannual program review requirement? So again, I will tackle this question.

Slide 38 (Answer 2)

Yes, it is permitted. Because the PHS Policy allows the use of *ad hoc* consultants and who better to serve as *ad hoc* consultants than AAALAC, as long as the requirements of the PHS Policy are met. I will refer you to OLAW's [Guide Notice OD-00-007](#) for more details.

Bill or Dawn, what's your position on using the AAALAC site visit to satisfy the semiannual program review at U-of-M?

>>*Dawn*: Thank you, Neera. Neera, we do not use our site visit to count as our program review because of timing purposes and because of the size of the institution and gathering people to get them coordinated in order to count this as the same as our program review.

>>*Bill*: Yeah, I'll add to that, Neera, and say there's a lot of things going on during the AAALAC site visit, so we don't want to distract from that and we spend our time with AAALAC and doing the site visit. And then we want to make sure that the IACUC also is engaged in the program review and they're looking at it with the IACUC's set of eyes.

>>*Neera*: Right. And so, it's not a one size fits all. If it works for your institution, it may work differently for other institutions.

Slide 39 (Question 3)

>>*Neera*: Question number 3: Does U of M routinely utilize *ad hoc* consultants for their program review?

>>*Bill*: We do have here at U of M, we do have the Director of our Environmental Health and Safety Office on our committee, and they are routinely engaged in our program review process as it relates to Occupational Health and Safety. Other than that, we perform the review using the committee and using the expertise here at the institution. Now, I will add a caveat and say that we may use *ad hocs* during the review of a study that we haven't seen here at the institution before. And if necessary during the program review, we may update the *ad hoc* on what we found and then ask them for more guidance if we have concerns.

Slide 40 (Question 4)

>>*Neera*: Thank you, Bill. So question 4, and this is a two part question. Dawn explained that the U of M rotates standard documents during the year, basing one review on your institution's Program Description and next on the OLAW checklist. The first question is: Is the use of the OLAW checklist mandatory? And the second question is: Are all components that OLAW expects to be reviewed included in the institution's Program Description?

Slide 41 (Answer 4)

And I will actually tackle that first question with regards to whether or not the OLAW checklist is mandatory. There is not a requirement, there is no requirement for institutions to use the OLAW checklist. This checklist is simply a tool to help IACUCs conduct thorough

semiannual reviews. It covers the major topics of the *Guide* and the requirements of the PHS Policy and also includes links to relevant sections or topics within the *Guide*. OLAW encourages institutions to amend it as necessary to reflect their program and their needs; and if the checklist is modified, your IACUC should review it periodically to be sure that relevant topics are considered as your animal care and use program changes. Bill or Dawn, do you have anything else to add?

>>*Bill*: I would add, Neera, that relevant to the institution's program description, if an institution chooses to use the AAALAC template, then AAALAC has designed it in a manner to gather all of the relevant information comprehensively about an institution's program. So, I would say that, that PD, provided again it's the AAALAC template, would include comprehensively everything that is associated with the program. You know, after all, it is the document that AAALAC uses to familiarize themselves with the institution's program in preparation of their accreditation visit.

>>*Neera*: Okay. For the second part of this question, are all components that OLAW expects to be reviewed included in your institution's program description?

>>*Bill*: So that's basically what I was just discussing, Neera, as it relates to the AAALAC template.

Slide 42 (Question 5)

>>*Neera*: Okay. So, to question 5: Are the training opportunities, which are provided as part of the enhancement program review model, documented? If so, how?

>>*Dawn*: Neera, those training opportunities are documented within our new programs because we do it during the semiannual review of the program at a convened meeting; so those would be captured in our meeting minutes.

>>*Neera*: Thank you.

>>*Bill*: And also, any ideas are reflected in enhancements to our Program Description and through other documents. So, we have multiple ways that we're showing the activities associated with the program review process.

Slide 43 (Question 6)

>>*Neera*: Okay. And one final question we have that we received in advance was: Are all IACUC members provided the opportunity to review various components of the program review or are they allowed to specialize?

>>*Dawn*: We assign all our committee members and we rotate them through each of the different lists every six months so that they get an opportunity to learn and know about each section of the checklist or the institution's program. We may have some specialized areas such as field studies since we don't do very many field studies; so we may put a

person who is on the committee who has field research or expertise in that section to sort of help the group determine if our practices are appropriate.

>>*Bill*: And again, to add a little more to that, Neera, whenever the subcommittee team leaders present the information to the IACUC as a whole, it is an opportunity for each and every IACUC member to weigh in on all of the sections of the program review. And in some cases, we get good input from others that were not part of the subcommittee. And in some cases, we can obviously see that our goal of training committee members is working because they're asking questions out of curiosity.

>>*Neera*: And I think it's a great model, especially your nonaffiliated and nonscientific members can gain tremendously from this method, this process you have of rotating your members throughout the different subjects.

Slide 44 (Questions)

Thank you. And we've been getting lots of questions from the audience, and I'll start with the first one.

[Question 7]

Does the program review need to occur semiannually? And the answer is yes. The program review must occur semiannually as required by the PHS Policy and the Animal Welfare Act Regulations.

[Question 8]

So, the next question: Is a departure distinct from an identified incident of noncompliance? And I'll answer that, I'll take that one again. Yes, it is. In some situations, often for scientific reasons, the IACUC approves a protocol that requires a departure from the *Guide* standards. This would not be noncompliance, but an approved departure that must be included in the report to the IO.

[Question 9]

Next question, and this is directed to you, Bill: Is there an Ag Guide checklist available somewhere to assist the IACUC in meeting Ag Guide requirements or expectations during facility inspections?

>>*Bill*: There are some checklists available that have been developed by specific institutions and it's related to their specific programs. During some of our past meetings where we pulled community members together for Best Practice meetings, some of these ideas have been brought to our group and discussed. So, the answer is yes, but they're normally documents that live within the context of an institution's program. Having said that, you know, our philosophy as a community is to share, steal, beg, borrow, and plagiarize. So, I'm sure that, you know, if asked, we could find copies or suggested ideas of a checklist that would be associated directly with the Ag Guide.

>>*Neera*: Yes, Google is a wonderful tool out there, the Internet. So that's a place that folks can turn to for some templates that may be available from other institutions. Next question.

>>*Bill*: Whoever is asking the question, if you reach out to me directly, I'll look back in the archives of the Best Practice meetings and see if I can find an example. If not, I'll try and find who presented that information and help you identify a checklist for the Ag programs.

>>*Neera*: And we can also post it on the website, at the transcript site as well if it's something that we see it's necessary.

[Question 10]

Next question: How are you preparing staff for the extensive compassion fatigue training and the researchers? This is broad, but can you generalize?

>>*Dawn*: The compassion fatigue program originally started out with our husbandry staff and that is actually run by the husbandry staff in an enrichment program in that they provide the training, they let people know what kind of symptoms they may go through. They describe some of the symptoms they may have. They also provide them with resources, whether its university resources or outside resources, that they can get help from as well. And that's a fairly new program here at the University of Michigan and it started with the husbandry staff and the training of husbandry staff to recognize those types of symptoms. We will be eventually doing the same program in this reach-out program to our research community as well. So, stay tuned for more information about this since this is in the infancy with this program currently.

[Question 11]

>>*Neera*: Okay. Next question: How many members usually participate in the subcommittee during the program review process? And what membership roles do they hold if they are IACUC members?

>>*Bill*: Dawn discussed whenever she went through this in her slides that we will try to mix folks up. So, we have 27 IACUC members, we have four nonaffiliates, two nonscientific members, we have three people from the Compliance Division, and three veterinarians. So, one of the things that we try to do, depending on the specific section that we're looking at, is mix up the committee members, the scientific, nonscientific, and nonaffiliate members, and give them new topics all the time. And then we'll keep, for example, a veterinarian as part of maybe a euthanasia section or veterinary section. And again, that particular individual is, yes, a committee member, but they also have some expertise related to veterinary science, so they can answer questions from a veterinary perspective and provide clarification.

The same concept on more of an oversight or a post approval monitoring side where the compliance staff, folks from Dawn and my office, we just have them available to answer questions specific to maybe compliance expectations as it relates to reporting, conducting reviews, training, and things like that.

Again, our goal is to rotate committee members through the system, so they all have an opportunity to see a different component. And I say that in a sense that the subcommittee digs a little deeper into things than what we would typically dig into during the discussion with the whole IACUC. So, it allows people to get a better understanding of a section and to better answer questions for committee members. I hope that hits on the point that you were trying to get from the question that was asked.

>>*Neera*: Yeah, I think that's pretty clear there.

[Question 12]

The next question we have, and I think this is directed to you, Bill. You mentioned program enhancements are documented in the minutes. Have you been questioned by AAALAC as to why recommended enhancements have not been implemented? If that's even maybe, it's a misunderstanding on what is implemented versus just documented? I'm not sure.

>>*Bill*: Yeah, I think that's the misconception. So, one of the questions that we had is how do we document the program review? And we have multiple ways of documenting enhancements. You know, one of them is through the minutes, which obviously talks about the program review discussion, and it identifies specific points that occur during that time. And then from there Dawn mentioned that we take that document and we use the minutes as almost a checklist. And we sit down with the minutes and we look at the things that the IACUC identified and looked at their plans for if it was a deficiency correction, and we do that. And if it was an idea for enhancing the program or improving efficiency, we also consider the things that we can do. And we will do that.

So all in all the process starts with the program review, then it goes to an IACUC meeting with the items documented in the minutes, then from there we take that document and the Animal Care and Use Office will update the Program Description, put notes in the Animal Welfare Assurance, and reach out to anyone else that we need to reach out to to do the things that have been requested by the IACUC. And enhancements would be reflected maybe in the Assurance or the program description or even in policies and guidelines and other SOPs that represent our program.

>>*Neera*: Thank you, Bill. Now this one, either Bill or Dawn can address it.

[Question 13]

>>*Neera*: What are your institution's thoughts on having quality assurance members on the IACUC and have them being involved with the post approval monitoring?

>>*Bill*: You know, through Best Practice meetings we've seen a dozen different ways that institutions do this. I will say that we started Best Practice meetings in 2005 and traditionally the idea was to keep the PAM [post approval monitoring] folks and the QA [quality assurance] folks off of the committee and have them function independently so they can do their QA services and help PIs without having a direct role through membership on the IACUC.

Here at our institution, we've chosen not to have Quality Assurance people on the IACUC, but we have chosen to ask the Director of the QA Division to give routine reports to the IACUC which gives committee members the opportunity to ask about specific components of the program. So I think directly answering the question, the institution needs to decide what would work best for them; and then having said that, having the Quality Assurance people associated or connected to your IACUC is critical because they in effect are the eyes and ears of your committee and they're the ones that are out there in the areas all the time.

>>*Neera*: Okay.

[Question 14]

Next question: Does your veterinary medicine program review include all vivarium SOPs and IACUC policies?

>>*Bill*: Does our veterinary program review?

>>*Neera*: Yes, the review of your veterinary program. Yeah. Maybe it's the University of Michigan program review. Does your program review include a review of all SOPs, your vivarium SOPs, your IACUC policies, and other SOPs?

>>*Bill*: So, our practice is this: we have certain policies that are reviewed and approved by the IACUC. Those documents are reviewed and approved on a regular basis; at least once a year we take a look at them as part of a program review. Changes are made when necessary and the document is updated. Now, some of the veterinary guidelines and documents within a veterinary program, they are changing based on changes in veterinary medicine. So, we like to keep those particular documents flexible at the discretion of the university attending veterinarian. We do look at them as a committee, we understand, and we make sure that the overall veterinary care program, which may be a collection of SOPs, guidelines and other documents, if formalized, we do make sure they comply with the *Guide* and they meet the general philosophy of *Guide* expectations as it relates to the care and use of animals. But again, we don't like to formalize in a way where the IACUC reviews and approves it and then before the veterinarian can make a change to it, it needs to come back to the IACUC for review and approval again.



I think that I'll add one note and caveat that institutions should be aware of. If you're using your veterinary documents or guidelines as it relates to a VVC [Veterinary Verification and Consultation] policy that you may have in practice, then it may require you to make sure your IACUC is reviewing and approving it. So, it may tie your hands a little there, but I think for the most part a common practice for institutions is to try to keep their veterinary practice documents, living documents and let them be enhanced at the discretion of the attending veterinarian, especially if it relates to animal welfare.

>>*Dawn*: Neera, I'll add to that. We also have a subcommittee or a committee that specifically looks at policies, guidelines, and standard operating procedures. And on that committee, it includes staff from the Animal Care and Use Office for compliance as well as lab animal medicine. So, we are really working together as both groups and looking at different policies, guidelines, and SOPs that actually are within our program.

>>*Neera*: Thank you. Thank you, Bill and Dawn. And we have one final question.

[Question 15]

Can you help define teachable moments?

>>*Bill*: Teachable moments. The teachable moments, that was coined by the USDA, and as you know the USDA a few years ago set up a scenario where when the VMO comes to visit us if they find something that could use some improvement, rather than citing us as an institution, they use it to help enhance and train whoever it is they're working with. And VMOs are typically working with the leaders of the institution's program.

So, we try to expand that idea to specific animal care and use programs. I think teachable moments are very valuable. I think that the caution and the caveat I'll add to that is we should always be aware that if we're going to use a teachable moment that we need to address the regulatory components as well.

For example, if we find something that is specifically listed as a reportable noncompliance, then it may involve a teachable moment so we're teaching the PIs or whoever is involved the issues related to that and how to fix it. And then we do the relevant background things, in quotations, that we need to do, which is could and would involve maybe a committee review of an activity and then also a report to OLAW. And if necessary the USDA and AAALAC.

So, I think teachable moments is, I won't call that a novel idea anymore because we've been talking about it for some time, but I think it's a very effective tool for quality assurance programs and also for veterinarians as they're working with PIs in the hands-on case by case basis.

#### Slide 45 (Questions)

>>*Susan*: Hi everyone. This is Susan Silk. Now we come to the end of our online seminar on Semiannual Program Review. Participants, if you have additional questions, and we do have a few that have been submitted, on this topic for Dawn and Bill or for OLAW, please submit the remainder of questions that occur to you by email to [olawdpe@mail.nih.gov](mailto:olawdpe@mail.nih.gov). You can see the address there on our screen. Our speakers will address the questions and the answers will be posted on the OLAW website.

Thank you to Bill and Dawn for a second wonderful talk. We at OLAW appreciate the time, effort, and care you put into providing these terrific webinars to our community. I also want to thank all of you listeners for participating in our webinar and especially to those who sent in questions.

This is a special moment for me because I am now saying goodbye to you. I will be retiring after 20 years of federal service at the end of December. The OLAW Online Seminars are a fun and rewarding project. I've loved working on the webinars with all of the wonderful speakers who volunteered their time. Thank you, participants, for your enthusiasm and your questions throughout the years. I will miss you, but not too much, because I will have the opportunity to work with many of you again in 2019.

After taking January off, I will be consulting to OLAW. I will continue to direct the [ICARE Program](#) and I look forward to working with the IACUC Administrators Association. So, I plan to see many of you again soon in my new roles.

Now I return you to Neera Gopee who will be serving as the Acting Director of the Division of Policy and Education starting on January 2, 2019. The OLAW online webinar series will continue in the capable hands of Neera.

#### Slide 46 (ICARE Workshop Schedule)

>>*Neera*: Thank you, Susan. And as you can imagine, I have some ginormous shoes to fill. And although this is not good bye, I am sure that everyone would agree that it is an understatement when I say that you will surely be missed. For any and everyone that know you, and that's a lot of folks, they all know that your passion for ensuring animal welfare has always reflected in all that you do. Most notably your endeavors and your sweat invested in the ICARE Program.

And as you can see here, the 2019 ICARE schedule is posted for everyone who is interested. Registration for several of the workshops is now open and we anticipate opening registration for the remaining workshops shortly. You can find information about the ICARE Program at the url [<https://olaw.nih.gov/education/icare-interagency>] provided on the slide and can telephone or email OLAW if you have questions.

Slide 47 (Superstar Rats Teach Empathy to Researchers)

The next OLAW Online Seminar will be on March 21st, 2019, when Dr. Catherine Schuppli from the University of British Columbia will present a talk titled "Superstar Rats Teach Empathy to Researchers." It describes her research using a novel educational intervention to test if exposure to socialized rats that demonstrated complex mental and behavioral abilities, promoted compassion amongst animal researchers. I wish everyone a good winter and look forward to having all of you join us for our next webinar in the spring of 2019. Good bye and Happy Holidays to all.

### **Additional Submitted Questions Not Addressed During the Webinar**

*The following questions were submitted in response to the Semiannual Program Review webinar on December 13, 2018. Although we did not have time to address these questions during the webinar, OLAW and the speakers have prepared the following answers.*

**Question A:** Is not meeting a "should" in the *Guide* considered a departure?

>>*OLAW:* There are different reporting requirements for "should" statements in the *Guide* based on the situation. Refer to OLAW's webpage on [Departures from the Guide](#) to learn more.

**Question B:** Does OLAW have any checklist for semiannual program review?

>>*OLAW:* Yes, OLAW developed a [Semiannual Program Review and Facility Inspection Checklist](#) to help institutions conduct their semiannual reviews of programs and facilities. Institutions are not required to use this checklist, but it is provided as a tool that institutions can modify to suit their programs and needs.

**Question C:** During the webinar on Semiannual Program Review, there was a little bit of discussion regarding the use of Program Reviews for conducting ongoing training for IACUC members. Does this mean formal training or informal training as in discussions about the Program? We are a small research non-profit institution that has a small IACUC and small animal care and use program (mainly involving research on mice). I'm struggling with what training I (I am the Institutional Official) could offer to my IACUC members. We have 6 IACUC members. Our semiannual reviews are usually brief, not lasting more than 1-1.5 hours.

>>*Bill:* I believe training is training whether you want to call it informal or formal. I would say it is formalized once the training is documented. The "training" could occur as a discussion during an IACUC meeting in which you have a discussion about each section of the program (using for example the OLAW program review checklist). If you feel your committee is well trained on all programmatic matters, you could simply call this a refresher (i.e., ongoing) training. I would say that 2-3 hours of training relative to the animal care and use program per year is good.

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