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Self-Evaluation & Reporting: Always Let the *Guide* be Your Conscience

Speaker:

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Broadcast Date: December 15, 2016.

View Recording: https://youtu.be/77_gmxTsCMQ (Youtube)

Slide 1 (Self-Evaluation & Reporting: Always Let the *Guide* be Your Conscience)

>> *Swapna:* Today is December 15th, 2016. I am Dr. Swapna Mohan, from the Division of Policy and Education, OLAW. And it is my pleasure to welcome Dr. George Babcock from the University of Cincinnati (UC) to present **Self-Evaluation and Reporting: Always Let the *Guide* Be Your Conscience or How to Encourage PIs and Their Staff to Self-Report**. Dr. Babcock has a background in immunology and obtained his PhD from the University of Nebraska Medical Center. He completed his postdoctoral training from the University of North Carolina-Chapel Hill. He serves as a professor in the Department of Surgery in the College of Medicine at UC where he performs research in the area of trauma/sepsis, infections, wound healing, and immunotoxicology as it relates to the immune system. He also directs the flow cytometry core facility. He is the Chair of the Institutional Animal Care and Use Committee, or the IACUC, at the University of Cincinnati, which oversees animal welfare at three main campuses, two branch campuses, and the Shriners Hospitals for Children-Cincinnati.

Welcome to OLAW, George.

Slide 2 (Objectives)

>> *George:* Thank you very much, Swapna. Could I have the next slide please? My objectives in this webinar are to cover the following topics:

- The *Guide* [[Guide for the Care and Use of Laboratory Animals](#)] and reporting
- The *Guide* and self-evaluation
- Suggestions for self-evaluation
- Specific self-evaluation suggestions for the IACUC, veterinarians, veterinary technicians, and the animal care staff

- Self-reporting by PIs
- Dealing with noncompliance
- My perspectives on noncompliance
- Personal observations relating to PI's self-reporting.

Slide 3 (Reporting)

In a perfect world, where no protocol deviations or noncompliances occur, reporting is really a moot point. Unfortunately, very few institutions are perfect. So it is the IACUC's responsibility to know what should be reported and to report it.

Slide 4 (Disclaimer)

Self-evaluation and reporting are complex areas and can be major sources of stress for IACUCs. There is no one best way for an institution to address these, although there certainly are wrong ways. In this webinar, I will make suggestions that have proven to be effective at my institution, University of Cincinnati. Therefore, think of this as one of many acceptable models of self-evaluation and reporting. Personal experiences will also be discussed, which may or may not apply to your institution.

Slide 5 (What Does the PHS Policy Say About Reporting?)

What does the PHS Policy say about reporting? In PHS Policy [section IV.F.3](#), the IACUC through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- Any serious or continuing noncompliance with this Policy;
- Any serious deviation from the provisions of the *Guide*; or
- Any suspension of an activity by the IACUC.

Slide 6 (What Does the *Guide* Say About Reporting?)

What Does the *Guide* Say About Reporting? The *Guide* includes a section entitled "Investigating and Reporting Animals Welfare Concerns" (pp. 23-24). The institution must develop methods for reporting and investigating animal welfare concerns. In the U.S. this responsibility rests with the IO and the IACUC. The IACUC must communicate such reports to the IO including the issue, findings, and corrective actions taken.

Slide 7 (NOT-OD-05-034: Prompt Reporting to OLAW)

According to [NOT-OD-05-034](#): Prompt Reporting to OLAW, institutions should use rational judgment in determining what situations meet the provisions of PHS Policy IV.F.3 and fall within the scope of the examples below. I would like to stress that if your IACUC is in doubt, it's best to consult with OLAW. They have expertise at good animal welfare practices and can help your institution remain in compliance with the PHS Policy.

Slide 8 (More about NOT-OD-05-034)

NOT-OD-05-034 provides excellent guidance on reporting including:

- Specific examples or issues which are and are not reportable. However, the list is not comprehensive.

- The time frame for reporting.
- The information which must be included in the reports.
- Directions on where to send the report.

NOT-OD-05-034 is an important document and should be consulted if your IACUC is in doubt regarding the reporting process.

Slide 9 (What Guides Your Conscience?)

What guides your conscience or the conscience of your institution? You can follow the recommendations in the *Guide* or you can just not report, and the institution's reputation will remain intact. This is definitely not recommended.

This may seem like a joke, but at one unnamed institution, which I am very familiar with, it was found that the IO was not reporting violations to OLAW which had been reported to him by the IACUC. This, of course, put the institution in jeopardy, and eventually produced administration shake-ups. The IACUC must have the IO on their side.

Slide 10 (What Does the *Guide* Say About Self-Evaluation?)

So what does the *Guide* say about self-evaluation, which is different than reporting noncompliance. The *Guide* uses the term "Continuing Review" and this includes continuing protocol review, oversight and evaluation of facilities and animal use areas, regular review of the [animal care and use program], and ongoing assessment of animal care and use.

Program review and facilities inspections should occur at least annually as per the *Guide*, or more often as required by the Animal Welfare Act and the PHS Policy. The PHS Policy requires semiannual program and facilities review. And as we all know, when there are two guidelines, PHS Assured institutions are expected to meet the more stringent guideline.

Slide 11 (Self-Evaluation)

Although continuing review of ongoing animal related activities by the IACUC is a requirement imposed by the PHS Policy and USDA animal welfare regulations, there is a lack of uniform understanding and application of these federal requirements. A variety of mechanisms can be used to facilitate ongoing protocol assessment and regulatory compliance, including postapproval monitoring. Thus each institution must devise its own plan for self-evaluation which meets the federal requirements.

Slide 12 (Self-Evaluation and Continuing Review)

In a paper by Oki et al. a model for continuing review is presented along with a form which can be used for this purpose. The paper entitled "Model for Performing Institutional Animal Care and Use Committee: Continuing Review of Animal Research", was published in 1996 in *Contemporary Topics*, and the authors are listed here [GWENN S.F. OKI, MPH, ERNEST D. PRENTICE, PHD, NELSON L. GARNETT, DVM, DALE F. SCHWINDAMAN, DVM, and CAROL Y. WIGGLESWORTH]. It provides a starting point for a self-evaluation model. The [link to this paper](#) is available on your GoToWebinar control panel.

Slide 13 (Continuing Review (cont.))

The review process and report form described in this publication meet the requirements of the PHS Policy and the USDA regulations for continuing review. Use of this model for performing IACUC continuing review satisfies the PHS Policy requirement for triennial *de novo* continuing review, as well as the USDA annual review requirements. So the suggestions and the form described in this paper meet the minimum requirements for self-evaluation, but is this actually enough? You must decide if it comprehensive enough to uncover many problems commonly found?

Slide 14 (How Does Your Institution Evaluate?)

How does your institution actually self-evaluate? As we talked about before with reporting, if your institution doesn't evaluate, this puts you at risk. You can let AAALAC or the USDA evaluate your program when they come in for site visits, but this is not a self-evaluation, and it may not give you the answer you are looking for. You can meet the minimum requirements, as covered in the Oki paper that I referenced. Or you can develop a comprehensive program for self-evaluation, as we did at UC, which I will describe shortly.

Slide 15 (Self-Evaluation Methods)

Self-evaluation is more difficult than most of us realize. We are often too harsh or too lenient on our institutions. One method which has been successful is to have many pairs of eyes and ears to get a diverse opinion. People should come from all parts of the animal program including outside member, attending veterinarian, Principal Investigators, animal care staff, and especially veterinary technicians. It cannot be emphasized too much, how important outside members and vet techs are for semiannual evaluations. These diverse individuals provide an inside and outside perspective, and a behind-the-scenes view of your program.

Slide 16 (Suggestions for Self-Evaluation)

Some suggestions for self-evaluation: of course, you must meet the minimum requirements for both OLAW [if your institution is PHS Assured] and USDA [if your facility is registered with USDA]. However, semiannuals provide only a snapshot in time. At UC we were determined not to settle for just satisfying the minimum requirements. So we made it a true team approach which included everybody involved such as the IACUC committee and staff, veterinarians, laboratory animal staff, and PI and the research staff. The PI's laboratory members can be very helpful in allowing the inspection team to understand how their labs approach various procedures and animal care and can provide true insight into what is happening on a specific study.

Slide 17 (Suggestions for Self-Evaluation (cont.))

By doing this the IACUC will foster a climate of trust, openness, and teamwork. The IACUC should stress to the entire animal care program that by being part of the team, they are protecting both the animals and the institution. Being part of the team includes training all members of the team, and fostering a strong and transparent relationship with the IO.

Slide 18 (More Suggestions for Self-Evaluation)

Start with a positive attitude. Individuals often sense when the IACUC projects a negative approach. We are all humans, no one is perfect, and no program is perfect. The vast majority of the PIs and staff wish to do a good job, to reduce animal suffering, and to be proud of their work. A major goal should be to develop a system devoted to continual learning and improvement of animal care, top to bottom and end to end.

Slide 19 (Self-Evaluation (IACUC))

Here are some specific suggestions regarding self-evaluation for the IACUC:

- Standardize approaches to inspections. For instance, have a common form that everyone on the inspection team can use. You can also share this form with your investigators so that they know what you are looking for when you come into their laboratories.
- If you have newer members, pair them with more experienced members, so they can learn from them.
- Encourage IACUC members to ask questions and discuss potential problems with staff members including laboratory animal staff and research staff.

Slide 20 (Self-Evaluation (IACUC), cont.)

- Try not to act as police. This is very important. Acting as police will undermine transparency and will prevent complete participation by the PI and laboratory staff members.
- Make post-approval monitoring (PAM) a friendly, non-confrontational experience. Don't go in with the idea that you are going to monitor animal room activities just as a way to uncover noncompliances or deficiencies.
- Instead, use PAM as a teaching experience or a training tool.

Slide 21 (Self-Evaluation (Veterinarians))

Now here are some suggestions for veterinarians on self-evaluation:

- You should try to develop a positive relationship not only with your own staff but with the PIs and the research staff as well. Encourage the PI and research staff to look to the IACUC as a positive information-giving resource.
- You must have a good rapport and be transparent with the rest of the IACUC members. Discuss protocols with vet techs. I'll say more about this in a minute.
- If you have a chance, participate in PAM visits, particularly as a trainer, so that everybody on your IACUC has a concept of what PAM is all about.
- If you act as police, this will undermine your transparency and prevent participation by the PI and the laboratory staff who will subsequently be less cooperative with you and the IACUC.

Slide 22 (Self-Evaluation (Veterinary Technicians))

Suggestions for veterinary technicians:

- Encourage vet techs to be part of the PAM program. They have their feet on the ground and often know what's happening behind the scenes.

- Vet techs should become familiar with the animal protocols as they often can observe potential problems like protocol deviations and prevent them from happening.
- Encourage vet techs to interact with the research staff and promote good laboratory animal practices and techniques.

Slide 23 (Self-Evaluation (Lab Animal Staff))

Suggestions for the lab animal staff for self-evaluation:

- Another method that we've found to be very successful at the University of Cincinnati, is to have PIs give seminars to lab animal husbandry staff. This promotes an understanding of research procedures and identifies the importance and goals of the studies among the husbandry staff. In this way, the husbandry staff understands these animals as being important in a study, rather than just animals that they have to take care of. These seminars don't need to be technical and instead, can be just a review of the goals and the procedures used to attain them.
- Encourage lab animal staff to observe procedures being performed in their work area so that they can understand what the various researchers are actually doing to the animals. They can often be helpful to the researchers and prevent possible problems.

Slide 24 (PI Self-Reporting)

When asked to self-report [noncompliances], the typical response from PIs which we saw at our institution was, "Why don't you just hit me again, IACUC?" As an example, I once walked into a lab on an IACUC inspection and the PI said, "Well, the IACUC Gestapo is here." This is not how you want PIs to think of the IACUC or inspection teams.

Slide 25 (Quotes to Remember When Engaging PIs)

A quote from Lucian Leape at Harvard is very important in this respect: "No one admits to an error if you punish them." They will be less forthcoming. "The single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes." Mistakes will happen. They have to be corrected but they don't necessarily have to be punished.

Slide 26 (Gaining the PI's Trust and Cooperation)

Gaining the PI's trust and cooperation: stress the importance of a compliant animal program to the PI. It's not about just his or her lab but it's about the whole program. Explain that corrective actions don't necessarily equal punishment. They are just that – to correct the problem. Use PAM to train PI's lab members in problem areas. We have found this to be a very effective strategy at UC. Lab members are encouraged to be a part of all aspects of the program, including reporting. Often our reports come from laboratory staff members rather than the PIs. Offering incentives for reporting will also increase the rate of self-reporting at institutions. For example, in letters to the IO and OLAW, PIs can be given credit for promptly disclosing and/or correcting a noncompliance.

Slide 27 (Dealing with Noncompliance)

However, because a PI self-reports a noncompliance, it doesn't mean that you can forgive or overlook the problem. Reported noncompliances must have a corrective action attached. One approach is to make it more difficult for those who don't self-report, for example, have a stronger corrective action. For example, we often ask a self-reporting PI to come up with a self-correction action plan. We evaluate the plan and it's often accepted.

Slide 28 (I didn't mean to deviate from my animal protocol...)

Self-reporting is important and in some ways should be rewarded. However, self-reporting should not alleviate the need for a corrective action. This would go against policy and is not a good practice.

Slide 29 (Dealing with Noncompliance)

Here are some suggested corrective actions to use when dealing with noncompliances, some of these would be used in more severe cases:

- Suspension of protocol – This one has many ramifications, such as the return of funds to NIH, delays in research, layoffs of lab staff, the return of funds to NIH, and so it should only be used as a last resort.
- Retraining in the area of noncompliance – This is typically used by many institutions and can be very effective. The IACUC just has to make sure that they know if the same lab has to be retrained over and over. If that is the case, then it means the training is not effective.
- Regular unannounced PAM visits – PAM visits help to uncover problems. When lab staff knows that they have to expect unannounced PAM visits, they will be working to alleviate noncompliances. At the same time, when PAM staff comes in, lab staff need to be collegial and use the visit as a training tool.
- One approach that we've had great success with at UC is to have lab members and the PI attend IACUC meetings separately. We find that when there is a deviation or noncompliance, by calling them to an IACUC meeting in the absence of the PI, the lab members become very transparent and cooperative with the IACUC. Sometimes we find that lab members often don't know what's in the protocol. So we have some of the IACUC or vet staff members discuss the complete protocol with them, particularly during the PAM process. We find this works well.

Slide 30 (Dealing with Noncompliance)

Some additional corrective actions are:

- Stress to lab members that loss of funding could mean the loss of their jobs. Often I've been surprised at how shocked some people are on learning that their job is tied to the grant, and it could go away if the IACUC has to withdraw a protocol.
- Another corrective action for serious noncompliance is to have regular visits by a vet tech, with their hourly rate charged to the PI. So an unannounced or an announced visit costs the PI something.

- Another less aggressive option is to require a veterinarian or vet tech to sit in on animal experiment planning meetings. Many of the PIs have regular research meetings and having a vet or vet tech sit in can help us understand how the PI is relaying information to the laboratory staff.
- Something we've used in extreme circumstances is to assign a vet tech to the laboratory. We had one particularly noncompliant PI, where we suspended the protocol. In order to get the protocol reactivated, this PI was required to pay a vet tech's salary for one year. The vet tech would then come in every day, help with some of the experiments, and monitor how the laboratory was performing.
- In certain cases, we have also set conditions for reinstating a protocol, such as appointing a lab manager to oversee the animal work in the PI's lab. This is often a person who is already in the lab but may or may not manage other lab members.

Slide 31 (Personal Perspective on Noncompliance)

Some personal perspectives on noncompliance:

- One reason might be that English is their second language. This can be a difficult one because sometimes they literally don't understand the rules. At UC we try and find a person who can speak the same language to help them understand. It is helpful if these individuals are IACUC members.
- Cultural differences relating to animal experimentation can sometimes cause lab members to disobey rules. This could be because their normal cultural practices relating to animal experiments are not the same as ours. We see less of this than we used to.
- In times of tight funding, there is often pressure asserted by PIs on their staff to perform experiments quickly and economically. This approach of "cutting corners" might sometimes lead to noncompliance.
- Fear of retribution from the PI is another factor causing noncompliance in animal research. We even had a case where the PI threatened to have a lab assistant deported if they didn't follow what he was saying.
- Sometimes lab members do not read the protocol. Since this is a requirement for working with animals, it should be the PI's responsibility to ensure that everybody on his or her staff reads and understands what's in the protocol.
- In some large labs, we have found that there is very little communication with the PI. So essentially the lab staff is on their own. If they have a good leader or manager, everything is usually fine. If not, then we often find that noncompliances can occur.

Slide 32 (Observations Following Our Experiences with PI Self-Reporting)

Since UC introduced self-reporting of noncompliance by PIs, 80% of noncompliance reports now come from PIs or their staff. Prior to the introduction of the concept of self-reporting, there were zero self-reports from PIs. So this is a tremendous increase.

However, the total number of noncompliance reports have also increased. And they probably should, because we might have missed many noncompliances if they had not

been self-reported. So this doesn't necessarily mean that more noncompliances have occurred, just that more are coming to the surface.

Communication between PIs and IACUC and the vet staff has greatly increased. Much of this is because of PIs being collegial and also realizing that the consequences might be slightly more severe if they don't self-report.

We have had a great increase in the requests for training from the vet staff. In other words, if PIs and their staff were not exactly sure how to carry out a procedure, they are now more open to asking for help from the veterinarians.

Slide 33 (Observations (cont.))

We found that PIs who self-report rarely repeat noncompliances. So we found a much lower number of noncompliances from these PIs. Members from such labs are far more open to discussing noncompliances as well. As I mentioned, they often make reports or ask questions such as, "Would doing this be a noncompliance?"

Our PAM visits have also become more collegial, and we are using them more as teaching tools than to find noncompliances.

Most of our noncompliances now come from a small number of very resistant PIs and these are the ones we have the most problems dealing with. On the other hand, because this is a small number we know who they are.

Slide 34 (Summary)

So in summary, use the *Guide* as your conscience for reporting. Try a team approach for self-evaluation based on transparency, honest communication, and trust among all parts of the laboratory animal medicine group. Use PAM as a non-confrontational teaching tool. Include PIs and their staff as a major part of the evaluation. Also, and I think this may be the most important thing – train, train, train.

Thank you, and I will take any questions.

Slide 35 (Questions?)

>>*Swapna*: Thank you, George. We have received some questions and I will start reading them out. [Question 1] The first one is: Some of the things you are proposing appear to actually increase regulatory burden? Would you comment on this?

>>*George*: Yes. This is probably a fact and it's probably true, but I view regulatory burden as being two types, both bad and good. If it helps your program stay in compliance and also helps your PI's research, then the additional burden is worth the effort. I feel the things I've mentioned fall under the good burden. However, it is indeed an increased burden, but is not just a paperwork and uncomfortable burden.

>>*Swapna*: Thank you. [Question 2] Our next question is: I'm from a small institution with only a consulting vet and no individual responsible for a formal program of PAM. How do the things you propose help me?

>>*George*: Well, I think the concepts are still valid. Just their applications would be slightly different than the way I just discussed them. If your institution is PHS funded or using USDA species, you must have an IACUC. This committee can accomplish most of what I proposed at a small institution. For example, a member of the committee can go over the protocols with the lab members and thus provide additional training. Required inspections may be sufficient as a continuing monitoring tool if your institution is small.

>>*Swapna*: Our next question is also from an institution. [Question 3] Our institution has a robust formal PAM process, with a Compliance Liaison office doing continuing review and reporting to the IACUC. Why do we require self-evaluation and reporting?

>>*George*: Continuing oversight is required by federal laws, policies, and regulations. However as I stated before, there's some flexibility in how institutions perform this. The PAM process by a compliance liaison officer can be used for self-evaluation if it is shared with the IACUC. Reporting is a responsibility of the IACUC and the IO, so the IACUC would need to follow-up on any reports and share these with the IO. Using the PIs to evaluate their own labs and self-report, adds a level of self-evaluation that would generally not be seen by the compliance liaison during the PAM process.

>>*Swapna*: Thank you. [Question 4] The next question is: There have been instances when a PI observes a procedure being performed incorrectly by research staff and goes on to provide more training in order to correct them. Should the PI report these self-corrective actions to the IACUC or should this be considered part of the training provided to the PI's staff?

>>*George*: Well, that actually depends on the nature of what was observed. So I'll give you my opinion on this, and it's just that, opinion. It is also the way we do it. If the procedure being performed was a reportable incident as defined by the federal regulations, it should be self-reported. Because a noncompliance, we feel, is a noncompliance. If it's a minor procedural problem and the animals were not harmed, then I would probably suggest to use as a training tool and not report it. However, the reported training of PI and/or their lab may be sufficient to be included in the OLAW report and used as the corrective action, so it accomplishes two things. The PI has helped train their lab and it also is a corrective action to the OLAW report.

>>*Swapna*: Thank you. [Question 5] Our next question is: At our institution, animal transport is handled by a contractor. How can we extend self-evaluation and reporting to animal transportation in this case?

>>*George*: Well, this could be a little more difficult, but what I would suggest is, one, you meet the requirements and inspect the vehicles for such things as cleanliness, check their sanitation records, etc. Yes, they should have sanitation records. [The

health of the animals should also be monitored and reported to the IACUC if problems occur following transport.] Now, a problem I can foresee is in extreme weather conditions, either hot or cold. So if you're expecting these, I think it's reasonable to ask the contractor to have a recording temperature gauge and you would probably have to provide this to them, but that way you could get an idea if the temperatures within the truck stay within the guides.

>>*Swapna*: Thank you. [Question 6] What is the most common corrective action taken by your IACUC for noncompliance involving deviation from an approved protocol?

>>*George*: Our most common is a two-prong approach. We retrain the laboratory and we also like to observe any animal procedures [being performed] in the laboratory. [The observation can be by either] the animal lab staff or the PAM staff. That would be for [deviation from actual procedures] which are actually being performed and not other deviations from the *Guide*. So [for those deviations involving procedures performed on animals] we use a two-prong approach.

>>*Swapna*: [Question 7] And then this person is asking: Does your IACUC suspend protocols of PIs that do not self-report more frequently than PIs that do self-report?

>>*George*: I haven't actually analyzed the data looking at that, but since we suspend very few protocols, I think all were PIs who did not self-report. However, I can never remember having a PI self-report something which we would consider suspending the protocol for. So we would not really consider self-reporting as part of our decisions on what to do with something so serious that it could lead to suspension.

>>*Swapna*: Yes, thank you. [Question 8] The next question is: What is the typical charge for a vet tech to visit or attend a lab meeting? Is it an hourly charge?

>>*George*: Yes, it's an hourly charge based on the vet tech's actual salary. We charge a half hour minimum for them to come in, and then charge additional time for time actually spent. This works quite well and most labs become more of a model for compliance once the vet tech comes in and observes. The normal charge would probably not be over \$30 for a visit.

>>*Swapna*: Okay, thank you. [Question 9] And then the next question is: You mention a standard form for inspections. Is this one your IACUC developed itself or is it based on OLAW's or another institution's form?

>>*George*: Originally we used one we developed ourselves, but now we use one from the USDA and [one from OLAW](#). We use them both. I would be glad to share it, but it's available online. You can modify it by adding things if you like. We found it's very comprehensive and allows for space to write things that you may have to go back and look at. So no, we don't actually use one that we made ourselves anymore.

>>*Swapna*: Okay, thank you. [Question 10] And what does your IO think about the self-reporting by PIs?

>>George: Our current IO is fine with it and actually encourages it. She's been a strong supporter of everything we do, but especially PI self-reporting because she thinks that it makes for a tighter laboratory animal medicine group.

>>Swapna: [Question 11] And then another question is: If I report all of my noncompliances, will I get in trouble with OLAW?

>>George: This is something we've obviously been asked quite a few times by our PIs and it depends on what the noncompliance was, but in most cases it's not the reporting that causes the problem, but the appropriateness of the corrective action. So the IACUC should carefully assess the problem and decide the appropriate corrective action for a specific problem. If they have any questions, you can contact OLAW. And in actual fact we have very few corrective actions which have ever come back from OLAW wanting further things done and the PI doesn't get in trouble.

>>Swapna: Thank you. We have several live questions coming in. And we also have Dr. Pat Brown, Director of OLAW with us. Our first question is similar to the previous one and both Pat and George can comment on this. [Question 12] What can an IACUC do if the IO does not want to report an issue because they're concerned about upsetting the organization that is funding the work?

>>George: Well, I can go from the only example I've actually had with this. And we have had one. We went over the IO's head to the president and it worked out well, but I'm sure there are other ways to do that and Pat's probably seen many more than I have.

>>Pat: Yes. Our advice is if the IACUC has such a concern that there are serious noncompliances that have not been reported because the IO is trying to hold them back, that they have a conversation directly with OLAW's compliance staff about this. We are there to assist and guide, and also provide encouragement to the IACUC to take the appropriate actions within the institution to have a cooperative process leading to a corrective action for such a situation.

>>Swapna: Thank you. The next question is for George. [Question 13] You suggested having the vet or the vet tech associate with the lab in a manner that costs the PI. Don't you think using these personnel is detrimental to their working together in the animal facility versus using compliance office personnel to be the ones assigned to your suggested corrective actions?

>>George: I don't feel it's a waste of their time, but we use both. It depends on what we want to accomplish. In specific cases the IACUC staff members just don't have the knowledge. These are usually on procedural things. And the vet techs are just great at this. And it's usually part of the retraining process too. They can help work through the particular problem.

The vet is used not nearly as often, but when they come in, it's generally because it was a more serious noncompliance, and in actual fact when the vet sits at the

meetings, we generally find that the noncompliance is corrected rapidly. So it's just sort of a hierarchy. Call it a little more aggressive, but that's for the vet. For the vet tech, if the problem is in their area, we send them in. If it's something else, IACUC staff comes in. [Actually the PAM group usually comes in first.] But our PAM is a committee that goes out in pairs [composed of mainly] IACUC staff members, but it also includes a vet tech.

>>*Swapna*: Thank you. [Question 14] The next question is I guess both Pat and George can comment. How do you convince a PI to self-report when they fear that it may have to be reported to OLAW?

>>*George*: What we've done is tell them that generally there's no punishment from OLAW. That what they need to do is work with us to come up with a good correction plan and to actually implement it in their lab so it doesn't happen again. And we give examples of things that have been reported. And OLAW and Pat can comment on this later, it comes back on the institution, rather than the PI, as far as I know.

>>*Pat*: And everything you said, George, is absolutely spot on. We are not in the punishment business, we are really in the corrective action business. We want to see that your IACUC, your institution has taken appropriate corrective action, preventive measures, and we want to commend you that you're doing that and show that when things do go wrong that there's still an appropriate response and it's been taken care of.

>>*Swapna*: Thank you. The next question is for George. [Question 15] You mentioned that there's an increased volume of self-reports. This increase volume of self-reports and noncompliance reports seems like it would require additional time from the IACUC staff to process and handle. How do you deal with the additional workload on the IACUC office?

>>*George*: It does require additional time and we've done it in two ways. One is we meet with the IACUC office, we being the IO, myself and the attending vet, to try to streamline their procedures as best we can. The second thing is – and this was some time ago when we started this – we asked for an additional staff member and we were given one. I think the institution realized, or the IO, she was the one that provided it, that this was an important part of the program.

>>*Swapna*: Thank you. The next question is also for you, George. [Question 16] The USDA is using self-reporting findings as evidence of noncompliance and citing such findings on inspection reports even though they can be over a year old and are promptly corrected. Such USDA actions may inhibit such institutions from having a good self-reporting program. How do you ensure the correct balance?

>>*George*: I'm going to give my opinion on this and stress that it is my opinion. I personally don't feel it is necessary to report things to the USDA that are not required. They receive, through memoranda of understanding, your reports from OLAW, so they know when you've had a noncompliance [[See NOT-OD-15-028](#)]. They come in and

inspect your records unannounced. And my feeling is that it really doesn't alleviate any potential bad outcome if you self-report. So we don't. And I know that this is a big debatable issue in animal care, but that's just the way I feel and my institution has backed me on this.

>>Swapna: Our next question is for Pat's comment. [Question 17] What definition of serious noncompliance should guide the IACUC's deliberations?

>>Pat: I'm going to provide some of the examples listed on our Guide Notice from 2005 on prompt reporting. Some of the examples are:

- Conditions that jeopardize the health or well-being of animals. This can include natural disasters, accidents, mechanical failures or any situation that results in actual harm or death to animals.
- Conduct of animal-related activities without appropriate IACUC review and approval are reportable.
- Failure to adhere to IACUC approved protocols.
- Implementing a significant change to an IACUC approved protocol without prior approval as required by the PHS Policy.
- Conducting animal-related activities beyond the expiration date established by the IACUC. And of course, as a reminder, complete review of a protocol is required at least once every three years from the PHS Policy requirement.
- Conducting IACUC business without a quorum. If there's an absence of a quorum then the activities would be considered not something that would be acceptable so that would be something that would be reported to us.
- Conducting official business during a period of time that the committee isn't properly constituted, where there's a lack of a required member of the committee on the committee that then official business cannot be conducted.
- Failing to correct deficiencies identified during the semiannual evaluation in a timely manner.
- Chronic failure to provide space for animals in accordance with the *Guide* unless the IACUC has approved a protocol specific deviation, and there's a written scientific justification.
- Participating in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained.
- Failure to monitor animals post-procedurally as necessary to ensure well-being. For example, during recovery from anesthesia or recuperation from a procedure. And again, this would be if there was harm or death to animals involved it would be reported to us.
- Failing to maintain appropriate animal-related records. And again, this is going to be the IACUC's professional judgment as to whether this is serious. When in doubt it's always best to call us and we will guide you as to whether what occurred is reportable or not.
- Failure to ensure death of animals after euthanasia procedures. And I want to just emphasize that we continue to this day to see this as one of the frequently reported noncompliances where ensuring death of the animals doesn't always occur and it's reported to us that animals are found [alive] in the freezer.

- Failure of the animal care personnel to carry out veterinary orders or treatments.
- And then, of course, IACUC suspension is a reportable – one of the three reportable requirements.

>>George: Could I make just one comment on this too? IACUC committees are made of individuals and we often discuss the things because people have different opinions. And I find it very useful that I take to every meeting a copy of NOT-OD-05-034 because sometimes we go astray and I read right from what Pat just described and it gets us back on track.

>>Swapna: Thank you, George. The next question is for George. [Question 18] You had mentioned that a small number of PIs who were very resistant and now represent most of the noncompliance at your institution. How do you deal with that? How do you treat that, I guess?

>>George: Well, we, of course, track all of the noncompliances over time and we look for two things: The total number and repeatable, particularly repeatable. So essentially the corrective actions become more complex the more it happens. And at one point, I think once we actually suspended a protocol for a noncompliance that was serious, but not one that you would expect, wow, we would suspend just for that, but because the PI had many noncompliances and the same noncompliance had shown up like four times. So essentially this is one case where collegiality may not apply. Sometimes you just have to get very, very "tough with them." Another thing is that in one or two cases, we just threw up our hands and let the IO handle it.

>>Swapna: [Question 19] How often do you get self-reports from PIs? Is annually enough?

>>George: Oh, no, no, well, from any particular PIs, they self-report when they have a problem. And how many do we get in total? We get one to two a month. Of course, not from the same PI.

>>Swapna: [Question 20] And how do you handle a noncompliant lab that doesn't change their habit, but just chooses to report the incident to cover themselves?

>>George: We've had that happen a couple of times recently. And what we've done is we make the whole lab come into the IACUC meeting and the PI comes in separately. We tell them the implications of what a noncompliance can be, including returning money and potentially that could affect their job if the money [which pays their salary comes from the project which must return the money.] We have them retrained and we retrain the lab separately from the PI. It's a different type of training. The lab would be trained in the procedures where they went wrong, and the PI would be trained in the responsibilities of what the PI should be doing. And generally a rogue lab – we found comes from the fact that the PI just isn't communicating things or isn't communicating anything. So if we get the lab online, then generally it falls into place.

Now, in one of these what we told the PI, we suspended the protocol and I think I mentioned this, to get the protocol back he had to appoint a lab manager. And it was a large lab, and from the dealings of PAM and IACUC inspections we knew one member was really good. However, she was not high up in the hierarchy, so to speak. There were 10 postdocs in this lab and they caused a lot of problems. So we required that in order to get the protocol back [the PI had to appointed this person] as lab manager and have the authority to manage the whole lab, including the postdocs, and the problems went away.

>>*Swapna*: George, the next question is also for you. [Question 21] USDA reviews IACUC minutes and records and uses those as a reason to indicate a noncompliance on their report. So how do you handle that?

>>*George*: Generally if they consider it serious, the USDA will come in. Or if they pick it up during an inspection, we handle it the way we would any noncompliance. We try to correct whatever the USDA found as a noncompliance. Having dealt with many VMOs (Veterinary Medical Officers) there is some differences in how they approach the problems, but generally if you have a good relationship with your VMO – we never try to hide anything or make it look like we're better than what we are. You go over [the noncompliance], you tell them how you're going to correct the problem, and generally that's always worked. Now, knock on wood, we've never had a major, major problem with a USDA species.

>>*Swapna*: Thank you. The next question is for Pat. [Question 22] They're asking if is; a three-year review, is it required to be three years to the day the protocol was approved or can a three-year review be three years from the month the protocol was reviewed? For example, approved on 12/3/2013, must be reviewed 12/3/2016 or can it be 12/31/2016?

>>*Pat*: We've been explicitly requiring that it must be three years to the day the protocol was approved. It cannot go beyond that or it is considered an expired protocol. So that's always been our position and we have not changed that for many years.

>>*Swapna*: Thank you. And the next question is also for you, Pat. [Question 23] Since PHS Policy and OLAW expect compliance with the Animal Welfare Act and USDA regulations, if and when applicable, would failure of an IACUC to conduct continuing review, at least annually as required by USDA regulations, be reportable to OLAW if it was a PHS or NSF funded study involving USDA regulated animals?

>>*Pat*: We would consider this something that would indicate that the IACUC is not carrying out its responsibility as required by the PHS Policy. We would want to find out the frequency of this in terms of how it is occurring and want a corrective action for something that was happening frequently.

>>*Swapna*: Okay. So that is all the time we have for questions today. Thank you so much, Pat, and thank you, George, for a wonderful talk.

Slide 36 (Thank you)

[I thank all of you for participating in our webinar, with special thanks to those who sent in questions. We look forward to continuing our OLAW webinar series in 2017. We are organizing a schedule for next year. If you have suggestions for topics that you would like addressed in the OLAW online seminar series, please send us an email at olawdpe@mail.nih.gov. Good-bye and thank you for joining us today.]

Additional Submitted Questions Not Addressed During the Webinar

[Question 24] I think there have been two questions now that are really asking how UC IACUC deals with the USDA VMO citing them for a noncompliance that had been identified by the IACUC and corrected and documented in the minutes.

>>*George*: Unfortunately, what an institution can do in the case you stated is accept the citation and confirm with the VMO that they understand and accept that the noncompliance has been corrected or appeal to the regional supervisor. We would consult with our lawyer before appealing.

[Question 25] How many IACUC protocols and approximate number of PIs do you have at your institution?

>>*George*: We have approximately 300 protocols and a slightly lower number of PIs. We generally want one protocol per PI but some PIs want to have more than one and occasionally we will ask for another if the PI is doing something totally different especially with a unique species.

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