

ICARE



Interagency Collaborative Animal Research Education

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ICARE Dialogues: Using Flexibility Provided in the PHS Policy and the Animal Welfare Act and Regulations (AWAR)

Presenters: Interagency Collaborative Animal Research Education (ICARE) Project faculty members: Bill Greer, George Babcock, Wayne Barbee, Neera Gopee, Bob Gibbens, and Susan Silk.

A record of this meeting will be posted on the OLAW website (<https://olaw.nih.gov/home.htm>) on the ICARE Project webpage (<https://olaw.nih.gov/education/icare-interagency>).

This document refers to slides. The slides can be found [here](#).

Silk: Welcome, everybody. We're delighted that you're here. It's my pleasure to introduce Bill Greer, who will be introducing his team. They will talk about **Using Flexibility Provided by the PHS Policy and the Animal Welfare Act and Regulations**. I have one more thing to say. Flexibility is Bill's favorite topic.

Greer: Yeah. Okay. [Laughter] Let me get us started here. Flexibility is it, huh? Anyway, so, again, welcome, friends and colleagues. I'm going to go first to my team and let them introduce themselves, but I will say that myself and my team will start with the idea of flexibility, and I think you'll find that will transition nicely into Mindy's [next **ICARE Dialogue** topic in the session] which will be on integration. Our objective will be to talk about things on your mind right now because of COVID, to help us all understand the flexibility that we always had and then some flexibilities that are unique because of COVID.

Slide 1

But before we get into the conversation, let me go to my slide, and I'll give you a little bit about my background and I'll let George, Wayne, Bob, and Neera talk about theirs. I may have met many of you. My name is Bill Greer. I currently serve as the Assistant Vice President for Research at the University of Michigan. I have been involved in IACUC and compliance oversight for over 30 years now. I spent half of my career at a vaccine company making animal vaccines. The other half of my career I was at Penn State for about 15 years. I was the Associate Director and

oversaw their animal biosafety and radiation safety compliance programs. About four years ago I went to the University of Michigan and I currently oversee their IACUC safety, controlled substance, autonomous systems, many other programs. I always appreciate and thank Susan and others involved in ICARE for the invitation and opportunity to participate. With that, I'll let George introduce himself.

Babcock: I'm from the University of Cincinnati. I am the chair of the IACUC and have been for well over 20 years. I'm also the vice chair for the IBC. I'm a professor emeritus in the Department of Surgery.

Barbee: Thank you. I'm Wayne Barbee, professor of physiology and biophysics and former IACUC chair at Virginia Commonwealth University. I have worked with a variety of lab animal species over about four decades and served on small and medium-sized IACUCs for roughly 20 years and also served on the committee to update the *Guide*.

Gibbens: I'm Bob Gibbens. I'm with the USDA. I've been with the USDA about 30 years. I have been a field VMO, field supervisor, a regional director and we got rid of regions in 2017 so now I'm the National Director of Operations, and I'm in Fort Collins, Colorado.

Gopee: I'm Neera Gopee and I'm the Director of Policy and Education in the Office of Laboratory Animal Welfare at NIH, and welcome, everyone.

Greer: Thank you, Neera. We have an hour and a half for each session. As we go through this session, if you want to ask questions along the way, please feel free. We've got about 25 slides in this first session. I will try to keep us on track. But if anything pops in your mind, feel free to chime in and join us in conversation. So with that I'm going to go to Neera's slides and she's going to talk a little bit about some OLAW resources before we get started.

Slide 2

Gopee: Good afternoon, everyone. OLAW is concerned about the impact of COVID-19 on the ability of institutions to ensure the well-being of personnel as well as animals in compliance with the PHS Policy and the *Guide*. In response to the current pandemic, what we did was release numerous resources all in one place to help our constituents during these unprecedented times. I encourage you to please visit OLAW's COVID-19 pandemic contingency plan and web page. It can be accessed by clicking on the red banner on OLAW's home page [<https://olaw.nih.gov/home.htm>].

Slide 3

This website has been created especially for COVID-19 in response to our constituents. It is updated as additional guidance is developed.

Slide 4

On this landing page [<https://olaw.nih.gov/covid-19.htm>], for those of you who have not visited it, you will find 20 COVID-specific FAQs including how to conduct semiannual facility inspection, program reviews, and business while maintaining social distancing. We also have webinars, articles, and useful links. Although this web page has many useful resources to help our constituents, it is by no means exhaustive. Please do not hesitate to reach out to OLAW and we are more than happy to provide much-needed advice and guidance.

Slide 5

We can be reached via e-mail [olaw@od.nih.gov], telephone [301-496-7163]. You can visit our website [<https://olaw.nih.gov>]. Be sure to follow us on Twitter [[@NIH_OLAW](https://twitter.com/NIH_OLAW)] and subscribe to our Listserv (subscribe through OLAW webpage [[NIH.OLAW.gov](https://olaw.nih.gov)] for news and announcements).

Slide 6

Gibbens: All right. This is just a list of the flexibilities we have in place during COVID. You can delay your semiannual inspection and semiannual program review as long as necessary. We do expect that you document the delay. You can do that in meeting minutes or any other way you want to document it. That way when we do an inspection, when we inspect your paperwork, you've got documentation that you have delayed your semi annuals.

We are encouraging the use of virtual semi annual inspections. This has to be a live video feed. And two IACUC members have to be involved in the review. It is perfectly acceptable, if you do want to do a semi annual via a virtual inspection. I think it's important to point out, too, that while you have to have two IACUC members involved in your semiannual inspection, they don't have to be in the same place. And each individual doesn't have to look at everything. You can have consultants and utilize them and send a consultant in one direction, send an IACUC member in another direction and another IACUC member in another direction. I think there's been some misunderstanding over the years that these two members of the IACUC have to be hand-in-hand, and they do not. So that's another flexibility that's in place.

Also, e-mail signatures are fine. E-mails from an IACUC member saying they approved the report to the Institutional Official serves as a signature. We're accepting all those.

Also, if you've got protocols that aren't active right now, they do not need to be subject to the continuing review not less than annually. But once they become active again, then you need to start those annual reviews again.

We have restarted inspections. We're basing this on the national dashboard from the USDA which classifies every county and every state as either green, gray, or purple. What that means if a county is green, it's passed its gating period and there's been a decreasing number of new cases for two weeks. We are currently doing inspections in green counties. We're averaging about 100 inspections a week now (September 2020). We have made numerous calls and e-mails to all regulated facilities. Hopefully if you're at a facility, your institution got contacted either by e-mail or by telephone. so that we could check on the status of your facility and see if you need any assistance.

If we come by for an inspection, what you should get is a call from our inspector from the parking lot and the inspector is going to ask if we can do an inspection. If you're not fully staffed, or if this isn't a good time or if you have COVID issues, simply tell your VMO - we would appreciate not having an inspection right now - and the VMO may offer something like a virtual inspection of your records. And some of you may have already undergone that.

Our VMOs are doing virtual records inspections, so if they can't come to your facility, they may want to look at your IACUC minutes, any protocols that are active, any other records they ask for, so we're doing virtual focus inspection of records at this time, too.

We want to make sure our employees stay safe and your employees stay safe, and as Neera already mentioned, our focus besides that is the welfare of the animals. I didn't create this slide (Slide 6) and I was a last-minute substitute for this group but if you've got any questions, feel free to contact animalcare@usda.gov and that will get distributed to the right person. You can call me at 240-461-9065; feel free to give me a call. You can also call your VMO or your field supervisor. We're not back in our federal buildings yet, at least not in Fort Collins, which is the main Operations office. We're all teleworking at home, so use e-mail and telephone to get ahold of us. If you haven't signed up for stakeholder messages, please go to our website and in the bottom left hand corner of the front page you can click on signing up for stakeholder messages [<https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare>]. And I'll stop there. Thank you.

Slide 7

Greer: This is a summary slide. Some of the things we're going to talk about and drill down on and it will reiterate some of the points that Neera and Bob just went through. So we want to look at the flexibilities that have always been there; we

have always had some flexibilities within the guidelines. Way too many times you have been to meetings and you hear about that gray area for institutions to analyze and determine what processes would fit best for their institution, their research portfolios, their policies and activities. We're going to talk about some of those. I'm going to hit on the new flexibilities that are there because of COVID. Again, Bob and Neera just hit on some of them, we're going to reiterate them and give us an opportunity to talk about them. Where you can find the flexibility, where are the opportunities for flexibility and where can they be employed.

We're going to look at engaging the IACUC. I'm sure you have been using Zoom and other ways to maintain involvement of the IACUC in the program along the way. Then we want to look at some ways to do semi annual inspections and also we'll look at program reviews.

Slide 8

Susan made a joke and said this has to be Bill's favorite footnote [PHS Policy footnote 8 page 13: *The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.*]. It's one of the things that gives you the most flexibility within your program. It allows your IACUC to do the things that it needs to do to evaluate and oversee your institution's programs. If you noticed, it talks about the IACUC having the discretion to determine the best means of conducting your programs -- the evaluation of your program and your facilities. In other words, your program review and your facility inspection. As you see, you can invite ad hocs. You can use various ways. And at the end of the day and the important thing to remember is - it's not something that an IACUC office does, it's not something that a veterinary team does. This is something that needs to be executed through your IACUC. As your committee is thinking about ways to conduct inspections and perform functions during this COVID pandemic period, take advantage of this footnote and take advantage of opportunities and brainstorming that your IACUC may come up with.

Slide 9

Neera mentioned many, many FAQs. I pulled out three, just to reiterate a few things. [COVID FAQ VIII.10, VIII.11, VII.12] You can see no later than 30 days. Both OLAW and the USDA have always given us some flexibility as it relates to do our inspections and our program reviews. In other words, you don't need to do the program review and the inspection exactly 180 days after the preceding one. We do have a 30-day flexibility, something reasonable that gives us time to get them done within a given time period. But you'll notice that both OLAW and the USDA have now given us some flexibility due to COVID. If you can't do your inspections within that 30-day flexibility, then you do have to reach out to OLAW and ask them for a formal exception. In other words, they want to know if you have to postpone your

inspections. Then the idea is that once you resume again you will keep them on that six-month period.

USDA, as Bob mentioned, you have the flexibility to postpone your inspections as needed. However, once they're up and running again the idea is that you will continue to do them in that six-month period. Back on the time schedule we can get it, but for now we have some flexibility of COVID and restrictions from the pandemic are causing you problems. That flexibility to postpone the inspections to whenever you can reasonably and safely conduct them again.

Slide 10, 11, 12

One other thing, OLAW -- I didn't hear you comment, Bob, so maybe you can. I know OLAW expects you to do your program review on time. In other words, you should still be on that six-month cycle. So when you're doing your program review, part of your discussion would be, you know, that the pandemic restrictions, is it interfering with your ability to oversee the program, how are you overseeing it now with the given concerns and various things like that. Bob, from a USDA perspective, is the same expectation there that the program review still occur on time?

Gibbens: No, the expectation is the same as it is for the semiannual inspection. If the program review needs to be delayed because of COVID, it can be delayed.

Greer: So from the USDA perspective we can delay that but if you are using PHS animals, in other words studies that involve PHS funds, NSF funds, and through your Assurance you should still be doing your program review in a timely manner every six months.

Slide 13, 14

So here is -- if you guys recall, this is from 2006 but there was a notice that came out from NIH in 2006, and this is a time where - as a community we had lots of questions about telecommunications. So this particular document still has a lot of bearing on what we're doing today. In other words, we've always had the ability for telecommunications. If you read into the notice, you'll find some specifics, but here are a few points that I wanted to make. All the members need to receive notice of the meeting. So, in other words, make sure that everybody is aware that you're having a meeting. And in red you'll see one of the most important things is if you're going to have meetings remotely and technology is needed, we need to make sure that all the folks that are working remotely have the ability to sign into Zoom or the ability to participate in a meeting. So keep in mind as you think about the Zoom meetings and the actions that you're using to have virtual IACUC meetings that you're able to meet the other requirements. Yes, you still have to keep attendance. You need to be able to prove that you have a quorum. You need to take meeting minutes. You know, whether they're virtual or not, you should still be having motions and votes. So the meetings should go on as it always has except you will be using Zoom or some other means of remote communication. Notice FCR and DMR.

As long as you're having your meetings you can still do full committee reviews. You bring the full committee reviews to meeting as you would any other time, whether you're face-to-face on Zoom, have your discussions, do your votes, approve, delay approval pending modifications, or disapprove as you would with any other full committee review.

Many of you that use DMR, you'll know that it truly isn't impacted. It technically was a remote process anyway. That was when you were assigning one committee member or more as a designated member reviewer. They did their reviews. They would respond back through your IACUC, typically through your IACUC administrator, correspondence would go back and forth between the PI and DMRs until ultimately the protocol is either approved or the DMR decides, oh, maybe we should take this to full review.

Slide 15, 16

One of the things we want to talk about, and I'm going to kick it over to Wayne is VVC. We want to make sure that you understand the flexibilities behind VVC. Have a conversation about it. We're going to ask Wayne to talk about it at his institution, and just some general comments about VVC so we understand the flexibility and the advantages that we can get from using it. Wayne, I'll turn it over to you.

Barbee: Thanks, Bill. Yeah, just a couple of comments about VVC, or Veterinary Verification and Consultation, is an additional tool that has been around for a while to provide flexibility and decrease regulatory burden. So a couple of key points can be used to modify procedures that are already part of an approved protocol, not to add new procedures. So, for instance, certain protocol changes that your IACUC has already deemed as acceptable, like changes in anesthetics, analgesics, or sedative agents that are part of the IACUC. Changes in mode of euthanasia, approved by the AVMA Panel on Euthanasia, that sort of thing.

But these next couple of items are clear. If you start thinking about the acronyms, the VVC, the vets are being consulted for a change and the vet is verifying this change fits within an IACUC approved policy but then looks at the protocol to verify this fits with that particular situation. For instance, a VVC may not be used to modifying an existing procedure if it causes a problem with animal welfare. For instance, I might be saying to my vet, I want to do some additional blood sampling after this hemorrhage procedure. And my vet comes back and says, well, it's in our policy of what blood can be collected but, Wayne, you have an animal that's already been hemorrhaged as part of the protocol, so this is a problem because it increases a chance of animal welfare problem.

And, finally, the VVC policy must identify one or more vets that have been authorized by the IACUC to perform these VVC changes to the previously-approved protocol. Now, at our institution, that's not all the vets but if you have a wide

discrepancy and experience you may decide it's for that sort of thing. And the policy must include the specific changes a veterinarian is authorized to verify. So something that can be used to increase customer service. If you haven't used it before, you can put your toe in the water by starting with changes in anesthetics, analgesics, and euthanasia methods. That's it for now. I can come back to it later, though.

Silk: Here's some fun history. OLAW released that policy, I think in 2014 and a lot of us were at the University of Wisconsin at Madison and Lou James, who is a participant with us today, named it VVC. We didn't have a name for it then and she named it for us. Good name, Lou.

Participant: Good memory, Susan. [Laughter]

Greer: Does anybody want to talk about the flexibility that they employ through VVC? I've seen some VVC examples where I'll give you one extreme where I saw an institution once that said as long as the PI has a specific behavior study approved on their protocol that is a category C behavior study, then more behavior studies can be added to their protocol, different behavior studies as long as they're category C. And then I have seen other institutions only use VVC for things like changes in anesthesia and analgesic. So I'm curious if you're willing to share some of the things that you've done in the past and make your VVC policy a little more PI friendly in that the veterinarian is able to do some things working with the PIs that still falls within the spirit of VVC, i.e., don't increase pain and distress for the animal, and yet it's still something that your specific IACUC was comfortable approving and delegating that through the VVC policy to vets. Anybody willing to share ideas or thoughts, things that they have seen in the past? Again, we're looking for ways to be a little more flexible here.

Participant: I'll give you an interesting one, and it's all interesting to me because I'm brand new to NASA. There's a lot of challenges presented by doing animal research on the International Space Station, which is the ultimate satellite facility. [laughter] One of the things we require is that food bars be changed out every seven days. But on occasion we'll have a slip and when animals were going to be returned or a procedure doesn't coincide with the ability of the astronauts because there's an issue on board or whatever. So in our VVC policy we allow for certain justification for expending up to three more days for changing out food bars. It has to meet specific criteria for it to be approved.

That's an animal care change whereas I know a lot of institutions will have, you know, changes in the route and volume of blood collections, the anesthetics, analgesics, and tranquilizers, but this one allows for animal care changes.

Greer: How does the vet get involved, participant? I think this is an opportunity to highlight - I'm going to guess it's a conversation or a phone call? Yeah, right, cell phone to the space station? What do you think?

Participant: Well, actually the attending vet is the chief veterinarian officer, who is Joe - I think everyone knows him. He's also the flight veterinarian. Typically what happens is we hear from people on ground that there's a slip and we have to go and extend the food bar change out and it goes to Joe or the duty vet, if he's delegated his responsibility to somebody else.

Greer: Okay. The point is the vet doesn't - in this case the vet is there, but the vet doesn't necessarily have to be present. It can be a conversation on the phone, it can be an e-mail, discussion, things like that. So use the flexibility that VVC offers. Anyone else have any suggestions?

Participant: Our VVC policy originally allowed only for the attending veterinarian to make changes. Our policy now has been expanded to allow all the clinical veterinarians in our facilities who are on the ground and know exactly what's going on, to also be available to make these changes. So we hope that that increases the flexibility on VVC approvals.

Greer: Very important point, thank you very much. Yeah, the point to remember here is it doesn't need to be just one veterinarian at your institution. It can be your veterinarian team. It needs to be decided by your IACUC. But as long as a veterinarian is involved, then VVC can be used. The policy doesn't require the veterinarian to be an IACUC member. The policy requires the individual to have expertise in veterinarian medicine, i.e., they are a veterinarian.

What else? We're looking for opportunities to use flexibility. A couple of other things I saw, I saw a statement in one VVC policy that provided the veterinarian the opportunity to make any changes in euthanasia providing the changes were in alignment with the AVMA Guidelines. Obviously, that's assuming there's already a method of euthanasia in the protocol. Analgesics, anesthesia, I have seen some where veterinarians can make changes, based on veterinarian standards, again providing there are analgesic and anesthesia use in the policy or in the protocols.

The idea here is you don't try to build your VVC policy to say the veterinarian can make changes in euthanasia -- in mouse euthanasia if it includes CO₂, isoflurane, and others. As long as we know the method of euthanasia being selected is in alignment with the AVMA policies and the IACUC approves it. The IACUC can say as long as it's in alignment with the AVMA board, then euthanasia can be decided upon by the veterinarian.

Curious if anybody has any concerns with that. We had a lot of conversation about it. It seemed like most people and those that were there from USDA had agreement.

I see a note on the chat. I think we allow the vet to verify blood sampling amounts and techniques. That's from a participant. Yeah, there are some institutions that give a lot of flexibility to the vet about blood collection. And some of the maximum flexibility I've seen, you know, collect blood over a period of time as long as it doesn't exceed that 1% by body weight over a two-week period. I have seen many, many different statements put into the VVC policies that build in the maximum flexibility.

Any other ideas or thoughts? I have seen some VVC policies that just reference out some multiple IACUC approved policies or veterinarian policies as long as things are in line with a veterinarian policy or an IACUC approved policy, it's okay.

Barbee: I'll just say we haven't done as many of these as I have anticipated, but the two perfect situations are a PI calling you and saying, look, I just got the scores back on my NIH grant and they have a problem with this particular anesthetic and how it's going to affect this thing I'm studying. And by the way, my next deadline is a month away. Or somebody does the same with a manuscript and says, oh, they liked everything except this problem with this anesthetic or analgesic and I have to redo the experiment. By the way, I have two weeks left to resubmit, can you help me out now?

Greer: So VVC can be used for the analgesic and anesthesia changes. Good point.

Barbee: One of the things we have done is incorporate our VVC policy as just sort of an overall amendment policy. As you pointed out there are different methods for reviewing whether it's full committee review, administrative review as well. And so that is just one portion of that. So we don't have to keep tweaking separate amendment processes and separate policies which just is an umbrella protocol amendment policy. We also give a lot of flexibility with several other examples that are a part of the VVC. So it's something to think about for folks in terms of how they structure their protocol amendment policies.

Greer: Perfect. Good point. Bob and Neera, before we move on, is there any conversation you heard that made you a little nervous? Do you think these ideas that we have heard from our colleagues, not just here but points that we have been asked at other meetings, do they all seem within the spirit of VVC or are there things that you would be a little cautious about?

Gopee: I just want to make sure our participants are familiar with the VVC and they do realize that it's a process that needs to be implemented correctly. Many time we

have seen it implemented incorrectly because they may not have a policy in place which addresses critical steps in implementation of VVC program which includes, as you mentioned, Bill, but many times have been overseen by, for some reason or the other that they need to have reference documents or SOPs in place, that the IACUC has reviewed and approved prior to implementing these changes and that's a document that the authorized veterinarian is going to be using in order to verify that these changes are appropriate. So that's important for institutions to realize that you must have these reference documents in place and it's appropriate for the species, it's appropriate for the agent that's being used. That it doesn't fall outside of those parameters.

As one of the participants mentioned you can authorize as many veterinarians, but it has to be authorized by the IACUC as well. That's also important.

The third thing - it must be documented. There must be some way that the IACUC can document that this change has been administratively handled and verified by the authorized veterinarian and it's somewhere reported, recorded in the protocol -- approved protocol. I just want to make sure that caution is made, the veterinarian is actually doing the work that's already been IACUC reviewed and approved so he or she is not acting outside of his or her purview.

Greer: Good point, Neera. Anything, Bob?

Gibbens: I don't have much to add, Bill. This is a program developed by OLAW and we fully adopted it and the main thing we look for when we go on an inspection is the documentation.

Greer: Back to the slide (Slide 16) really quick. These are the points of a VVC. Neera made a good point. Make sure you understand how to use VVC. But the reason we're bringing it up today is because it is one of those opportunities for flexibility. And given that the feet on the ground, your veterinarians are out there all the time and they're going through the facility doing well visits, it is an opportunity for you to have a well-developed flexible VVC policy to have the veterinarians engaged in helping the PIs to enhance their protocols, make changes. Again, the important thing is they are in alignment with the VVC policy. So one thing to think about.

Slide 17

So with that, let's move on to our next topic - facility inspections. And here, you know, we're thinking about footnote 8 and we're thinking about things the IACUC can do. You can do the facility inspections virtually. I know you have heard some of this conversation. And directly speaking from the footnote, you can use ad hoc consultants or specialists. The potential exists for you to use on-site staff. Is it okay for you to use members of the veterinarian teams or vet techs that are going through the facilities on a regular basis? Can you use post approval monitors, quality assurance staff? Who else could we use? We know the traditional way that

we have two IACUC members. They go through the facilities by using two IACUC members. We're ensured we're meeting the USDA regulation and we're ensured we're meeting the OLAW expectation. Most of these five -- well, four would not necessarily fall within USDA expectation because it's not mentioning a committee member. I'm not going to jump into the weeds on these bullet points because we have some scenarios that will work these out a little more and we'll be able to look at them in a practical form in a scenario base. So I just wanted to throw this out there for you to think about.

Slide 18

We want to do another slide on program reviews and then we're going to jump into some of these scenarios that will allow us to get more into the weeds of this. Again, the main point here is to think about facility inspections and how footnote 8 can be used and the various ways that we can do it. Any questions before I move on?

Participant: Bob, can you revisit the USDA expectation of facility inspections, specifically -- well, particularly during the COVID time and then how that compares to prior to COVID.

Gibbens: Sure. I think the point of confusion that's been around for years is how the two IACUC members need to be used. The confusion for many years seemed to be based on an interpretation that the IACUC members involved in the semi annuals had to go hand-in-hand and inspect the facilities together. The regulations aren't written that way. The regulations require a minimum of two members to be involved. They also state that no member wishing to be involved can be refused. Beyond that, it's up to the IACUC to determine the best way to deploy two or more IACUC members. The regulations also allow for the use of consultants. You could have -- just for an example -- two IACUC members involved plus a consultant. These three people don't have to go hand-in-hand. They can be sent to different facilities to conduct different parts of the inspection. And this hasn't changed during COVID. This has been in place for many years. I know there was confusion out there based on some differences on how the Eastern region and Western region looked at it. There's no longer any confusion. Also, prior to COVID, we would allow a virtual inspection as long as we had approved it and knew about it ahead of time. So for example, a facility in California might have a site in Alaska and they wanted to do a virtual inspection of that. In that instance, we would provide an approval letter for that. During COVID, we're fully supporting virtual inspections. So the only caveat is it does have to be a live video feed so that members of the IACUC who are reviewing the video feed can direct the camera to focus on different things or different animals or different records. As long as The video feed is live, virtual semi annual inspections are very much allowed and encouraged.

Greer: Okay. Thanks, Bob. So before we move on, I wanted to kick this over to George who is going to talk about a little bit about facility inspections under his purview at his institution and give us an opportunity to get into more questions.

Babcock: Thanks, Bill. We would really like to get some discussion on this and one of the best ways is I'll go over briefly how we do it - how we used to do it, and now how we do it. We've used sort of a hybrid system, which I'll go over some of the things that have just been covered in flexibility. In the past, we used three members per team. So three members went to each facility. And we had 18 -- we divided the facility in 18 zones. And we've totally changed that now because of the COVID response. I also want to say that besides the USDA and OLAW and these regulations we have, some states have, for your institution, may have specific rules that they want you to go with. So it may alter the way you have to do your inspections. The states that are in red or purple [COVID zones], particularly or counties, may have to alter them quite a bit because some institutions totally shut down their animal care programs and they're just not opening up. We did not shut ours down. We prevented the ordering of new animals, but we allowed investigators to use animals that are already on site. So our facility didn't shut down, per se. So what we've done, IACUC spent a lot of time into trying to decide how would be the best way, given the circumstances, that we can do this, the inspections. So what we do is we've divided up -- we got two members who volunteered to do the USDA site, just because it's easy for them to go in than it is virtually. We don't have a lot of USDA covered species. If it was more, we would have to do something differently. For our other sites, which are most of our other facility, what we've done is we have got ad hoc members appointed. They include our IACUC office staff, all had some experience. One actually was director of a small animal facility. One's always been an IACUC staff member, and one actually was a supervisor in our laboratory. So we appointed those as ad hocs. And we also have a couple of our vet techs, which we appointed as ad hocs. Using that we cover most of our facility with in-person inspections. But not with IACUC members, except for the USDA. Where we ran into some problems in our planning was how are we going to get to some of more remote satellites. Our vet techs only go there less often, like once a week or something. And we have a lot of sites and we have a limited number of ad hocs. So some of those we actually are doing virtually using video. And we have the PIs, in most cases, do the video and the IACUC inspectors watch them.

Now, a problem we have come into, because virtual inspections - the videos must be good. Sometimes the PI is running around with his camera and we're looking at things like what is that? What are you showing us? So you have to be careful with that. We had always done videos for our BSL3 facility. So some of the people in labs do that - we don't allow any IACUC members into BSL3. They are very good and they have been doing some of them. But the PIs, you may have to give them a little bit of encouragement how to do it. We don't use - our non-affiliates are always involved in the on-site inspections, just like any other member, but in this particular

case, the non-affiliated members are not allowed on campus until things get better. They are in the virtual IACUC meetings but they're not allowed to do any on-site inspections.

So what I'd like to do quickly, before we talk actually about programs, is find out what you guys are doing. You can either do it in chat or by raising your hand or a yes or no. So some questions: Who is doing it as they have always done it? They are fully operational. So we can get a feel for how many institutions are doing that. Could you say yes or raise your hand or say we are back to normal.

Greer: I'll see if I can get folks encouraged, George. At the University of Michigan we kept doing inspections on a regular basis, but we did similar to what you're doing and used ad hocs. We sent the husbandry staff, vet techs, and others out to the facilities to gather information, bring it back to the committee and gather information that way. It's been working very well for us that way.

Silk: A participant tells us that at her institution they're back to normal, but they split up to keep social distance.

Babcock: That's probably a requirement in most states. That's what I mentioned to follow the state or institution regulations. Who is using ad hoc members to do part or all of their inspections? Do you want to share? Let's expand that to include ad hocs or a hybrid where they use some members and some ad hocs. I guess Bill does what we do.

Greer: I thought you said -- oh, your ad hocs weren't allowed on campus, George.

Babcock: No, our outside members aren't allowed on campus. Our ad hocs are.

Silk: A participant says - slowly getting back to normal. Only IACUC members are going to be present to ensure the social distancing.

Babcock: Anyone else? Wayne, do you want to share what's going on at VCU?

Barbee: We're starting back but with a smaller group of people. Two members at the USDA areas and support areas as well, but definitely fewer members. And some of us more vulnerable population have been given the option of opting out.

Silk: You mean the old guys, huh? [laughter]

Babcock: Yes.

Silk: A participant is using a combination of hybrid system of IACUC and ad hoc members.

Babcock: I will throw in one thing on streaming. I have seen this work really well at site visits, and the three keys are you have to have the right lighting. You have to have a really nice decent device, but you also have to have the appropriate bandwidth to handle all that data. You have to have all three or you may not be able to see well.

Silk: Another participant tells us - we're going to have ours for the end of the month. We have four IACUC members with social distancing, facemasks, face shields. Planning to livestream for the rest of the committee and consult with the PIs virtually. It really sounds like they have planned that well, doesn't it?

Babcock: Now, there's another option. How many people are planning on using the flexibility to postpone their inspections as long as possible? You would have to have a waiver from OLAW and just keep it documented for the USDA. Is anybody planning on doing that?

Silk: We've got a couple of raised hands. A participant said they have a waiver. I see another one, we requested a waiver.

Well, how about another participant wants to say something, I think? Participant says they have a waiver too and they're still in the planning stages, but they haven't got back to work yet. So that's her note.

Greer: I'll share with you guys that last week we had an AAALAC site visit at our institution. That's one of the overpowered semiannual inspections. We did all of it using social distancing, face shields, facemasks, PPE. We went to the facilities. We had just our square footage as far as rooms, how many people could enter a room based on the square footage of the room. It went very well. I'm talking about the pandemic-related issues. We were able to manage them, everyone felt fairly comfortable. We had some PIs that weren't real comfortable with it so we took them off the list. I can tell you they're starting to implement the site visits again using the pandemic restrictions. So it went well at our institution and I know others have done it too. Something to think about. And I'm seeing in the notes that most people are thinking about the pandemic restrictions and what's next.

Babcock: You made an interesting point, Bill. Some institutions don't allow outsiders in the institution yet. So are they flexible with that to postpone?

Greer: AAALAC is very flexible. That was the first thing they asked me. Are you comfortable doing this? Because there is a formal process to ask for a postpone until the institution is comfortable with having folks come in. I mean, we're in Michigan. I had site visitors from four different states. We sat down and thought about where they were coming from and all of that. We had a lot of conversations with the site team leader to make sure they were comfortable coming to the

institution and also comfortable following our restrictions, which they were, so it did go well.

Silk: Here's a participant commenting on her state university. We had a waiver from March and we don't believe we'll need another one. Participant, you're keeping an eye on your infection rates when you make that hopeful prediction, right? [waivers from OLAW do not expire, see below.]

Participant: So right now we're just in the planning stages of getting some of our labs inspected. As I mentioned before, it's just IACUC members so they can be socially distanced. But obviously if we see an increase, we'll reevaluate the need for another waiver.

Babcock: Yeah, everybody has to be nimble now. It changes day-to-day almost. I worry not so much from our institution as far as the PIs because they have already been back since July. But the students are coming back and we have seen a couple of spikes and that they can spread it fast.

Gopee: If I can provide some clarification on some of the issues here, if that's okay. What I would like to say is just to clarify the waivers that OLAW granted for the semiannual inspections, there's no expiration, per se. So if you weren't able to do your first annual semiannual, and for some reason you cannot conduct a second, there's no need to request a second waiver. But I will tell you that we do not recommend that you postpone your inspections indefinitely. COVID is unpredictable. We're not sure how long this is going to last. And so, institutions need to start thinking about incorporating these flexibilities and trying to get the inspections done, simply because the longer you delay these inspections the more likely you are to have animal welfare issues as well as noncompliance issues arise. So we're encouraging institutions to employ these - to consider these flexibilities. There are many flexibilities we discussed today and to try and get those inspections done as soon as they can safely be done, without having to delay it indefinitely.

So it's important that institutions start these discussions, even though you have a waiver, start this discussion and see how best you can get these inspections done. As you mentioned, you can use ad hocs. You can use one qualified individual. That's all we require. That's as much as you need. One qualified individual. It doesn't need to be live video stream, from OLAW's perspective. If you have that one qualified individual, that's sufficient. If for some reason the IACUC feels more comfortable having a bird's eye view, then that one individual can actually record that area or those areas and report back to the IACUC to see for themselves what deficiencies they identify.

Another thing I would like to also caution, George mentioned non-affiliated because of liability issues not allowed to participate in inspections. But keep in mind that no

member wishing to participate in inspections should be involuntarily excluded from the inspection. So there should be a way, if for some reason your non-affiliated, decide they want to be a part of the inspection - maybe be creative and innovative and consider the flexibilities again. How can you accommodate this non-affiliated member? Can we do a livestream and have one individual go there face-to-face, personally, in-person and have that person virtually livestream or even record those areas so that non-affiliated becomes a part of that inspection and is not excluded from the inspection.

Babcock: That's a good point, Neera. Ours did not want to be part. They were elderly.

Greer: I've got one quick question and a participant had a question about AAALAC. If they have a waiver, do you require documentation like the USDA does?

Gopee: In your annual report you will be required to justify or to explain that you did not conduct your semiannual because you received a waiver. Those who did not receive a waiver, they're out of compliance because that's our requirement. In order to skip that inspection or delay the inspection, you're required to get a waiver. Your 2020 Annual Report, which everyone knows that our reporting period has been aligned with USDA's federal fiscal year reporting period of January 1st to September 30th. So it's due no later than December 1st. In the 2020 Annual Report you will be required to state that a waiver was granted, and we do have records to verify those waivers.

Barbee: Neera, A participant had a question about how does AAALAC's site visit work? When it was planned for April, does it mean the next semiannual would need to occur in July? I told her I think that's correct but I just want you to confirm that. The AAALAC site visit was essentially reset the clock.

Gopee: That's correct. And they have six months plus 30 days from that AAALAC site visit. If they did get a waiver, they can extend that but get that discussion going with your IACUC, how can we safely conduct these inspections using these flexibilities.

Babcock: Neera, I have a question. If an institution has multiple sites, maybe in the same state but different counties and the different counties have different regulations based on the COVID pandemic, can you do part of your semiannual inspection if you can do it safely? And then get a waiver for some of the other sites that maybe have different rules?

Gopee: So we granted a waiver. It's a general waiver that covers all facilities and areas included in your inspections. So you may describe in your Annual Report that

we conducted inspections of facility XYZ but were unable to do ABC, but we have that waiver. It will automatically cover those areas.

Babcock: I'm just going to say very few words about the program review. Bill, next slide over.

Greer: Before we move on, George, one point about the participant's question. The AAALAC site visit, if you want to use your AAALAC site visit as a semiannual inspection, you don't have to do that. But if you do, you should be sending to your IACUC members along with the AAALAC. The AAALAC team shouldn't be doing the inspection for you. If you make the decision that AAALAC is going to do your inspection, it resets your clock. If you choose to not use AAALAC as inspectors, then you stay on your same schedule. At our institution we choose not to use the site visit as an inspection. We choose to do our inspection independently. So there is a decision that needs to be made by the institution when it comes to that. By your IACUC. Just a point of clarification.

Babcock: That's a good point, Bill. I know you and Wayne are both AAALAC site visitors, but I would say for, you really don't want your site visitors to go by themselves.

Greer: Agreed. If they said they found this and you didn't see it, you're vulnerable there.

Yeah. I respect AAALAC for what they do but your IACUC may be digging deeper into the weeds than what AAALAC would and you could uncover some dust bunnies that would do damage to your institution. It's not that you don't want to have full transparency, you do, but you could extend the time of your site visit simply because your semiannual inspection may be much more detailed than an AAALAC site visit and it depends on the institution. Our site visit we had last week was very detailed and they dug in deeper than what our IACUC does. So it really is a decision that you need to make at your institution. And I think it's best left at that.

One thing we do in our inspections, our IACUC inspections, we're not doing it right now, but we often correct problems we find. And during AAALAC they're not going to wait for you to correct problems.

Silk: I heard something that I think Neera should clarify. Neera, you said something about coinciding with the USDA's year and then you mentioned something from January to September. Were you talking about a special situation that is related to the 21st Century Cures harmonization.

Gopee: It definitely is, Susan. It's one of the harmonization as part of the 21st Century Cures Act initiative. We have harmonized our Annual Report which used to

be a calendar year from - January to December of that calendar year. And we've now aligned it with USDA's reporting period on a federal fiscal year.

And so for the 2020 Annual Report, everyone should have gotten notice of this and we do have a lot of resources out there. We have a webinar. We have instructions, you name it. It's very useful where we have now announced that our new reporting period will extend from January 1st, 2020 to September 30, 2020. And it's a partial year since we haven't continued from the previous year. And that it would be due no later than December 1st. And there's going to be a lot of nuances in the 2020 Annual Report in the sense that there will be institutions we have granted waivers for. So they may have only one semiannual inspection to report in that Annual Report, or they may have none, depending on when their inspections were done and when the waivers were granted.

Silk: So we should be very clear to say that the federal fiscal year is perhaps different from the university's fiscal year. So you're talking about the federal fiscal year.

Gopee: Federal fiscal year, yes.

Na: And then also just for clarification -- this is Jane Na from OLAW. If people are thinking way far ahead in advance, the following year's annual report is actually going to be a complete year. The only reason this year is partial is because we need to deal with the fact that it was a calendar year prior to our switch over. So this is a transition year, which means there's only going to be nine months in the annual reporting period. And then all subsequent years the complete annual reporting period will be the federal fiscal year of October 1st through September 30. So Neera was talking just about 2020, a special year.

Silk: Very good clarification, Jane.

Greer: Thank you. Thank you for the clarification. I'm going to move us along to George's slide on program reviews and then we'll chat a little bit about this and move, I believe, into scenarios.

Slide 18

Babcock: Yeah, I'm not going to say too much. We can chat. Normally the way we do this program review is we have facilities manager, the attending vet, and three IACUC members go over the inspection report and write up the program review, the deficiencies, and take it to the IACUC.

We're not doing it now that way. The whole program review will be done by the whole IACUC. All the information that the ad hocs and the members have during the inspection will be forwarded and we'll do it at the IACUC meeting, virtually, and

we decided we're going to use that as educational too. Some of them, I think, don't always look at the results that carefully. Now they're going to have to participate in it. So that's what we're doing. It's going to be program review by committee. Does anybody have any comments or suggestions or how they're doing it?

Slide 19

Greer: Okay. It's quiet on program reviews. We're going to assume that folks have found a way to work it out. Zoom meetings are working very well for all of us. I think the important thing to realize is OLAW still expects us to do our semiannual program reviews every six months, so use your virtual systems in the processes to make sure we can still do them.

Slide 20, 21, 22

Here's our first series of questions and the reason is for us to reiterate some of the points we went over. In some cases it's going to be a review and in other cases it may help us clarify questions that you have. Due to the pandemic restrictions we are unable to conduct our facility inspections. What do I do to ensure my program remains compliant? So everybody should know the answer to this question now. Does anyone want to tell us what we've learned as we've gone through the conversations? Feel free to talk too. You don't have to just type. Feel free to jump in there.

Okay. As a point of review, no need to worry. Your program remains compliant if you didn't or couldn't do your inspections from the USDA perspective with the one caveat that you should be contacting OLAW and getting that exemption if you're unable to do it. So your program remains compliant if you don't do your inspections, from a USDA perspective with the idea that once you start up again and get back on the six-month time-frame, from an OLAW perspective, your program remains compliant if you can't do the inspections with the expectation that you've talked to OLAW and you've gotten the formal exemption from them.

Silk: Bill, there's another way to look at that question. When you're not doing inspections, are the activities that are proceeding inside the facility compliant? And this is where a good culture of compliance in your institution really pays off. It's just one of the places. But if you have well-trained people committed to their jobs then they should be carrying on their procedures in a compliant fashion. But you also mentioned that you would have veterinarians and vet techs and people in and out of the facilities. And so everybody could be helping everybody else, ensure that their procedures are compliant.

Greer: Sure. That's the way the IACUC decided to do the inspections and that's up to how people want to employ that footnote 8. Other point to that is that would be the discussion we mentioned on the previous slide, how is the IACUC overseeing

the program if they can't do their inspections and that's where veterinarians and even PIs are involved to make sure there's a strong communication.

Babcock: On a day-to-day basis we have always used our veterinarian staff. And we've gotten to where almost 80% of our non-compliance reports come from the PIs. We make it a little easier on them if they report it, and if we find something they haven't reported, we're a little tougher on them, and that's worked out well.

Hollander: I would like to make a comment about this topic. Remaining in compliance in the animal facility -- and we'll get more into this, but I just want to mention it now. You know, some of the COVID restrictions need to be in place and are going to be affecting the day-to-day processes that occur in the animal facilities, such as social distancing, potentially additional PPE, altered exit and entry procedures. And so if the COVID pandemic is adding additional requirements on to work in the animal facility, so I think it's important to remember that hey, yeah, we're staying in compliance with the current policies and procedures but now are they staying in compliant with added COVID restrictions that are being integrated into their policies and procedures. And I just wanted to mention that now, since it came up. We will get more in-depth about that later in the next presentation.

Greer: Perfect. Thanks, Mindy.

Gopee: I would also like to mention many institutions are in sort of a recovery or return to work phase, and so it's important that PIs and IACUCs and everyone involved in research keep in the back of their minds that they are still required to comply with the regulations. And so a lot of PIs, you know, they may not remember or may not be cognizant of these regulations and rules and may tend to fall out of compliance very easily because they come back to work and they're all eager to get their research up and running, and who knows whether they're in compliance or not. And so monitoring is very important as staff comes back to work. It's important that any work involved with animals, that you really recognize and you really look into this-- as work resumes that everything is done in compliance with the approved protocol, with your SOPs, with your policies, et cetera. That's important. It's been six months plus since people have been out of commission and so when they come back there tends to be negligence and they tend to forget what was approved and what was required. So it's important that when you return to work that the IACUC is cognizant and they make it aware to researchers that you need to make sure that compliance and animal welfare is first and foremost on their minds.

Slide 23

Greer: Good point, Neera. Thank you very much.

Number 2: With the pandemic I haven't been able to inspect my facilities for eight months now. If you recall sometime ago, the first note that came out was we can ask for a six-month exception, and we're beyond the six months now. Neera made

it clear that once you get your exception it's good until the pandemic restrictions are lifted until we're back on a normal schedule. And Bob made the same comment basically for inspections, as long as we're in the pandemic restrictions, we have the ability to postpone them as necessary. The health and welfare of the individuals. I have talked a little bit about and Susan mentioned a few minutes ago, there's ways to oversee the program and your institution would need to decide how things are going on and what practices you would use.

Slide 24

I'm going to move to number 3. My IO report typically includes a summary of my program review and inspections reports. Due to COVID I haven't been able to do my inspections. So do I still need to provide the report to the IO. So we know you need to do the program review. We have talked about that. So that should occur. So in this particular example now you would write an IO report and then you would provide a discussion to your IO that talks about the fact that you had to suspend your person to person inspections. In other words, your walk-through of your facilities. You may want to note that you've gotten the exception approved through OLAW. You may want to note that the USDA is fine with it (see below). The idea is to make sure that your IO is aware and you have documented your program review on a regular basis, i.e., every six months, and that you have documented when you had to stop your facility inspections, so when you do get back to them you can get back on a normal schedule and you've got that information available for your subsequent reports, OLAW report or wherever else you need it. Anyone have any questions or

Silk: A participant asked - didn't Bob state that the USDA doesn't expect semiannual program review during the pandemic?

Greer: Yes, he did. He did say that. I'm sorry. You corrected me, participant. Bob made the statement that the program review was not required for USDA. But it is in the FAQ from OLAW that it is required for all species our activities that are NSF funded. Thank you for pointing that out. Anyone else?

Participant: Bill, I'd like to include NASA at well. We recently signed an MOU with NASA, so it involves NASA funding as well.

Greer: A couple of more points. Again, just reiterating things that we have talked about. I'll go through these quickly and if you have any questions, let me know. Again, this is a form of review for us.

Could the IACUC conduct its inspection by using others to first tour the facilities and gather information? We know they can. Footnote 8 allows us to do it as long as it's under the discretion of the IACUC. The caveat is the IACUC needs to be the one to make the decision, to have the discussion, set forth and approve the process. And

who could gather this information? So could it be the administrators? Could it be the PAM staff, husbandry staff, veterinarian staff, PIs, or managers? As long as it's done under the discretion of the IACUC and the IACUC agrees then any of these can be used.

The question would be is there any conflict of interest with PIs? If the IACUC actually wants to do this then you would need to ask yourself whether or not you're concerned that the PIs have a conflict of interest and they should not be inspecting or overseeing their own facilities. This kind of goes back to Susan's point about the team effort. It depends on your relationship with your PIs. George said his PIs self-report so it would be up to the institution. Any questions there? Any thoughts?

Barbee: The IACUC also needs to decide if the people are qualified that they appoint too.

Greer: I would expect all of these people are qualified.

Silk: Bill, I just wanted to add I think it's implied that all on that list, at least two of them, need to be members of the IACUC.

Greer: If USDA species are involved. I agree. That's an important point to remember along the way. I think we're all used to idea that two IACUC members need to be involved in some way. Bob gave us some flexibility options. We have a scenario in a minute that might allow us to ferret that out a bit, but remember the IACUC members have to be involved in one way or form with the inspections.

Participant: Typically, we have tried to stay away of having the veterinarians be inspecting areas that they oversee because, again, this point of conflict of interest, but it's something that me personally think that it shouldn't be. So what I hear here is it is okay for us to use veterinarian staff, including the veterinarians, to inspect areas where animals are housed, that they do the veterinary care and oversight for? Is that correct then?

Greer: You make a very good point, participant. I think it's the same scenario as PIs. There's certainly a conflict of interest. They are responsible for the oversight of the vivarium. It's going to have to be an institutional decision -- this is my opinion. Anyone else can weigh in. If your veterinarians are engaged in a way that they are reporting issues, potential non-compliance and things in their own area and you 've got that relationship at your institution, then it's certainly up to your IACUC if, as a committee, you feel those conflict of interests exist, that would be for husbandry staff, veterinarian staff, PIs, all the way around. I think you need to be cognizant of the conflict of interest and manage it. What do others think?

Participant: I would suggest if you have multiple vets and they are responsible for different areas that you cross them over in terms of the inspection so they're not looking -- they could tour with the IACUC members in their facility but it would be preferable that they actually go over to another veterinarian's facility using their expertise on that inspection team.

Greer: That's a good point, participant. It allows you to manage the conflict of interest and that's a perfect way of doing it. So you can get the job done and manage the concerns.

Participant: You don't want to cut them out.

Hollander: Isn't it important to have the vet or a vet from that facility along, even if they're not considered, quote, unquote an inspector. Because a lot of times they can give context to what the IACUC members might see, since it's their facility. And also I notice that a lot of vets like to be there and hear what they're finding so they can then have that fresh in their memory and go to their staff and kind of discuss it and say, hey, these are the things that the IACUC has pointed out that we need to address. But that they were there firsthand so they heard the issues firsthand and saw them.

Greer: I agree, Mindy. Our standard procedure -- not now but our standard procedure is to have a facility supervisor, a vet, and two IACUC members on our inspections.

Barbee: It's also pretty challenging for smaller institutions that may only have, you know, one full-time veterinarian. And so we always try, in addition to having the veterinarian who may be reviewing her own areas, but that's just like when you do an announced inspection to a PI lab, having PIs or lab people be present. We also have someone from the compliance area. Again, that's just the way that we manage it.

Greer: Good points. We have come to the end of our session. Now we will have a 5-minute break.

End