

# ICARE



Interagency Collaborative Animal Research Education

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## **ICARE Dialogues: Using Flexibility Provided in the PHS Policy and Animal Welfare Act and Regulations**

**Presenters:** Bill Greer, George Babcock, Neera Gopee, Bill Stokes, Cody Yager, 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>).

Silk: Welcome, everyone. It's my pleasure to introduce Bill Greer, who will introduce his team. Bill and his team are going to talk about Using Flexibility Provided in PHS Policy and AWAR.

Slide 1

Greer: Thank you, Susan. Welcome, friends and colleagues. To give you a prelude of what we're going to do, we have a few slides, but ten minutes in we'll get rid of them. We're looking forward to active conversations with you. So, bear with us a little bit on the slides, we just want to give you some upfront information.

Slide 2

I'm going to start by giving the folks that have been working with us an opportunity to introduce themselves. This is a team that you'll be working with on the flexibility. So myself, for those that I have not met, my name is Bill Greer, Assistant Vice President for Research at the University of Michigan. I've been involved in compliance, animal care and use, safety, all those things for over 30 years. The first 15 years of my career was on the PI side for a pharmaceutical company where I made animal vaccines. Then I went to Penn State, spent 15 years there as an Associate Director overseeing various areas of animal care and use, and other compliance programs. And at Michigan now I oversee the animal care and use program and a couple of other areas. So I'm going to turn it to George and let the team introduce themselves. So, George, please.

Babcock: Hello, everyone, I'm George Babcock, Professor Emeritus of Surgery at University of Cincinnati. I've spent 32 years as a PI doing research. I'm currently a Chair, I've been that for 21 years. I'm the Vice Chair of the IBC.

Gopee: Hello, I'm Neera Gopee, Director of Policy and Education at the Office of Laboratory Animal Welfare at NIH. Thank you.

Yager: My name is Cody Yager, Supervisor Animal Care Specialist with Animal Care USDA in Dallas, Texas. I supervise seven inspectors.

Stokes: Hi. I'm Bill Stokes, currently working as an independent veterinary consultant in animal research and welfare. I've got over 40 years of experience in biomedical research, including serving as an attending veterinarian at four research facilities, including two of the National Institutes of Health. At NIH, I also directed the National Toxicology Programs in our agency center. I was responsible for validating and gaining global acceptance of new refinement and replacement methods for testing. And most recently, I served as assistant director for animal welfare operations at the USDA. Looking forward to our discussions, and appreciate everyone joining us.

Greer: Thank you to all. I'm going to turn it over to Neera. She has a couple of slides, and then we're going to go to the questions and answers.

#### Slide 3

Gopee: Thank you, Bill. We are concerned about the impact of COVID-19 on the ability of institutions to ensure the well-being of animals and personnel at institutions while maintaining compliance with the PHS Policy, *Guide*, and approved animal welfare Assurances. In response to this current pandemic, what we did was we released numerous resources which can all be found on one dedicated COVID-19 landing page. This page can be accessed by clicking on the red banner on our home page.

#### Slide 4

This website has been created specifically for COVID-19, and it's updated as additional guidance is developed.

#### Slide 5

And you will find we have 21 FAQs. We released a new one last week. It includes FAQs on how to conduct semiannual facility inspections, program reviews, and other business while maintaining social distancing. We also have available webinars, articles, examples, disaster plans up and useful links. And this web page has many valuable resources available to help our constituents. It is by no means exhaustive. Please do not hesitate to reach out to us. We are more than happy to provide guidance and advice that you are seeking.

#### Slide 6

And finally, we can be reached via email, telephone. You can find a lot on our website, like I discussed earlier. Please feel free to follow us on Twitter. And you can also subscribe to information. And I'll hand it over to Cody for USDA's information.

#### Slide 7

Yager: First off, I want to start with our contacts so you know how to get ahold of us if you have questions. The email address is [animalcare@usda.gov](mailto:animalcare@usda.gov). There is the main phone number for the Fort Collins office. And then there is our website, the link there that you can click is there and find a bunch of resources that we have there, along with the stakeholder announcements. And you can subscribe so you get those as soon as they come out.

#### Slide 8

I know ensuring the safety and health for your staff and animals is going to be your number one priority, and it needs to be. Here at USDA, we are allowing facilities to delay some of their administrative regulatory requirements now. Currently, we're not putting a specific date on when we expect you to commence those semiannuals or annual reviews, because we really don't know how long COVID-19 is going to impact your facility's operation. We just ask that you document that delay. And you can use a blanket statement, that is perfectly fine to do so.

When you do start to do those semiannuals, just remember two voting IACUC members have to be involved. We leave that up to the facility to determine the process. You can use ad hoc consultants in conjunction, and you can use the IACUC members that are conducting the inspection. They do not have to be in the same area at the same time. They can be totally independent, inspect different areas individually. You can also use live stream video, or the most recent AAALAC site visit if it meets the requirements listed in our Inspection Guide, 7.1.2.

IACUC meetings can also be done virtually. And you can refer to our Inspection Guide in 7.1.8 to see those specific requirements. Emails from IACUC members acknowledging an approval of semiannuals serves in lieu of a wet signature. If the delay extends beyond the time for the required not less than annual protocol review, that should be documented, and the review should be conducted when the activity starts. Reach out if you have any questions. And I think we just sent out the annual report packets to everyone electronically this year. Hopefully everyone got those.

#### Slide 9

We've been limiting inspections based on our assessment of risk to inspectors and facility personnel. We're also conducting the focused virtual inspections on paperwork. I assume some of your facilities have seen that. In the event that we do conduct an in-person inspection, we understand that you may have some exposure concerns or be dealing with a very limited staff. Our inspectors will work with you to address those specific concerns. We may use videos or photos, or simply come back at another time. This will not be considered a refusal of inspection, but rather a joint effort to address those serious public health emergencies, while still assuring the welfare of animals.

Lastly, all these flexibilities discussed do not need approval from USDA, but the delay should be documented so our inspectors, during their next inspection, can verify what took place. And if you have any concerns, please reach out to us. We want to work with facilities. I know the past few months have been really hard on everyone, but please reach out if you have any concerns and let us be a help to you and your facility in this trying time. Thank you.

#### Slide 10

Greer: Thank you, Cody. So, real quick slide here, and then we're going to go to questions. So, we do want to cover, obviously, the flexibilities that have been in place to deal with the pandemic restrictions, but we also want to point out that there are some flexibilities that are naturally inherent to the regulation. And I highlight this footnote because this footnote really gives you a lot of opportunity to figure out what's going to work at your institution. This is from the PHS Policy. PHS Policy footnote 8 talks about how the IACUC has the discretion to determine the best means of conducting semiannual inspections and about the ability to use ad hoc consultants to do assessments, and various things. You can use your imagination. As long as it works for your institution, and your IACUC has a conversation and you agree on it, there's various opportunities for you and your institution to use some flexibilities. So we're going to go through some questions. We're going to put a slide up. And we will highlight the questions that were posed by our attendees. And then we're going to a round table opportunity for discussion. And we hope that you guys weigh in and give us some ideas and thoughts. And we will do the same.

#### Slide 11

Let's chat about this. It's all about Zoom and Zoom meetings. Now that we've been doing this since March, there are some ideas and questions coming from our members.

- Due to COVID, we're not meeting as often as we did when we were face-to-face. Could that lead to potential issues?
- Does the IACUC ever need to go back to meeting in person?
- Can we continue to use this teleconferencing or videoconferencing? Is it an acceptable alternative now, or is this just something in the interim and during the pandemic restrictions?
- What IACUC business, if any, cannot be conducted by virtual methods?

What are your thoughts? So, again, we're talking about mobile or remote IACUC meetings. What's the benefits, what's the risks, and what are the limitations now, and what are the limitations when we get out of the pandemic restrictions. So we'll let you guys chat first, but we'll weigh in. Go ahead, George.

Babcock: I was just going to comment on the first one. Could this lead to potential issues, meeting less frequently? I think a big one is if you have noncompliances. If you don't, I don't think it's a problem. But if you need to discuss the noncompliances on a regular basis, and if you meet less frequently, I could see them potentially getting out of control - hopefully not, but that's a possibility.

Greer: That's a good point. One thing I'll add to that, as well, is we can get into this space of complacency where it's easy for an administrative office or a veterinary team to do all the business, and then the IACUC slowly gets left out of the picture. So you really need to make sure that your IACUC remains a dominant feature in your program. They need to know what's going on, so if your admin office finds something, your IACUC administrator finds something

and you're not meeting regularly, you may lose the potential, the ability to get the IACUC engaged. And they may become unattached to the program. So I encourage that we make sure that we keep the IACUC engaged as much as possible.

Participant: Thank you for having this. This is great. And I recognize the hypocrisy of what I'm about to say considering that I'm not showing my face, but I really do feel that not being in person distracts from the discussions that the committee has. You know, I have two kids distance learning, and my husband is working at home as well, and there's a whole bunch going on in the background, so I never turn my camera on. But I look forward to going back in person. And I think that people might not talk as much or share their opinion, or really get that sense of what is being discussed, or the tone of it through the computer. And when our committee meets on Zoom, we do a lot of discussion through chat. And somebody reads the chat. And I think it loses a lot of the tone and intent. And I think that's a disservice to the discussions that the committee is having. The Zoom certainly affords people ease of joining, because there's a reduced transportation time, difficulty with parking and all of that. But I look forward to returning in person and having those discussions face-to-face.

Participant: I also want to share about our IACUC meetings. We're still meeting every two weeks, but right now I'm at work, so my connectivity is great. But depending on where we've been living, people will drop out. So all of a sudden, you'll be talking away and they're gone, and you miss the discussion. You have to take the time to sign back in. So that's been one of the limitations. We have a very large IACUC. We'll have a meeting that's like 17 people. All of a sudden, we have a discussion, are they gone, are they back? But it is good that everybody can attend, they don't have to drive 50 miles in big city traffic. But Zoom does have limitations. They cut out. Only one person can talk at a time. You don't get that interaction back and forth. That's very difficult. It does have limitations.

Greer: Do you guys consider the quorum issue, that people are dropping in and out? That's one concern that you have to ensure if there is official business that's being conducted, that requires the quorum at a convened meeting, that you maintain that quorum or that business is tabled or left for another meeting when you can reestablish quorum. That's the important thing there. You can conduct other business, but anything that requires that quorum, which specifically would be a suspension or a full committee review, those two would require quorum at a convened meeting. So please keep that in mind.

Participant: But if they dropped out and logged right back in, you wouldn't consider loss of a quorum.

Greer: No, as long as they kept apprised of what business went on during that period.

Participant: We have our IACUC meetings in an auditorium-type room, so the chair and administrative staff are facing us, but everybody else is facing them. So the Zoom to me is better because you get a face-to-face contact with every person. And I always have trouble hearing people. That's just my own personal problem. But I find that with online meetings, it's

beneficial to me because I can hear what everybody says. So it works out better for me. And it's more convenient, as other people said.

Greer: Good point, especially if you're on a campus that has tons of parking problems, and then you've got people trying to get in, and find a place to park. There are definitely advantages to Zoom.

Participant: I appreciate the Zoom. We've had better meeting attendance utilizing Zoom, better presence. And if a team of staff members monitor if someone drops out, when they come back in, admitting them back in so we can monitor quorum, but also monitoring the communication during the meeting. They raise a hand, a staff member will cue the chair that Joe has his hand up and would like to raise a comment. That way they can verbally talk about their concerns rather than someone else interpreting or reading it from chat, which I've found to help facilitate the meeting a little better. I think that connectivity is a challenge for some folks and can be a barrier. But I think that overall, I hope that there won't be a change in the post-pandemic use of videoconferencing to conduct meetings, because I think that this is a path forward from here on out.

Participant: We have a relatively small IACUC program, but the advantage of the virtual meeting, I agree that attendance is improved. And I'm a little bit worried about internet connection. But also, in addition to Zoom, we also have been experimenting with Microsoft Teams. The good thing about Microsoft Teams is it is inside your institution, and it not only can run, it will be more efficient to share documents, because you can set up the access. It will be easier, not only for the Zoom meeting, but also for the other operations. Even in our other operations we tried to transition to Microsoft Teams.

That's the tip I'd like to share. A question, normally with the attendee's agreement in the past, we did use record to record the meeting deliberations. Are we okay, with the agreement from all the attendees, we will keep the Zoom recording for the purpose of record tracking and then we would delete the record after the meeting minutes are finalized and approved. Would that be okay? Would it be acceptable by law or USDA?

Greer: Is the question if you can use that to record your minutes, the videoconference, the Zoom meeting?

Participant: It's not to serve as the meeting minutes, just to try to help to draft the minutes. But once the minutes are finally approved, we delete the digital recording. Would that be okay?

Greer: Yes, there's nothing against it. You can do that.

Participant: We made it very clear at the beginning of the meeting, so all members agree to be recorded.

Babcock: Just as a suggestion for others who use that method, delete that as soon as possible, because videos are FOIA-able. We record ours, too. But within a day it's gone.

Greer: That was going to be my point, too, George. That's a critical point. If you forget and start to save your video recordings, and somebody FOIAs all of your recordings, they've got access to all of your Zoom IACUC meetings. So, my personal opinion is, it's important to use it as you soon as you can and as soon as you're done with it, whether it's immediately or after the IACUC approves the minutes, delete it so you no longer have it in your files.

Participant: Our meetings have not been impacted in terms of contribution and participation, but what I've found is it's great because we record them, and afterwards when we're going over the meeting minutes, people have questions. Well, didn't we ask to vote on that? Didn't we say this. And we can actually go back and reference the recording, which is a fantastic thing that using Zoom has allowed us to do, to be able to say, no, actually, we all had this discussion and we agreed this. And then we can delete things if we have to, but the recording feature is fantastic.

Participant: We recorded ours when we were in person.

Participant: It's clear from the discussion that, as with so many other things, there is no firm answer here besides that we need the guidance to remain flexible. So, our group, we've had some of the same benefits and complications that other people have described. The biggest complaint I'm getting is that obviously we're not serving anybody lunch right now. [Laughter] In our case, I'm pretty sure that the enough of us feel like when it is acceptable to be gathering together in a single room where we can resume lunch deliveries, we will be back in person. But I think we're going to definitely be more flexible moving forward and maybe do a little bit of a hybrid is what I expect. And certainly before we were forced to work like this, that wasn't on any of our radar. We weren't even considering it. We didn't even have people calling in. Because we serve lunch and I let them pick their lunch, we don't have quorum problems. [laughter] We always know who's coming and that we have enough people. So I see a lot of opportunity here for building in flexibility so that programs can use what works best for them.

Greer: You need to do Door Dash or Uber Eats for your online meetings [laughter]

Participant: Oh no, extra delivery fees, we just don't have the budget. [laughter] But because of this Zoom, everybody attends. I haven't had to use alternates, for instance, since this started, because everybody is able to log in for a Zoom meeting. And so if I had to do Door Dash for every single one of them, think we have 16 members right now.

Babcock: I'd like to ask a question to the group. We found the same thing. We have increased attendance of our members, but we have a lot of auxiliary people that go to our IACUC meeting. And their attendance is not as good in Zoom. We have our biosafety officer. Their attendance hasn't been as good. Are other people seeing that?

Participant: We've seen the same thing.

Silk: We have a couple comments in the chat line. A participant says, "Don't forget to check whether your Zoom recordings are saved in the cloud. I think you have to delete the cloud-saved recordings through the Zoom portal."

And another says. "She doesn't get lunch." Participant, if you start sending lunches, can you send one over to this participant, please? [laughter]

Participant: I'll see what I can do about that. [laughter]

Greer: There you go. Let me ask a general question for Cody and Neera before we move to the next question. We were kind of forced into Zoom meetings. And we all did the face-to-face thing. There was a telecommunication from OLAW and the USDA. It was one of the NOT announcements from 2006. [<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-052.html>] There was a lot of effort made that if we need to use telecommunication, we can use it, but shouldn't be the norm. It shouldn't be out of convenience. It promotes meeting face to face. So, given that we've tested Zoom since March, some of us, and Zoom is working well and really, we've got a face-to-face meeting. I think when we get back to a sense of normalcy, would OLAW or the USDA frown upon the use of Zoom for regular meetings? So, what would your opinions be once we get back into some sense of normalcy or back to where we were.

Yeager: For USDA, we want to promote the most effective communication means with the IACUC. So the IACUC thinks that a digital format is best, or in-person, then we're going to be pro either way.

Gopee: I agree. Bill, when our telecommunications guidelines came out in 2006, I mean, it's come a long way since 2006 to 2020. There's a lot more immediacy. It's a lot more face-to-face communication than we had predicted back then. So, I don't think there's anything that would preclude the use of these telecommunications, as long as it's in accordance with our guidance and it meets the criteria outlined in our guidance, I think it would be something that would be encouraged, especially in light of the fact that this pandemic is not going anywhere anytime soon. And so if folks want, they may make this a permanent part of their program. And as most participants discussed, they're actually seeing an increased participation in the IACUCs as a result of this, which is what we're encouraging. We're encouraging nonaffiliated members to attend. So if this is encouraging that, and you're getting that conversation and discussion going, why not? So I don't see there's any reason why we would discourage it.

Greer: Neera hit the main point. Back in 2006, when it came out, most of the telecommunication was a phone call and we put a phone on speaker in the middle of a table. But now that we can actually use this technology that's available, I can actually see the IACUC members much clearer than I can in a huge conference room. And we can see and hear. And I like it. So I'm glad to hear that given the current technology, that we're all in support of using this when it's practical and when it makes sense for us at our institutions. Go ahead, Cody.



Yeager: I know there's pros and cons to either way. I was wondering if any IACUCs had thought of doing in-person once every quarter, or doing Zoom meetings in between. Has anyone had that experience, and how's that been?

Greer: One participant mentioned a hybrid.

Participant: What I was thinking was more in terms of most of the team being in one location and having a conferencing setup in the room where we could have people who weren't able to make it to the physical location for parking or weather. So we are actually meeting in a building that is not currently directly connected with walkways to any other building, and we are having more and more flooding events. And so potentially this would be a way where the people that are in the main building could set things up and the rest of us could participate through the Zoom interface.

Participant: As far as just having in-person meetings quarterly, what I see as the drawbacks of the telemeetings in the first place, the auxiliary people - and I hadn't really given it a whole lot of thought, but maybe because of the lunch thing, maybe that was the only reason they were making the time and putting it on their calendars and telling everybody else they were off limits, was because we fed them lunch, too. But we're seeing a lot less participation from them. We are not heavily utilizing the chat function, so we're having real-time discussion that mimics more what we would have in in-person meetings. But one thing I have definitely noticed is it's a little easier for somebody to get sort of lost in the background. I'll hear somebody, and the chair will call out whichever voice he heard the loudest, and there's not anybody saying, yeah, but I have a question, I have a comment, the same way that they would in face-to-face meetings.

Greer: Those challenges exist. There are some chats popping in. One of the things that a participant said a minute ago, I want to echo. Because if you're at an institution where you have remote locations that are miles away, this is an opportunity for you to get people at those sites involved in your IACUC and involved in those conversations. Too many times we hear - they make all the rules at central campus and throw them to us to follow, miles away, we don't get to weigh in. That's an important opportunity.

There are many other comments popping in. We've got one participant saying we have held hybrid meetings for years using WebEx.

So it sounds like we've used some of this at some of our institutions, based on our needs. But now that we're all forced into it, it truly is an assessment of how this is going to work, and how it's been working at our institutions. Is there anything else you want to touch on for telecommunication before I move to the next questions?

Stokes: I wanted to ask the group what their experience has been in terms of the depth and extent of discussions and comments on protocols in particular, as well as perhaps semiannual program reviews and inspection reports. I think sometimes when we're doing this by video, particularly if it's some video and some in-person - one of the participants brought up that you

need to make sure that you ensure that the folks on video get a chance to say what they want and remember to check in with them. So I think the chairs need to be aware of that. But I just wondered what people's experience was with the level of discussion, and whether you had to have the chair work to make sure that the discussions are as vigorous as they would be in person.

Babcock: In one area, Bill, we've seen full committee reviews are not the same on Zoom, at our institution. Our people - I won't say they go after each other, but they really go through a protocol in full committee. And on Zoom, not so much. The presenters - we always have two people present the protocols. Whatever they say sort of goes.

Silk: A participant says the quiet people are still quiet, and the talkative people are still talkative. [Laughter]

Participant: That's pretty much what we've noticed.

Participant: But in person, you can see the body language and the facial expressions of the more quiet folks shaking their head no or half-raising their hand and you call on them. It's difficult to see in Zoom.

Silk: You can see it if you turn your video camera on.

Participant: Do you want to see my son without his shirt on at his computer? [laughter]

Greer: Some of the things we've seen on Zoom since March - cats cross the screen and all kinds of things, so it's hard to say. [Laughter]

Participant: It's when they walk on your keyboard and disconnect you.

Silk: Here's another interesting comment. Someone says they're thinking of doing a hybrid with in-person meetings for policy discussions, and they're going to vary it by the topics of the meetings.

Participant: That's what we're thinking about, when the meetings are more talking about updating policies, or doing more serious discussions. Definitely for the semiannual program reviews we'll meet in-person so we get more of a discussion going. We meet every two weeks to go through protocols, because we get so many. We haven't started this yet, but we're thinking of having in-person meetings when doing policy discussions and stuff like that. So it's something we're thinking about when we come back.

Slide 12

Greer: Many of these topics interlink. Let me move to the next question. And I'm sure we'll still be talking about remote use of processes. Are there alternate ways to conduct the required semiannual program reviews? How are you guys doing your program reviews right now as

compared to how you've done them in the past? Anybody want to describe their process at their own institutions?

A couple of points. Cody said USDA is not requiring the program review if the restrictions are causing problems. That if you take a look at OLAW's FAQs, OLAW still wants you to do a program review using some remote methods. So, those two points are on the table that we need to consider. But having said that, those of you that have done some of these program reviews remotely, how have you done it? How effective was it compared to your last version? Let's share with our colleagues what's been effective.

Participant: We did ours recently. Because we've always done hybrid remote for community members that couldn't come in or people who were in a clinical area and only had so much time, and we did it by WebEx, we did it by Zoom, and it really wasn't much different than when we did it in person. People who had questions raised their hands, spoke out, asked for clarification.

Where we had to get a little creative was collecting signatures. So we did that using DocuSign, where we basically sent it out and made sure members who had attended received it and asked them to return it as quickly as possible so we could send it to the next member who had attended to sign off. So we had a little technical glitch with the DocuSign, but we figured it out, and otherwise it went off without a hitch.

Yeager: For USDA, an email confirmation will serve as a signature.

Participant: I don't know if we were aware of it at the time, so we decided to figure out how to get the official electronic e-signatures. And we have all the emails to all the participants and their signatures. So we have plenty of documentation that people signed off on it.

Babcock: Neera, will OLAW accept email?

Gopee: We will. We have an FAQ that says an email acknowledgment is acceptable.

Participant: We looked into the DocuSign before. I emailed OLAW and said, 'Can we just have people email as long as it's clear who it came from and that they are specific in what they are approving or agreeing to?'

The DocuSign issue was that there's a distinct separate cost to it. And unless you have an institutional license, or you have some sort of internal policies that require signatures on a lot of different things, for my group, we're talking about needing that functionality twice a year. We couldn't justify the cost of it, so we went with the email option. I would like to see some sort of better solution. I know somebody was suggesting the Acrobat digital signatures. But we have our community members who don't have access to the same centralized resources in the same way that we do. And when people are using noninstitutional computers - that stuff just gets very complicated. So, we were very thankful for the email option. So, thank you, Neera.

### Slide 13

Greer: I'm going to jump to the next point. A participant inquired about the impact PPE had. I believe the next slide is on inspections. And that particular question did come up with inspections. If you've got people that want to participate in the inspections, as we can't stop anyone from participating, what do we do if we don't have the PPE? So, here's the inspection slide. A few questions. We have waivers from OLAW to temporarily suspend. Remember, if you want to suspend your inspection, you need to have a communication with OLAW. There were questions about:

- How we start up again?
- How do we conduct the inspections while adhering to the pandemic restrictions?
- PPE and the inability to provide PPE to all the IACUC member, so all of them couldn't physically be in a room inspecting all the animals, if they wanted to. That was a potential concern that this particular individual wanted to bring up.

This rolls right into number 3. Everybody wants to participate, and how do we do that when we have restrictions? So let me stop sharing. Let's chat about the facility inspections and things associated with that.

Participant: I have a question. We did our facility inspection right when COVID came. Our animal facility is in a hospital, so PPE was a huge issue. We actually limited research due to it until we got some local places that actually make it for us. But is there a way - we always have a vet, and a number of people. We asked for volunteers. We told them there's limited PPE. Sometimes people feel forced to do the inspections, if they didn't do them last time. So we have like a rotation - it's not official, but it just seems like people rotate, but there's always vets, our animal facilities people that go through.

We use some human areas for our animals. So we do the inspection at 6:00 a.m. when nobody is in the building, basically, for the human areas. And, again, it was limited. No one really complained that they were missing out on anything. And in the future, it won't be a problem with the PPE, I hope. However, I know one time many years ago I remember someone saying they videotaped areas, like if it was a biosafety issue and only one person went in. Is that acceptable? And I'm trying to remember everything I learned a long time ago, and I can't. [Chuckling]

### Slide 14

Greer: I'll add a couple of thoughts, and this is probably a question for Cody and Neera. I know that videoconferencing is being used across our community. I've seen everything from Skype to FaceTime, to all different ways of getting people engaged. So maybe if you've only got PPE to send two people into an animal room, they can have an opportunity, through FaceTime, to let others participate electronically. I know that we've talked about the electronic processes in the past, and I'll let Neera and Cody expand. I know the idea is to do it live if there's questions.

Yeager: It needs to be a live feed. So that inspection process needs to have someone that is there and able to investigate, ask questions in real time, okay? So it can't be a prerecorded video that's sent up. So we need to have at least one person either filming the process or is there an ad hoc consultant.

Gopee: OLAW will accept a prerecorded. That's one caveat there. So, let's just say you have, you know, all your IACUC members want to see that area for some reason, but for safety and logistic reasons, it's not possible. You can have one person assigned to go in there. You can live stream if you like, but they can record the entire area and see what's been identified, and then take that recording back to your IACUC for them to view. They can confirm whether deficiencies are identified or not. So for OLAW's perspective, it does not have to be live stream.

Babcock: If you think the people from your facility are qualified, they can be appointed as ad hocs and report back to the IACUC.

Participant: That's what we do with the smaller team. We don't limit anyone from going; you're not allowed. This time we said there's no limit, but please be aware of PPE. So please let us know if you're coming for sure so that we can prepare. Most of our inspections are via smaller committees. I was just wondering how you would do it virtually. And I remember Bill talking about it. And I thought it always had to be live streamed, so it's good to know about OLAW. A mouse room might be able to be recorded, the regulated rooms could be different.

Greer: Does the person that records it have to be an IACUC member or appointed by the IACUC?

Gopee: No. That's the beauty of the flexibility we have inherent in the PHS Policy. As long as it's a qualified individual, that person does not have to be an IACUC member. They can have existing access to the building, as long as they are considered qualified. In my definition, qualified would be a person who has some experience or training or knowledge of what an inspection entails being able to identify deficiencies, significant versus minor deficiencies, and all the elements that comes with an inspection. So that's what you want, someone who's able to identify anything on an inspection. And that's another thing, participant. You don't even need a recording, as long as you have one qualified individual, one ad hoc, that is all that is required on OLAW's side. So a recording is not necessary at all unless someone wants to see it and for some reason, they're unable to do it. But you can't exclude them from the inspection. So that's a way of incorporating some flexibility and having that person be involved in that inspection.

Greer: Good points.

Participant: A question for Cody, a clarification on two voting members for USDA covered areas. As long as there are two voting members participating in an inspection event, they do not both need to put eyes on a specific space. They can go to different areas. Or do they have to go with each other and both physically see the space at some time?

Yeager: Great question, participant. No. As long as two IACUC voting members are involved, they don't have to be there together. They can be in an office building looking at a live video of it. They don't have to overlap. They don't have to both look at Room A. No. We can have an individual IACUC member look at room A and then the other look at room B. They don't have to crisscross. And then, as long as you have two IACUC members involved, you can have ad hoc consultants inspect remote sites and then report back.

Participant: That's good to know. We've never used an ad hoc consultant for a USDA-covered space. We only use them for nonUSDA covered areas because we were under the impression two IACUC members always had to go to those spaces together. I was introducing administrative burden for ourselves. Thank you for that clarification.

Yeager: The only time that that an ad hoc consultant couldn't just do the inspection themselves, is if that's the only location. Because the members have to be involved. And if that's the only location, then the IACUC members have to be involved. But if they're involved in a different part of the inspection that ad hoc person can report out.

Participant: Excellent. Thank you.

Participant: In case people are still working on getting their inspections up and running, just remember that your institution may have social distancing policies. For example, at my institution, we had to apply for permission to actually be able to go in because of social distancing. They wanted to limit how many people were in certain locations at certain times on certain days. We started the process in August and I just got permission, this week, to be allowed access to certain locations just on Tuesdays and Fridays. So, keep in mind that you may say, we have inspectors and we can get up and running, but make sure you check with your institution so that they can actually walk in the building and not be denied access.

Babcock: I recommend that you also make sure your state or county doesn't have different guidelines, because ours put in some that were a little tighter than our institution, but we had to follow their guidelines.

Silk: I hope you are registered for our October 6th session on integrating other rules into your existing policies and programs.

Neera, you have a question from a participant. She says, "If an institution is subject to Sunshine Laws, even if you delete the recording, are there remaining risks of FOIA?"

Gopee: I'm not quite sure what you mean by remaining risk. If you delete that recording, the only remaining record would be a semiannual documenting those findings. So that's dependent on your state and your FOIA laws, your open records laws. It might be FOIA-able. But I think it would be regardless of whether you have it recorded or not, it would just be a documented semiannual report. I'm not sure if I'm answering the question.

Silk: She was talking about a recording of an IACUC meeting. I'm going to chime in a little bit and help Neera to say that as a national agency, the people of OLAW are not familiar with individual Sunshine Laws in individual states. But NABR has that posted on their website, so you can find out what your own laws are.

How do you feel about this, Neera? When we talk about FOIA at OLAW, we talk about the federal FOIA. And the only people subject to the federal FOIA are feds. So somebody can't invoke that against anybody else but feds. But I want to support Neera and say, what else is there? If it's deleted, it's gone. You can't make it come back. So if they can request anything under your state laws, they can request whatever you have, right? Your records, your written meeting reports, whatever they normally would request.

Greer: I can add a little bit to that, Susan. Participant, Michigan has comprehensive Sunshine Laws. They're crazy. I think the one point, if you have a policy that says you're going to record, and then use the recording, and once the minutes are approved you delete the recording, what you deleted - you don't have it, for one thing. So they can't access it. But having said that, if you've got a couple that are in the queue, they're not deleted yet and you get a FOIA, you're not allowed to delete them. And that's the problem with deleting. Once you get a FOIA request under Michigan Sunshine Laws, even if you've got a practice to delete them, if you haven't done it at that point, you can't delete them after the request comes in. They are then eligible - fair game for the requester. So it really is important to be diligent. And if you've got a practice to record them, once you do your minutes, get rid of it, because as soon as you get that request and it's timestamped, from that point forward, whatever you've got is accessible.

Babcock: I would suggest you contact the university lawyer, because they'll know the specifics. The key, as with so many other things, is how your policies are written. You have to be very clear in your policies that you're getting rid of stuff at a certain point and then make sure you do it. [Chuckling] Like, set a calendar reminder to make sure.

Participant: When I first took over my office, we had documents going back 30 years, because my predecessors apparently didn't believe in getting rid of anything, ever. And so while that was fascinating to have a historical perspective on why certain PIs were being treated differently than all the other PIs on campus, it's not really stuff that I would have cared to share. So the first thing I did was revamp all of our retention records and I get rid of stuff as soon as possible. So. A policy.

Babcock: We had the same problem when I took over, and our state requires five-year retention. But the federal guidelines don't, so we've applied to the state to get an exemption so that we can get rid of our records regarding animals in three years, because you're right. You don't want them out there too long.

Yeager: There's a question for me from Ashley that I wanted to address.

Silk: I want to say, listen up. This is the third time. Cody is saying something that you really will want to hear. So, everybody pay attention. News flash. The question was, "Could Cody please repeat the statement about ad hoc consultants?"

Yager: Is it that an ad hoc consultant can go into room C and report back while the IACUC members are seeing room A and B? And so let's go through a little thought process here. Are two members of IACUC involved? Yes, in A and B. You can use ad hoc consultant in room C. They can report back. So you're good to go. Any other questions about that?

Silk: I've heard USDA say that you can have an ad hoc running the video camera and you can have two IACUC members watching the video and commenting on it.

Yeager: Absolutely.

Silk: Only one person has to be there. The other person -- the other member could participate via video. You said that, right?

Yeager: Yes.

Silk: It's too good to be true and they're afraid to believe it.

Yager: Talking to inspectors, it's a historical thing you had two IACUC members hand -in-hand, go through the rooms together. And hey, that's great if the IACUC wants to do that, thumbs-up. But you guys are putting more burden on yourselves than what the regulations say.

Greer: That takes it to a new level for most of us, because we've always thought you had to have two IACUC members. And those two members had to do the inspection. Not in the same place, but maybe in the same area. But this is the first time I ever heard the USDA say if I have five on my team and only two are IACUC members, the other three can go to other rooms, as long as they're qualified, and do inspections. As long as they're able to report back to the two IACUC members that are present, conducting the inspection. So that's even more flexibility. That's good to hear.

Yeager: This is permanent, not just because of COVID-19. It should have always been this way, and it always will, this regulation will not change. Understand that? Symbiosis is not required, right?

Participant: This is me again. One more clarification on this.

Yager: Sure.

Participant: We have a waiver. We are getting ready to start back with our site inspections. And I want to make sure our plan currently is to have the office staff, our typical office staff that goes with our site inspectors to the locations, go to these locations and do a live video feed



back to any and all IACUC members that want to be present. So I just want to verify that we don't have to have an IACUC member with us in the facility, that it's fine that they are back on wherever, in their office at home, watching the live feed.

Yeager: Absolutely, participant. You have two IACUC members involved, right? It sounds like it's going to the whole IACUC. But you have at least two. And so you can use ad hocs to do any other parts of the inspection. The IACUC members do not have to physically be there. They can be on the receiving end of the live video.

Participant: Okay.

Silk: Bill, can you address a participant's question about DoD in the chat? I don't think we planned to talk about DOD regulations today? We keep inviting DOD to join the ICARE faculty, but so far they do not have anybody available to join us, and so we can't speak to their issues right now. Bill, do you know anything about that?

Greer: I don't. Give me one minute here and Bill, you can weigh in. I know I saw a statement come out from DoD. I don't know, maybe within the year, where they made comments that they were going to follow the same practices as it related to annual reviews as USDA. But I've had so many issues with clarifications from DoD. I've called DoD and gotten mixed information from different people that I've talked to. So I don't know. I can't tell you that DoD is going to give the same flexibility that Cody just described. Bill, do you know? I'm sure Cody, I don't know if you've got colleagues there that have had conversations. No?

Stokes: I don't know the answer to that but having served in the Army as a live animal veterinarian, the regulations are strict and straightforward, particularly for all the Army labs, but I'm fairly certain those regulations now extend to contracted facilities. And so I would definitely contact the office. There's a lab animal veterinarian at Army Research and Development Command that oversees all that and I would have a conversation with them before you stray from the traditional interpretation, just to make sure.

Greer: I would agree. We have a few DoD-funded projects at the University of Michigan, and we're diligent to make sure that we do what we need to do there as far as make sure there's two people involved and available and we're doing inspections, do the annual reviews the same way we could do for USDA. I don't know. It depends on how many you've got. Sometimes if the number is few, just pay additional attention to it to get them out of the way and not worry about it. It's up to you and your institution. That's a tough one.

Silk: Cory, maybe we should have a whole webinar on what two members means. A participant wants to know, if "involvement" of the IACUC members could include a report back without those IACUC members having eyes on the rooms?

Yeager: Great question. Usually, yes. USDA is not going to define involvement. We're going to let the IACUC pretty much define that. The only exception to that - it was kind of what I said

before. If you have just one area for your whole facility that you're inspecting that you're going to use an ad hoc consultant, the IACUC - those two IACUCs' involvement has to look at that room, that building, because I don't see how the IACUC members could not be involved without looking at that one building, if that's all you have. Does that make sense?

Participant: Yes. I laughed when you said we're not going to define involvement, because that's what our committee wants. [Laughter]

Silk: The government never defines reasonable, either. [Laughter] A participant says everyone is afraid because we are dealing with processes in a manner we have never done before due to circumstances beyond our control.

We understand that. And that's why we're here to try to help resolve some of these things that are so worrisome for you.

Yeager: Don't be afraid. Pick up the phone. Call me, call Neera if it's an OLAW question, call your inspector, call the office, don't be afraid. We're here for you.

Greer: The next four slides are on inspections. One of the questions was related to whether or not people are actually using ad hocs, if so, how you identify them? So has anyone actually done it, and how did it work for you, and how did you report back to your committee? We've got about 20 minutes left, so we've got a slide on -- the next three are inspections. We've got one on how to use veterinarians to modify protocols. And then that brings us pretty much to the end of the questions that we have documented. So if you have other questions, we can save some time for that, too, or try to. Anyway, let's get back to inspections. Who's tried to use consultants, how has it worked? Just give our colleagues an idea.

Participant: The IACUC just approved a policy prior to COVID that allows ad hoc consultants to conduct inspections of non-USDA-covered species areas but all laboratory spaces where USDA-covered species are used, we still have required two voting members to go to those laboratory spaces. It has saved time. The team members provide a report back to the committee, communicate findings. They get a draft report, then they get a final report. So I think that it's really improved some efficiencies and lightened the workload of committee members to be focusing more on technical issues and reviewing the final report. Use of ad hoc consultants for USDA-covered species in the facility we have not rolled out yet.

So I'm excited to hear about those opportunities, because I think using them for facility inspection will definitely help with -- especially during COVID -- navigate getting teams and getting the inspection accomplished.

Greer: Could you tell us how you identified your consultants, who they are, what's their background? At your institution, who would qualify to be an ad hoc and do the inspections for you?

Participant: We have team members with laboratory animal or training backgrounds. And a vet tech. We bring them forth to the committee, report what their training is, and then the committee approves the ad hoc consultant at a convened meeting. That's the process we do. The committee approved the modified or truncated version of the OLAW checklist that the ad hoc consultants use to conduct the visit. They have an SOP, a whole process they follow that the committee put their blessing on so that they could perform inspections.

Gopee: Since you've changed your SOPs to reflect the use of ad hocs, is this a permanent change?

Participant: Yes. We had ad hoc consultants built in and never used them. I wrote to the OLAW and asked about it, and they said we don't have to update it because we built in that wiggle room in the Assurance.

Gopee: It was described in your Assurance. Okay.

Participant: I was going to describe our attempt. [Laughter] I wasn't there at the IACUC meeting when this was discussed, but I heard about it. We had proposed to the IACUC to have our quality assurance associates in the office through the animal care and use office to perform the inspections of even just the euthanasia-only rooms of lab rooms where all they did was euthanize and say that the QAs would take on that part of the inspection, and the committee said, "No thank you." [Laughter]

Greer: That is perfect for me to use. That is an opportunity to go back to that footnote [PHS Policy footnote 8] and remind us that it has to be under the jurisdiction of your committee. So your IACUC needs to decide. In the case that the participant just described, the IACUC wanted to have the opportunity to talk to PIs and didn't want to lose that face-to-face contact. So this was an opportunity where they could have used PAM people to do - a CO<sub>2</sub> tank in a euthanasia chamber and make sure it's clean and the regulator is set correctly and they're doing it correctly. But rather than deferring that off to the PAM, the IACUC wanted to do it themselves so they could shake hands in a no COVID time and say how are things going and have a conversation.

So this is where it's important to remember when you're thinking about these ways to introduce some flexibility into your process, the IACUC is on board and they agree and it's not pushed in their direction. Another participant made a comment about husbandry staff. When we at University of Michigan got in a pinch and we were not allowed to have our people in the building, the fact is, the husbandry staff were there because they had to take care of animals. So we helped them with a checklist and said here's the things you really need to be aware of.

They're not ignorant to the fact of inspections because they're there when they do them all the time, but on the other side of the fence. They know what kind of questions are asked and what to look for. We coached them a bit and helped them help us to get some of these inspections

done. How did it work for you, participant? What did you do with your husbandry team and your caretakers?

Participant: Our research facility is part of our clinical and research center. It's a cancer hospital. We did have and we still have very stringent restrictions. For example, you may only have access to one building, or only one part of the building. And they built walls between the hospital and the research area. So we were really limited on where people could go and what they could do. In the vivariums, we have the veterinarians, and then we used our supervisors as ad hocs to conduct the inspections in the vivariums, and then for the laboratories we used our research investigator members that had access to those buildings to go do the lab inspections.

So I think it worked really well. I think we provided some guidance on what to look for, but I think as you said, they're very familiar with what to look for. And the thing that I really appreciated is we have two facilities that are about 120 miles away and we would have to drive up there and spend an entire day going back and forth. And this time we just had the local people do it. And they're members of those facilities, so I appreciated not having to spend two days driving back and forth to do inspections. And I'm hoping we're going to be able to do that from now on.

I wanted to ask - I had a question. Someone talked about having their committee approve the ad hocs, which is great, but is there a requirement to do that? Because our leadership group - I had to talk them into the fact that that's okay to do that. But does the committee have to actually approve of that? Or only if they're changing their permanent policy?

Yeager: It says in 2.31C3 the IACUC invites these ad hocs to help with the inspection. So, to me that's - if the IACUC is inviting, that's an IACUC decision.

Gopee: The PHS Policy says the IACUC at its discretion may use it. It's up to you how you would like to approach the selection of ad hocs.

Participant: The committee must officially approve persons A, B, and C?

Greer: I don't know about the individual. That's how the participant does it at her institution. When we did it at my institution, asked about the PAMs doing the inspection, we said the entire PAM team, given their experience. And we brought it to the IACUC as a suggestion. And the point there is the committee had a chance to weigh in. We just didn't send the PAMs and have them do inspections and then say here, we did the inspections for you. It is all about making sure you've got a way to engage, whether it's by invitation or at their discretion, as long as they've had an opportunity - this is my opinion, and Neera and Cody, you can correct me if I'm wrong.

Yager: As long as the IACUC has had an opportunity to weigh in on it and it's not just something sprung on them.

Gopee: It would be important to have the IACUC be informed of the decision. And if anyone objects, they have to take that into consideration. You know. But if there's no objection, then the IACUC has given their blessings.

Participant: We had to get special permission for people - because they were also on shift work. Research personnel were only allowed to come in at a certain time of day. And they were supposed to go straight to their lab, do as little as possible and leave immediately. So we had to get permission just for our investigator members to go to other people's labs in their area. So it was still pretty restrictive. But I see what you're saying. And we should have gone to the committee ahead of time. I think they just accepted it.

Babcock: When I said we were going to use ad hocs, they went, whoopee.

Participant: Do the individuals need to be named every time, or can there just be a blanket approval for use of ad hocs?

Greer: That's part of flexibility. As long as the IACUC is engaged, you could have a list of ad hocs that you're going to grab from, or a list of units that are qualified for inspection by ad hocs. It really is up to you and up to your institution. As I said and as we've discussed, it's important for the IACUC to be engaged, but once the committee has participated in that decision and decided how to document who those ad hocs are, then you've got the resources and the availability to do the things you need to do.

Participant: I wanted to comment on why the committee voted. We had a restrictive policy. We had to make changes to the policy. The committee then voted to accept the changes and to accept the ad hoc consultants we put forth.

Greer: George, do you want to take a minute to talk about how it works at the University of Cincinnati? The next question that came up was whether or not the attending veterinarian has the flexibility to make changes to pain management that's already documented in a protocol. And I think before we talk about VVC [veterinary verification and consultation], really quick we should let Neera just make some points about VVC, and then we can talk about how we use it, because we're making some assumption that folks know the details.

Gopee: I would like to trust that VVC would be an excellent way of implementing flexibility. However, it's really important that it's implemented correctly. And when IACUCs decide to implement VVC or employ VVC, IACUCs are required to ensure that they have a documented policy which describes the VVC process. It's important you have that IACUC-approved VVC policy which describes the type of changes eligible for VVC. The IACUC must also have approved reference documents such as policies, SOPs, formularies, euthanasia guidelines can be a reference document for euthanasia. And it has to be acceptable for use for that change that's eligible by VVC for the veterinarian to use. And then you must also have a designated veterinarian or veterinarians who are authorized to verify that the requested changes are in accordance with your approved policy. Once you've got all of that in place, there must also be a

way to document that these changes have been verified for the particular or specific protocol in question. So it's a couple of steps. It's not straightforward. But once you have those steps in place, you have a VVC policy ready to go. And you can use it as one of your flexibilities for protocol for significant changes.

Babcock: Neera covered it. We use it during this time for anesthesia, drugs, etc. It's in the policy.

Gopee: In this case, it has to be within the same class of compounds and it has to be specific for the species. Your reference documents should be specific for the species, the class of analgesics or anesthetics, whether it's inhalation anesthetics or injectable anesthetics, so it should be within the same class of compounds and used for the same species so that when the designated veterinarian is able to verify the changes, it's easy for them to cross-reference those changes.

I also think it's important to consider that the attending veterinarian, when they're working with the principal investigator on pain relief that's going to be needed for the protocol, if there's some uncertainty about what the extent of that pain, this is not a routine procedure they've got good experience with. The AV should recommend putting some flexibility into the protocol about range of doses, perhaps even range of agents, because they may not have experience in whether the specified agent that he or she thinks will work for relief of postoperative pain, for example, might work. So they may want to include some flexibility there so that there's not issues, particularly if you don't have the VVC in place. I would recommend flexibility in all your protocols. We put in as much as we can within the guidelines.

Babcock: Definitely, such as drug doses.

Greer: That could be a discussion in its own. We could talk about how to build a protocol with the right flexibility that allows the IACUC to conduct its assessment of the animal activities, but yet gives the PI some flexibility to do the research within acceptable parameters. So Bill and George make great points there. If you can think about how you can build protocols with flexibility, that's an advantage all the way around for your IACUC and your PIs.

Just a real quick comment about VVC, this is the process that allows you to make a significant change to a protocol. If your vet is walking through a facility and the PIs are using isoflurane in mouse studies and they want to use Ketamine + Xylazine, if you have the policies and you've done everything Neera described, the veterinarian can allow them to do that on the spot and start using Ketamine + Xylazine. Then you just need to have an administrative process to formally get it into the protocol. So there is a lot of flexibility to be had with VVC. You can expand it to whatever level of comfort you have at your institution. But you do have to understand how it works and make sure that you look at the parameters that are described through OLAW, references and resources.

Silk: We're coming to the end. Do you want to say a real quick wrap-up, Bill Greer?

Greer: Team, anything you guys want to say? It was a great opportunity. Good discussion. George, Bill, Cody, Neera, what do you guys think?

Team: I'd like to compliment everybody on the level of discussion. It's one of the best we've had. I agree. It was good to hear from everybody and the questions, so please keep them coming. Good discussion.

Greer: One quick comment, Susan. If there are questions we didn't get to, I apologize. If you want to reach out to us independently, send them to Susan, to Erin, let us know if you have other things we didn't touch on. We're happy to reach out to you individually.

Silk: Thank you. It's generous of you. Thanks, everybody.