

ICARE



Interagency Collaborative Animal Research Education

August 4, 2020

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

Presenters: Bill Greer, George Babcock, Wayne Barbee, Neera Gopee, Bill Stokes, and Cody Yeager, 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: I would like to introduce Bill Greer and his team for our topic today, **Using Flexibility Provided in the PHS Policy and the Animal Welfare Act and Regulations**. Thanks, Bill.

Greer: Good afternoon, friends and colleagues, and welcome. Just going to do quick introductions, we are going to move through a few quick slides so we leave some time for conversation. I'm going to go around the team. I'm going to start, my name is Bill Greer. I'm Assistant Vice President for Research at the University of Michigan. I've been running IACUC Administrators Association (IAA) (<https://iacucaa.org/>) Best Practice (BP) meetings. I was one of the original ICARE faculty; I've been doing these types of things for quite a long time. So I will just give my friends and colleagues a chance. George, you want to start? We'll go down the list.

Babcock: I'm George Babcock from the University of Cincinnati. I'm the chair of the IACUC.

Barbee: I'm Wayne Barbee, professor of physiology and former IACUC chair at VCU. I've been doing research for decades on a number of species and in addition to serving on the committee to update the *Guide*, I've been involved in leadership and training of IACUC for about two decades.

Stokes: Hi, good afternoon, I'm Bill Stokes. I currently work as an independent consultant in animal research and welfare. I have over 40 years of experience in biomedical research including working as an attending veterinarian at army research facilities and two of the NIH Institutes. At NIH, I also served as a Center director, overseeing the international validation and global acceptance of safety testing methods that incorporate the three Rs, and most recently served as an assistant director for animal welfare operations at USDA. I look forward to our conversations today.

Gopee: I'm Neera Gopee, and I'm the Director of Policy and Education in the Office of Laboratory Animal Welfare, OLAW, at the National Institutes of Health.

Yager: I'm Cody Yager. I'm a supervisor with USDA, APHIS, Animal Care. I supervise 7 inspectors and our team covers most of Texas, Louisiana, Mississippi, a little bit of Georgia, and Alabama.

Greer: Perfect. Thank you all. So, we're going to start off with just a brief presentation from Neera and Cody to give you guys an idea of the resources and FAQs that are already out there regarding flexibility. There's a handout ([ICARE Dialogue: Optimizing Animal Welfare During the Pandemic Resources and References July 22, 2020](#)) that you've seen that Bill Stokes and his team put together, so we appreciate that. Let me turn it over to Neera first, and she will work through her slides.

Gopee: All righty. Thank you, Bill. So OLAW is deeply concerned about impact of COVID-19 on the ability of institutions to ensure the well-being of personnel and animals while maintaining compliance with the PHS Policy, the Guide, and their animal welfare Assurance. Therefore, in response to these concerns and pandemic, OLAW released numerous resources which can be found in one page and it's designed to help institutions during these unprecedented times. I encourage you, for those who are not familiar with our website (<https://olaw.nih.gov/home.htm>) to please visit OLAW's pandemic contingency planning web page, landing page, which can be accessed by clicking on the red banner on our home page, and you can find all of the valuable resources that's available there.

This is what that COVID-19 landing page looks like (<https://olaw.nih.gov/covid-19.htm>). It's a dedicated page that addresses all of the concerns that institutions may have. It's updated as needed when new guidance is developed, we update this web page, and the little sticky tabs that inform you when there are new FAQs or new updates that's available on this web page. On this landing page, you will find there are 20 OLAW specific COVID FAQs including how to conduct business, semiannual facility inspections, and program reviews while maintaining social distancing. We also have listed on this landing page, Guide Notices, webinars, articles and useful links. The FAQs are also available on the NIH Grants and Funding page (<https://www.nih.gov/grants-funding>) for those who may be interested. Although this web page has a lot of resources that is available, it's not at all exhaustive, so please do not hesitate to contact OLAW staff should you have any questions or concerns, and we are more than happy to provide much needed advice and guidance.

We can be contacted through e-mail (olaw@od.nih), phone (301-496-7163), you can visit our website (<https://olaw.nih.gov/>) and there's contact information for each OLAW staff there. You can subscribe to our listserv and you can follow us on Twitter, and with that, I'll hand it over to Cody from USDA.

Yager: Perfect, thanks, Neera. Hey, everyone, we know ensuring the health and safety of your staff and animals needs to be your number one priority, so we're allowing facilities to delay some of their administrative regulatory requirements now. Currently we're not placing a

specific date on recommencing semi annuals, facility inspections, and annual reviews because we really don't know how long COVID-19 is going to impact facility operations. We just ask that you document the delay. When you do restart your semi annuals, just remember two IACUC members have to be involved, but we really do leave that up to the facility to determine the specific process. And you can also use ad hoc consultants in conjunction with the IACUC members, and furthermore, the IACUC members who are conducting the inspection do not have to inspect in the same area. They can each inspect different areas individually. You can also use live stream video or the most recent ALAC site visit if it meets the requirements listed in our Inspection Guide 7.1.2. IACUC meetings can be done virtually as well, please refer to our Inspection Guide under 7.1.8, and lastly, e-mails from IACUC members acknowledging an approval of semi annuals do serve in lieu of a wet signature.

If the delay extends beyond the time of the required - not less than annual protocol review, that should be documented and then that annual review should be conducted when the activity restarts. How those animals would be reported in the facilities' annual report would depend on the circumstances, but we will be sending out the annual packets soon with guidance in them. And they can also be sent in electronically this year. As most of you know, we've been limiting our inspections based on our assessment of the risk to the inspectors and to your facilities personnel.

In the event that we do conduct an inspection, we understand that you may have exposure concerns or be dealing with very limited staff. Our inspectors will work with you to address those specific concerns, or we can use videos or photos or simply come back at another time. And, this will not be considered refusal of the inspection, but rather a joint effort to address this serious public health emergency while we're assuring the welfare of animals. And lastly, all the flexibilities I just discussed here do not need approval, permissions or waivers from USDA. The delay should be documented so that our VMOs, during their next inspection, can verify what took place. And again, if any facility has specific concerns, please reach out and we will work with that facility.

I know the past few months have been really hard on everyone, but please reach out to us if you have concerns and let us help you, and your facility, in this trying time. [E-mail: animalcare@usda.gov, Phone: (970) 494-7478 and Fax: (970) 494-7461] Thank you.

Stokes: Hi. I just want to briefly address the flexibility that you might choose to incorporate in your animal care programs. But we want to do that without compromising animal welfare. We're fortunate that the policies and regulations do incorporate the opportunity for flexibility and are performance-based in most cases. Again, if you want to take advantage of this flexibility, you should always continue to ensure appropriate and adequate animal care and welfare whenever you do apply the flexibility, and that needs to be considered before it's approved by the IACUC, if that's part of that flexibility process.

We're going to focus more on animal welfare considerations in the second hour, where the topic is **Optimizing Animal Welfare During the Pandemic Crisis**. I think that everything we do

focuses on that. This session will talk about how we can figure out how to apply flexibility to best serve your needs during this time.

Greer: Okay, thank you, Bill. We looked through the questions and the ideas that everyone sent us, and we're going to try to focus on engaging the IACUC and we're going to include semiannual inspections, we're going to include ways that inspections can be done. We're happy to chat about other things if you would like, we'll follow your lead. Let's start with this. What I'm going to do is look over to George and ask George to talk a little bit about semiannual inspections at his institution, the times or ways that he's doing them or considered doing them, we'll give Neera or Cody an opportunity to weigh in from a regulatory standpoint and obviously Susan will be watching for questions, and we'll just go down that path for now and see where it leads us and obviously take time for more questions. Now, what we want to do is engage everyone. George, how about I kick it over to you, and you talk a little bit about the University of Cincinnati med school and how you do your inspections, things you think about, things you talk about, and how we can get more into the weeds for folks.

Babcock: Okay, thanks a lot, Bill. We must take into consideration all programs are slightly different, and your institution or companies need to follow your state and local guidelines and regulations. So, I'll discuss how we're doing it. We're using a lot of flexibility that you've heard about and Neera and Cody will cover, but we're not using all of it. Some of it we are doing our normal way. Our institutions, animal facilities - never closed down, they stayed open. We prevented new animals from being ordered, but investigators could come in at one investigator per laboratory at a time and do their experiments and check their animals. Not all institutions are that way. So, that gives us some flexibility on inspections also.

What we're doing is we are limiting our inspection group to faculty who are on the IACUC and regularly going into the facility. We normally use always two inspectors, sometimes three, but we're going to limit it to one per room. So, this gives us a little more flexibility so we can use less inspectors. We're also going to be using some ad hocs, some former members of the IACUC and some people from our veterinary staff to help, because some of our people are not on site right now, so it's a burden for them to come in. We're going to use a little bit of video and maybe some other things. So we're doing inspections the normal way for the animal facilities per se, only using one inspector, okay?

Now, a satellite facility is where we run into problems, because they're spread out all over, so in that case, what we're doing is - some of the IACUC members have volunteered to go to some of the satellite facilities, and for the others, we're going to be using either videos provided by the PIs of the satellite facility, or vet techs have volunteered, because they go to every satellite facility to provide us with videos and short written reports so that we don't have to send out a member.

We are not going to be using our unaffiliated members. They regularly do our inspections with us, but we feel that this could be a potential liability to have an outside non university employee in the facilities during the pandemic. The reports will go back to the full committee,

IACUC, and that's the way we're going to be doing our program review, virtually, with the full committee, looking over the reports, looking over the videos, and any pictures we may get, and go on from there. We always use videos for our BSL3 facility, so we're sort of used to that method. Our vet techs also help us with our PAM [Post Approval Monitoring], and we're going to be using this for some of our satellite facilities, and I think Wayne may be willing to discuss a little more detail and mention how Virginia Commonwealth University is doing. Wayne.

Barbee: Sure, thanks, George. We had a near total research shut down, and we missed one room in our semiannual March inspections but got a waiver from OLAW to finish that next month. We had some higher risk IACUC members that opted out of our fall inspection coming up, so we are also delegating smaller teams, albeit with at least two voting members in the USDA regulated areas to meet virtually with IACUC before and after the inspections and those inspections proceed with appropriate PPE, social distancing, and using a new, more complete checklist as some of our more senior members will be absent.

Some of our PAM activities have been reallocated to those at the lower risk and the nature of PAM activities shifted from traditional face-to-face meetings to more remote settings such as phone calls, Zoom meetings, file transfers, paperwork, pick up and return, that sort of thing. So, we've looked into this a lot and determined that we're appropriately using OLAW-suggested flexibility in the conduct of activities.

One thing for everyone to remember is that the IACUC remains the responsible party and therefore needs to look at the impact of their new eyes and ears and procedures and make sure they're fulfilling the responsibilities according to Animal Welfare Regulations and PHS Policy.

Greer: Okay, thanks, Wayne and George. So, a couple of things I'll throw out there for us to talk about, and welcome all of you to join in. I'll start with directing some questions to Neera and Cody, because these are some questions that you guys shared and also questions that I've gotten over the past two months from our colleagues. One of the big things right now is - all of this started in March - so there was some flexibility given to the institutions for delaying their semiannual inspections. So, we're coming around to the second round of semiannual inspections, - for those institutions that were due in March, are we going to be able to continue to extend this another period, for example? I know, Cody, you said from a USDA perspective, just mark the delay, and include in the records. Neera, Cody, any comments or any thoughts about that topic?

Yager: Yes, Bill, you're exactly right. We have not set another deadline, even if you're coming up to that six months from March, still just document it. When you do start doing the semiannuals, it will then be due for six months from that date. But there's still flexibility. We have not set any deadline or cutoff.

Gopee: And the same holds true for OLAW. We recommend that institutions -- we encourage institutions to consider conducting their semiannual facility inspection, as soon as they can safely do so, employing the flexibilities that's available to them, but there's no time frame, and

once again, like Cody eluded to, that once they've conducted that semi, we expect them to do subsequent semi six months plus 30 days, no later than six months plus 30 days from that semiannual inspection date.

Greer: I was just going to say as long as we've got the COVID restrictions in place, we as institutions, should just continue to monitor state expectations and things like that, and then once we can get back up to a regular schedule, that kind of resets the clock, and then we're looking six months out again, so we'll get on that six month schedule once the COVID restrictions let up and we're able to get back into some sort of routine.

Gopee: And I'd like to just mention one thing that this only applies for those institutions that were granted waivers for the semi facility inspections. So if your institution has not been granted a waiver, you're expected to conduct your semis as scheduled within the six months plus 30 days time frame.

Silk: OLAW requires a waiver and USDA does not.

Gopee: Yes, we [OLAW] do.

Yager: Correct.

Silk: And Cody, in the chat, one of our participants wondered, using one member for semi annuals is allowed? And Wayne picked that right up and said not for USDA. I know that under normal circumstances, one member can't do a semi for USDA, but what about now?

Greer: If I could add to that really, quick, Cody, I want to add to that, because that way, when you answer the question, you can get all -- another question related to that I've had was - if one person is out gathering the information for the IACUC, simply because they want to keep the people out of the facilities, that detailed information is then brought back to the committee so that all members have an opportunity to see it, flexibility within the USDA expectations, especially at this time. So it combines that idea of sending out one person yet involving more than one committee member for the actual assessment of the information that was collected.

Yager: It does. These are really great questions. So, yes, you don't have to have two IACUC members in the same building inspecting the same time at the same place. They can be separate and individual. And also, because I think it was George talked about satellite facilities, you can have someone who is not an IACUC member live streaming the inspection to an IACUC member, it just says that it has to be two involved. It doesn't mean that two IACUC members have to be the ones doing the inspection in person. Okay? So there's a lot of flexibilities of using ad hoc consultants. We [USDA] only say you have to have two IACUC members be involved with the semiannual inspection, and the specifics - we leave that up to you. I would like to add because we've had these questions that these ad hoc consultants, because we've had these questions, need not be IACUC members and they need not be someone that you have to hire. We've had people inquire that, hey, we don't have money to hire a consultant. It can be

someone such as your facility manager, who already has access to your building, who is there every day, and they can provide that inspection for you, for those areas.

Silk: When you say IACUC members, Cody, you mean voting members?

Yager: Yes, I do. Yes.

Silk: Okay. Any more on the USDA flexibility and the two voting members?

Yager: I know the question has come up - can they do pre-recorded video and then send that to the IACUC. No, for USDA covered species it has to be a live stream video.

Silk: Then we have another question from our colleague at FDA. This is for you, Neera. Practices that are different from those outlined in the PHS Assurance, do we need to communicate those to OLAW, like in the annual report?

Gopee: It depends on whether it's a temporary program change or permanent program change. So if these changes that you're implementing are just going to be temporary changes, as a result of COVID-19, we do recommend you document that in your disaster plan, and you keep your IACUC apprised of these changes, but there's no requirement to have it reported in your 2020 annual report, which is due no later than December 1st this year [2020]. There's no need to update your Assurance upon renewal. However, if your IACUC has determined that, hey, this is something we'd like to have as a permanent change to our program, because it helps reduce burden, it's more efficient, then by all means, yes, you have to describe these changes in your 2020 annual report as well as when it -- when your renewal comes up for your Assurance, you include that in your Assurance renewal document.

Greer: I think that you just answered the question, Neera, but to you and Cody both, I saw something from a participant, we're trying to figure out whether or not - are these flexibilities that have always been there? And obviously, that's with the exception of delaying the inspection simply because COVID, but these options of making sure we have one person involved, or two people involved with the USDA inspections, on campus, or in buildings, but we have the flexibility of sending one down one hall, one down another, or one in the basement, one upstairs, just trying to get an idea if some of the things that we're talking about right now as it relates to these flexibilities are specific to COVID or are these opportunities that we've always had that we could employ?

Gopee: So I could say from OLAW's perspective, many of these flexibilities existed pre COVID and will continue to exist post COVID as well. These are flexibilities that have always existed, and institutions are fully able to use them as part of their ongoing animal care and use program, apart from the waivers. Waivers for the semiannual, as Bill, you mentioned, is something that is unique to disasters and pandemics.

Yager: And USDA agrees with OLAW. The only thing I would like to add on that is for those semiannuals, they don't have to be in the same room for the inspections, that flexibility has always been there.

Greer: Perfect. Any other questions from the team? Participants?

Silk: There is one more question. How is the USDA determining when it's safe to perform their site inspections?

Yager: I am in Texas, and our infection rates remain high. So that is a complicated question. But what we have in USDA is a lot of epidemiologists putting together data and maps, and they go county by county to say, okay, are the numbers increasing, are they staying the same, are they downward projected? And we match those to the Phase 1, 2, and 3 guidance that the White House has put out. And so based on the data, we will list a county. Each week we evaluate these counties throughout the whole country, and say, okay, is this an appropriate county we can start to do a little bit of work in?

Now, that's just half the story. We're working with the individual facilities. If we do show up to do an inspection, and you have concerns about us being there, then like I said in my intro, let us know, and we don't have to do the inspection then. These are crazy times right now, so we know there's going to be times that happen, or if you have concerns right now, you can call up your inspector and say, hey, I'm dealing with only 20% of my staff here. It would just be really overburdensome right now to try to be doing an inspection. Okay? So reach out. We do have a method to evaluate the risk out there.

Silk: Bill, my feeling is that if you guys are probably ready to move on to a topic, and I just want to say that I'm so impressed with all of you for thinking about how can we make the best of this and how can we find flexibilities that we can use in the future? And I think one of the tendencies we have when there's a problem is to think how can we do what we've always done and solve it? And I think you guys are taking a very brave and thoughtful step forward in saying how can we do even better? This is the biomedical animal care and use community that I have always seen and that I respect. I love your ability to think big like that.

Greer: One more thing on inspections, and then we can go down another road. I see a question about can we have one voting member inspecting with another voting member taking notes on the phone somewhere? I think what I would like to do is really get the 30,000 foot view and think about this from an inspection standpoint, so I'm going to ask Cody and Neera to correct me when I'm wrong. As long as we've got a good resource collecting information and data about the facilities and the facility inspections and the IACUC is involved and engaged, whether they're seeing reports or other things, because I've heard a lot of ways that people are doing it, it seems like acceptable methods, and you guys, you're not going to hurt my feelings if I'm wrong, but if you've got somebody taking notes, they're in there to be the eyes and ears of the IACUC and gathering information, we've got one committee member gathering information, they've got access to an IACUC chair and they're making phone calls, as long as we can do a

good thorough assessment of the facility and the committee is in charge, and they're deciding how things need to work, it seems like it's a reasonable way of doing things. Are there any limitations, Cody, or Neera, that you want to throw out there? I mean, we're all in a position where COVID restrictions are tying our hands. We're doing the things we need to do and that's anywhere from an environmental health and safety person in a post approval monitoring, making sure the right PPE is being worn to Go Pros and video cameras and everything else. So what are the limitations? And where do people need to start having concerns? You know, what crosses the line? I guess that's the question.

Yager: For USDA, really, I've already mentioned this, if you're going to use video, it has to be a live feed. You can't use a pre-recorded video, and then we just say two voting IACUC members are involved. We really don't have any more specifics than that, we leave that up to you guys. So there's that flexibility and it has always been there so, that's it.

Greer: Can I ask you, Cody, just because I know people are wondering, involved doesn't necessarily mean walking into the rooms? And I know you went through this. But if we've got one person there and another committee member is available, via phone, that's acceptable.

Yager: Yeah, they seem to be two involved voting IACUC members, I would say.

Greer: And I'm going to keep pushing the limit. You tell me where I've crossed it. If PAM [post approval monitoring] people are out gathering information and preparing reports and bringing it back to the IACUC, is USDA okay with that, as long as the committee is doing the assessment of the information that's being seen?

Yager: Does the IACUC feel like two members of their IACUC are being involved?

Greer: That is it-- exactly, that's up to the IACUC. Can the IACUC make that delegation, if those people are trained and reporting back to the committee on a regular basis and are engaged in the animal program to that degree, you know, I mean, I'm seeing some skepticism with you, so maybe you're not comfortable from a USDA perspective, and that's all we're trying to find out.

Yager: What I would recommend, when you start getting a little bit in the weeds or specifics, reach out to your inspector. Reach out to me [cody.m.yager@usda.gov] and we can kind of go into the specifics of the scenario. But my understanding is we really don't put too much limitation. If you have two IACUC members, voting IACUC members involved in the semi annual, that meets our regulatory requirements.

Greer: Okay. How about you, Neera? What are your thoughts?

Gopee: I can tell you, the Policy says that the IACUC has the discretion to determine the best means of the performance evaluation. So as long as you have one qualified individual to conduct that inspection, that would be acceptable. We have to also keep in mind that no IACUC member should be involuntarily excluded from participating in the inspections, if they choose

to. So if someone does opt to do that inspection, you to find a way to include that person, in that inspection. That's one caveat. And the second caveat is that the IACUC is ultimately responsible for the evaluation and the report to the IO, so as long as whoever performs that inspection, takes that back to the IACUC, as you mentioned, Bill, and the IACUC remains responsible for that report and report to the IO, then we'll be fine.

Also we have to think about conflicts of interest, if we have a PI that's doing an inspection, you have to make sure that PI is objective in that inspection, and maybe that's when you would like to have – do - a recording of the entire area and have the IACUC assess whether there's any deficiencies identified in such areas. So that's something you have to think about. You don't want to have that inherent conflict of interest of any particular areas and have that be in a biased inspection.

Silk: Neera, when you say a recording, that would indicate to me that it's not realtime.

Gopee: It doesn't have to be realtime from OLAW's perspective, that's correct, Susan.

Participant: Hello, everybody, thanks to all of you who are hosting. So I think I have an answer to this, but I just want to hear it. I want some validation. The inspections virtual have been unfolding very well at my university; however, my committee and I are very concerned about records review. So we've tried a whole host of things of, you know, Zooming in, Zooming out, e-mailing prior to our arrival, you know, things such as PI managed training records, DEA controlled drug records. Looking at critical forms for those who still wish to have paper copies instead of electronic copies. And I think it's going well. It adds a few extra steps. But I just wanted to hear comments about that, and then any other suggestions that maybe my group hasn't entertained yet, and thanks so much.

Greer: So let's talk about the records. Cody, you mentioned realtime for records. Are snapshots of records okay for USDA.

Yeager: Yes.

Greer: Or do you need somebody there to talk through the record and what it looks like?

Yager: The records review doesn't have to be live streamed, no, you can do that.

Greer: Okay.

Yager: If you have questions, you should be able to ask those questions.

Greer: Okay. So as long as they've got contact people, I think this gets to your point, Susan. As long as you have contact people, if there are questions, you can reach out to, then the way that you do the records review is fine. Wayne, what were you going to say?

Barbee: And that's what I was talking about when I indicated we had reshuffled PAM, so we're having some people do file uploads, file sharing, via file locker or whatever other resource you might have for secure file transfer. In some, cases principal investigators are copying reports and having somebody pick those up from a room and take them back to another member, and go over them, and follow-up with a phone call or a Zoom meeting for clarification on these records. So, there's a whole variety of ways that you can do this.

Greer: So during COVID, and during the cutback, and just the need to make sure we have enough people to take care of animals, there were some questions swirling around the community about departures as it relates to cage change frequencies and some of the things that are outlined in the *Guide*. Typically, if we're going to have a departure for something like that, there has to be some fairly well-validated performance standards. So questions have come up, you know, when we don't have staff - let's say we have 50% of our staff out of the husbandry unit because of COVID or something like that, is it okay for us to have departures from those types of expectations due to personnel limitations or other things like that? So kind of getting into the weeds of COVID forcing us to do something that may be considered a departure, but we are identifying them as departures in the IO report, and we're being very transparent as it relates to that, so this question probably, Neera, more for you, but it may overlap a bit, Cody, I don't know, when you talk about some of the housing requirements for USDA species. So I wonder if you guys could comment on that for us and talk a little bit there, and I don't know, Bill [Stokes], if you want to weigh in too, if you have thoughts about whether or not this type of thing could have an impact on animal welfare. So what are your thoughts?

Gopee: I'll start off by saying that deviations from must and should statements in the *Guide*, in the absence of any *Guide* specific exceptions or well-established performance standards must be granted IACUC approval prior to implementation to ensure compliance. And such justification should be based on scientific, veterinary medical, or animal welfare issues. If there's no *Guide* specific exceptions, no performance standards, you need to get that IACUC approval. There's no getting around that. And they must be based on those three criteria, in order to prevent it from being a reportable noncompliance. I will say, though, according to some of the questions I have received, a lot of institutions actually go above and beyond the recommendations of the *Guide*. I've had people tell me - we routinely cage change once a week, regardless of density in the cage. And due to COVID-19, we'd like to move to once every two weeks, and I tell them, well, you're not deviating from the *Guide*. They're telling me they're departing from the *Guide*. I tell them, no, you're not, the *Guide* says at least every two weeks. So once you're within the recommendations of the *Guide*, even though it's not something that is a routine practice at your institution, but COVID has forced you to alter some of your practices, if it's still within the recommendations of the *Guide*, then you do have that flexibility in meeting those requirements but not deviating from it. So that's something that a lot of institutions may want to reassess their current practices, business practices, and see whether or not they actually exceed recommendations of the *Guide*, and they can still adjust to what COVID is forcing us to do because of reduced staffing or what have you, that they can still work within what the *Guide* is requiring, so that's something they might take into consideration, and I've told them many times, just see what the *Guide* says. You may be exceeding what the *Guide*

requires, and you can still fall within the realms of the *Guide*, but unfortunately, you've got to stick within what the *Guide* requires, and you've got to get IACUC approval, that's OLAW's position on departures.

Yager: And it's kind of similar to USDA. There's been no other flexibilities about the actual specific animal care husbandry regulations. I was just going to jump in and say you just need to take into consideration - what's the goals of your husbandry program?

Stokes: You always want your bedding to keep animals dry and free from accumulation of feces, but you also need to consider the microenvironment. If you have a static cage, and you're going out past a week, you're probably going to get excessive buildup of ammonia, so that's something that people are going to need to be monitoring for. However, there are a couple of things you can do. You can increase the ventilation in the room. If you've got ventilated caging, you can switch to that, which can extend the change period while keeping the bedding dry and getting rid of excessive ammonia and other gasses that can influence the animals. The other thing you need to be aware of is the impacts on the research, as you change the conditions of the animals. So I think that the investigators need to be aware of any changes in husbandry. They may want to have the option to not have experimental conditions changed if at all possible, especially while they have a particular experiment ongoing for animals under a study that is not yet completed.

Silk: A participant says they didn't do any semis this year, and she's wondering, Neera, if they end up not doing any inspections for 2020, should she state that in the Assurance and why?

Gopee: Well, it needs to be reported in your 2020 annual report, but, again, we do recommend that your IACUC sit and think about employing the flexibilities that are available to them. If you have employees that come in on a regular basis, have access to your facilities, they can serve as your ad hocs, and they can perform your semiannual inspections, the longer you wait on not doing those semis, you're jeopardizing the health and welfare of your animals. Of course we don't want to jeopardize the health of your personnel, but you can find ways of doing your semiannual inspections as safely as possible, and ensuring animal welfare, so we do recommend and expect that you sit with your IACUC and discuss some of these flexibilities and how can you incorporate these flexibilities and conduct these semiannuals. If you cannot do it safely, for some reason, you report that in your annual report. You have to really justify and let us know why it was something that was not achievable. At least between January and September of 2020.

Jarrell [ICARE faculty member Donna Jarrell]: Hi, everybody, I'm glad to be a part of the conversation. So I was just speaking about the performance or thinking about the performance standard, and like many organizations, our institution went to a spot changing schedule, and we also went to a 7-day work week instead of having a 2-week cycle for changing. And we actually tracked the length of time that cages had animals in, and we had 50% of staff on site at our lowest point. And we actually found that we processed on a daily basis anywhere from 20 to 28% less cages, so we actually reduced the number of cage changes needed by applying a

standard spot changing, and we did all of this with the IACUC's approval prior to implementation.

And one of the things the IACUC wanted was to think about the impact on an individual cage. So we tracked how long a cage went following the spot changing and found that approximately 80% of our cages still got changed within a two-week cycle, following the spot changing, but we were not changing the cages that didn't need to be, and that was the difference. And as Bill said, thinking of microenvironment, we also did look at temperature, humidity, and ammonia levels, at the cages in the two week cycle against the cages in the spot changing cycle. And we will be presenting that data to our IACUC in support of a performance standard going forward.

I guess my point is, don't assume that you are deviating significantly from the *Guide* in some of your performance standard pilots, shall I say, or experiments. [Comment from Barbee: Cage change at greater than two week intervals is a *Guide* deviation. That's not necessarily a negative, but data is need in this case to show that animal welfare hasn't been negatively impacted, as the group has done here.] Actually, collect the data and see if it really is having an impact on the animals. So I always promote that pilot concept or at least tracking that information. Our staff did it as part of their normal cycle. They put a date and a dot on the cage cards. The details of how they did it, I'll be happy to share if anybody wants to do that, (Dr. Donna M. Jarrell can be reached at DJARRELL@mgh.harvard.edu) but you can definitely put some simple things in to give back to the IACUC to let them know you have not impacted animal welfare in a negative way with your changes.

Silk: Bill, we have a couple of questions. One, a participant wonders if a departure is approved, Neera, but they don't use it, does it need to go in the annual report?

Gopee: Well, it doesn't have to be reported to us. It has to be reported in semiannual to the IO. If you haven't used that departure, it wasn't implemented, there's no reason to report it to the IO.

Greer: There were scenarios that the University of Michigan, part of the emergency disaster plan, that required us to have some departures approved by the IACUC and then reported to the IO. We never used them because they were written or they were put into play with the idea that we could lose a lot of people on our husbandry team and there were ways that we would do the things that we needed to do, so they appear in our IO report, and we never had to execute them, so Neera has already said this - once the IACUC approves the departure, then getting it back to the IO through the IO report is the primary thing you need to do. You really don't have to use it if you don't need it. It's up to the institution.

Silk: A participant wants to know if you have written your Assurance to exceed the expectations of the *Guide*, then what do you do?

Gopee: So if your Assurance, you've exceeded the expectations and the recommendations of the *Guide*, and your IACUC has determined that, hey, we want to reduce the burden, we want

to meet the minimum requirements of the *Guide*, especially in the challenges you're facing with COVID-19, by all means, your IACUC can vote, they can change their SOPs and their policies accordingly, as long as they're compliant with the PHS Policy and the *Guide*, and they'll actually report those changes, those animal care and use program changes, whether it be to your IACUC business practice or maybe occupational health and safety program or whatever, the PAM program, you need to incorporate that into your 2020 annual report, if that's going to be a permanent change that your institution decides we're going to change hence forth, and then, as I mentioned, it will also be reflected in your Assurance renewal. So when you're renewing your Assurance once every four years, it will also be included in that.

Silk: A participant says some institutions are gradually ramping up research activity after drastically scaling back. Is there a threshold where resuming semis would be expected?

Gopee: I would say there's no threshold. I would just, as I mentioned earlier, I would say OLAW's position would be that when your IACUC has determined that they can safely conduct it, implementing available flexibilities, then that's when you should start. You know, there's no hard and fast rule. Each state and each institution is different, and so we would just recommend that your IACUC really think about it, employ these flexibilities we have available, if you have questions, you can give us a call, we're just a telephone call [(301) 496-7163] or e-mail [olaw@od.nih.gov] away, and we can provide some advice and then you can conduct those semis as soon as you can safely do so.

Yager: And USDA would agree with OLAW.

Greer: Anything else from anybody? If not, Susan, I'll kick it back to you,

Silk: Well, thanks. I thought you guys did a superb job. Thank you very much.