August 4, 2020

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

**Presenters:** Interagency Collaborative Animal Research Education (ICARE) Project faculty members: Bill Greer, George Babcock, Wayne Barbee, Neera Gopee, Bill Stokes, and Cody Yeager, Susan Silk

A record of this meeting will posted on the OLAW website (https://olaw.nih.gov/home.htm) which is where the ICARE website (https://olaw.nih.gov/education/icare-interagency)

Silk: I would like to introduce Bill Greer and his team for our first 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 also from 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 semi annual 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 semi annual 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 semi annual 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 semi annual inspections. So, we're coming around to the second round of semi annual 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 semi annuals, 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 semi annual 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 semi annual 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 was 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, 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 kind of 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 semi annual 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 Nicole, 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 exist -- 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 -- utilize them as part of their ongoing animal care and use program, apart from the waivers. Waivers for the semi annual, 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 semi annuals, 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: We are in Texas, and our infection rates remain high. So that is a complicated question. But what we have in USDA is - we have 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, it has to be, 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 -- I'll turn it back to you. Does the IACUC feel like two members
of their IACUC is 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: This is Susan from Indiana University in Bloomington, 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 in Bloomington; 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 cut back, 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 must -- I will say, though, a lot of -- a lot of the institutions, 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, cage density. And we want to - 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, you know, 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 - the ammonia levels. 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: Naomi is up in New York and 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 annual report, the 2020 annual report, but, again, we do recommend that your IACUC, you know, sit and think about employing the flexibilities that is available to them. If you do 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 semi annual 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 semi annual inspections as safely as possible, and ensuring animal welfare, so we do recommend and expect that you sit with your IACUC and you discuss some of these flexibilities and how can you incorporate these flexibilities and conduct these semi annuals. If you cannot do it safely, for some reason or the other, you report that in your annual report. You have to really justify and let us know why it was, you know, completely, you know, 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. So we were able to -- 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, Tiffany 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 semi annual to the IO. If you haven't used that departure 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: Jyoti 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: Carey 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 you - your IACUC - really think about it, employ these -- look at all the 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.

Stokes: Welcome to the second half of this ICARE Dialogue: Optimizing Animal Welfare During the Pandemic Crisis. Clearly in the last four months, the COVID pandemic has caused, to say the least, enormous disruption and increased demands to animal care and use programs, and unfortunately it appears we're going to be continuing in an altered environment for some time to come. I do want to begin by extending a huge thanks to all of you and your staff members for your commitment to working hard to ensure the welfare of animals in your facilities in the face of very difficult operating conditions and often at great personal sacrifice. The effort to ensure continuity of operations and to support critical animal research at your facilities has been extraordinary. Especially research directly related to finding therapeutics and preventatives for COVID virus, SARS-CoV-2.

Obviously, this crisis has created huge challenges in assuring ongoing optimal animal welfare for IACUCs as they seek to fulfill their responsibilities relating to overseeing and ensuring animal welfare, as well as challenges for the animal facilities working to provide a high level of care throughout this period.

Facilities have faced challenges in personnel staffing to ensure adequate husbandry and enrichment, and in logistics to ensure they have the food, bedding, medicines and other supplies necessary to support good husbandry and veterinary care.
So today we want to dialogue with you, and we're particularly interested in knowing how you're doing as you deal with the day-to-day challenges. We'd like to hear from you about issues you are facing in maintaining a high level of animal welfare for your animals, and as a community want to share experiences, ideas and thoughts on how to address current issues as well as future issues that may arise. I especially want to thank all of those who responded with issues that you would like to have discussed and those will be what we will initially focus on.

So today I am pleased to share with four other ICARE faculty members the facilitation of this discussion. They all have an incredible depth of experience, and I think this will help them address the questions and hopefully offer helpful advice during the session. I'll ask each of them to now briefly introduce themselves and we'll start with Eileen.

Morgan: I'm Eileen Morgan, I'm the director for the Division of Assurances at OLAW, and a little bit of my background, I've come from the research program, although I've been in OLAW fifteen years. I, like you, have been involved at the program level supporting research in both the NIH Intramural Program and other facilities including Johns Hopkins. Thanks, glad you're here today.

McKinnie: Good morning, everyone. I'm Carolyn McKinnie with USDA. I'm a supervisory veterinary medical officer, primarily for the Pacific Northwest region. I've been with Animal Care for about nine years. Prior to that, I was attending veterinarian at a couple of facilities including a chimpanzee facility and have worked in academia at St. Matthews University. Welcome. Glad you're here today.

Thompson: I'm Tracy Thompson. I'm a veterinarian that started out in small animal exotic practice and worked my way into captive and wild animal veterinary service. I was with the USDA Animal Care program from the Western Region for almost 12 years before I was fortunate enough to find a position with the National Parks Service as the attending veterinarian, IACUC chair, as well as wildlife health veterinarian for that program, and I hope to be able to help you guys, especially those of you that may have aspects of wildlife research in your programs today, and specific questions related to the COVID crisis there. And thanks for having me.

Prentice: Thanks, everybody, for tuning in. I'm Ernie Prentice, I'm a professor Emeritus in the Department of Genetics, Cell Biology, and Anatomy at the University of Nebraska Medical Center. During my 45-year plus academic career, I was a basic scientist, and IACUC chair for a very long time, and an IO. So, again, we're looking forward to all of your questions and hopefully we can find some good answers for you.

Stokes: As was mentioned earlier, you were sent a resource and reference handout: **ICARE Dialogues: Optimizing Animal Welfare During the Pandemic Resources and References, July 22, 2020.** This included OLAW, USDA and National Park Service resources [VA resources have also been added](https://www.research.va.gov/programs/animal_research/). I would just like to go through and ask each of those who prepared these if they have any additional comments they
would like to highlight about those resources. Eileen, anything on the OLAW resources you would like to add?

Morgan: I just wanted to add that I went through them prior to this session - I went through the OLAW pandemic website and read through all of the flexibilities and all of the documents and Guide Notices we posted there. For those of you who haven't done it, there really is a wealth of information. And the majority of the questions that were posed, that Neera answered, have been answered on that - on those Q&As in the - on the website. So there really is a wealth of information and I'd recommend you, when you're developing some things for your program, that you take advantage of that, and just take a look through there. Also, there's webinars and the webinar transcripts are another -- obtain another wealth of information. Thank you.

Stokes: Okay. Thanks, Eileen. Carolyn, do you have any comments about the USDA resources?

McKinnie: Well, we have -- I have links, conveniently, to the OLAW website where there were joint webinars done with Dr. Bob Gibbons and Pat with OLAW, Pat Brown. I think that OLAW is a great resource. There are also links to the USDA website. It’s a good resource. Please make sure you subscribe to Stakeholder Resources, if you haven’t already done so. They will let you know as new things come up. [https://www.aphis.usda.gov/aphis/newsroom/stakeholder-info/ct_stakeholder_announcements] For example, an announcement was sent out when we were getting ready to resume inspections - so make sure you check that out. Thanks.

Prentice: I think that the resource lists are absolutely fantastic. I've downloaded an awful lot of them and read them. They are really great guidance, so I encourage everybody that's on the phone call today to go ahead and look at those resources. They're really, really helpful.

Stokes: And then finally, Tracy, do you have any additional comments about the National Park Service’s resources?

Thompson: I just wanted to share these with the folks that are participating today, and encourage you all to share these at your institutions or others that you're aware of that are involved in wildlife research, especially if they're involved in public lands through the Department of Interior, like Fish and Wildlife Service lands or National Park Service lands. This is all guidance that myself and my colleagues within the science community and the wildlife health community have put together as we learn more and more about COVID, and the risks not just to the humans that might be in close contact or working together in wildlife research, but also to those species that we have particular concerns about as being potentially impacted by exposure to COVID-19, and so these are just examples of what we have drafted. Obviously, things will change over time, so you'll definitely check back either with me (tracy_thompson@nps.gov; 970-829-6084) or with other colleagues to find out if information is altered over the next couple of months as we continue to learn more about what impacts we're seeing and whether or not field research will even be moving forward, particularly for high risk species like bats and felids, and so these are just things you all can take and modify to your own needs or share with colleagues that might be going out and wanting to conduct field research during this crazy time.
Stokes: Thank you very much, Tracy. If you know any colleagues that are doing work, especially with bats, there is excellent research guidance on using bats, and obviously there's interest, as Tracy mentioned, in finding out if they might be serving as reservoir or have a potential to serve a reservoir role. [Comment added by Tracy: we are more concerned about the possibility of bats contracting SARS-CO-V2 from humans, particularly those species already vulnerable from White-nose Syndrome; not that bats are a reservoir for human infections (this has been disproven).]

On to the issues that we heard from you all about. The most common issue that we received comments on had to do with animal care and research staff. There were three different areas here. The first involves challenges in supervision and keeping staff engaged and focused. Obviously, a lot of staff -- animal care staff particularly - find themselves working in isolation, and this can be emotionally challenging. A second area is compassion fatigue. One of our participants noted that they have seen attrition and decreased morale in research and animal care staff during the pandemic. And they noted the importance of ensuring and enhancing the welfare of staff. I think it's clear that the welfare of our animal care staff is inextricably linked to the welfare of our animals. You've got to have good welfare of the staff to have good welfare of the animals. And then finally, another challenging area is communications, where some of the employees may not have computer access, so they can't do Zoom meetings. There are restrictions on group meetings and other face-to-face interactions. And then there's limited supervisory interactions as well as limited staffing, so the camaraderie that's usually very strong within animal care staffs has certainly been challenged during this time. I'll start with our panelists, to see if you have any comments based on your experience, that might help address some of these areas.

Morgan: I just wanted to note that when I looked at these, Bill, the first thing that came to mind on many of these was communication and recognition for the animal care staff. What we've seen across the news for the healthcare workers in this country that are supporting our huge COVID effort for the health of our human population, this is also true for our animal care personnel [that are supporting the research effort], and the folks that are coming in at all stages of research. They're there serving the animals to help support us in the big picture. So what came to mind for me was signage and, you know, sure it's in posters and banners and I saw that the AALAS Foundation just put up another sale of the superhero's masks, and I thought that was such a great idea. So, you know, the rainbow, I was out there with chalk putting rainbows on my driveway thanking folks that were going to fly over in helicopters and see it, but, you know, there's just a lot of things we could do to make those folks know how the rest of us are supporting them.

Prentice: Okay, thank you, Eileen. If I could add a little bit to Eileen's comments. One, I think there has to be very clear safety protocols. If we don't protect our humans, it's going to be hard to ensure appropriate animal welfare. Secondly, it's already been mentioned. You've got to communicate. You've got to be a team that requires effective communication across all members of the team, which include not only the animal care staff, but also the researchers and their staff. Another key point, I think, is ensuring that there's adequate training, so that all
of the members of the team understand the elements of the disaster plan that should be in place at the institution. And then finally, I can't emphasize enough what Eileen said about appreciation and recognition, but also these are tough times. People have tough times at work. They have tough times in their own personal lives, and I would suggest that consideration be given to providing counseling to individuals who might need that.

Thompson: I'd like to add a little bit to that as well. I think what we're seeing within some of the federal programs that lack of connection that we often have when we go to our workplaces and do the work that we all have pride in, and I think having the recognition and appreciation as both Ernie and Eileen have mentioned has been critical within any circle of work companions and having an opportunity to recognize that everybody is dealing with those other things, like child care and health of their families that they may not be able to visit because of risks, and especially if they're working as essential employees, and therefore not being able to get together with those people that would normally provide the love and support that they also need and vice versa.

So I think we do need to see ways to build into whatever communications we can foster within our workplaces to recognize those individual challenges, and support people through whatever it might be that works in your environment, so for us, we've started through our director, he's facilitator for One Nice Thing, so somebody can submit anonymously a thought, a kudos, a recognition of an employee that gives some positive feedback to that person, and it can be brought to that individual anonymously by our director, so that nobody has to be out there or feel like they're doing something that could be perceived as gaining advantage over somebody, but still providing a mechanism that allows for those positive feedback opportunities, and recognizing that folks are there doing the work that maybe not all of us can be there doing. So that's one thing that we've tried to do, and the other is my own little internal group, we've started a Thoughtful Hour, which kind of started as a journal hour, where we would review journals, scientific journals. But in these times of all of these difficult topics where racial and social justice issues, as well as our limitations with COVID restrictions and the challenges with our work situations, to have a topic that we can all come together and discuss openly and safely and support each other in whatever those particular discussions might be to, again, give people an outlet that they might not have right now because of their restrictions of seeing other people.

So Teams and Zoom and these other formats that, you know, I can't imagine doing this a year or two ago with COVID, if we didn't have these forums to help see each other and communicate in a way that might really be beneficial for those of us that have the computer access, and the ability to connect this way.

Stokes: These are really good comments. I think some of the other things that I've heard from other groups is that it's really important for the supervisor to provide empathy. I mean, people have some extraordinarily challenging personal situations, many have been mentioned, and just having somebody that will ask about how they're doing, and listen to them, and perhaps even offer advice, and perhaps having access and to counseling services that can be used. Even having a counselor attend a team meeting could also be helpful, having people just be able to
talk about their feelings about what's going on, because typically they are trying to work very, very hard in the face of challenging circumstances. Do we have any other comments, Susan?

Silk: Colleen wants to know what some of the topics are you've discussed during the thoughtful hour.

Tracy: It's varied from week to week what as to what each of us has been feeling at the time, so some of it around COVID and around the stress, around the risk to our families from those folks that were essential workers, and maybe being isolated from their families. We've had discussions about those stresses and challenges and risks. We especially have been looking at the Black Lives Matter movement and particularly some podcasts and articles that have been brought to each of our attentions that we wanted to discuss particularly with regard to science and those often discrepancies or injustice within our own field and the lack of equality or a lack of racial justice in some of those fields. So for instance, we listened to or read Dr. Neil DeGrasse Tyson's piece [https://freespeech.org/stories/neil-degrasse-tyson-perfectly-explains-why-black-lives-matter-exists/] that he wrote following the Black Lives Matter first riots and protests and had some discussions about those issues, and how they are challenging us as people and scientists to look into what we can do better and where we all have our own biases and racist views, especially from those of us that are not people of color. So, we've had broad topics. Everything from about the pandemic and the impacts on research and impacts on our own personal lives, to what's happening with regard to social justice issues right now.

Silk: Tracy, I've heard of groups that are doing more social type things and I think that what you're doing is terrific. Ivonne [ICARE faculty member Ivonne Chand O'Neal] was telling me about a very large company that hired a chef, and everybody in the group brought the ingredients and they all cooked the same dinner together under the guidance of this chef, and then they ate dinner together so --

Thompson: I love that.

Silk: My point is a meeting could be very serious and very important, or it could also just be for some fun.

Eileen: On a different topic, Bill, I wanted to know if anybody in the group could address -- we talked about communications and recognition, but there's a note, a comment under communications, lack of computer access by some staff. So I wondered if anybody in the group that's out there besides the panel has some suggestions for that one? I had actually almost forgot that there are some animal care, or there are some folks that still don't have computer access, so how do you enhance communications with them?

Prentice: Eileen, I can perhaps comment as to what I would have done if this had happened on my watch a few years ago. I would have provided computers or laptops to the animal care staff, trained them how to use them if they didn't know how to use them. Ensure that they have access to the internet at the UNMC. Basically, that's what I would have done.
Jarrell: Hi, everybody, this is Donna Jarrell. We have about a hundred front line employees, most of them do not have access to computers at home. At the time of the shutdown, there were not a lot of laptops to purchase, even organization as big as ours [Mass General Hospital]. So we actually started recording messages, and so if we had a meeting - we did a lot of updates to the staff - nobody liked reading them. They were getting like thousands of e-mails coming at everybody, every single day, so by making a recording and - it had to stay under ten minutes, and that way when people came on site in their rotation, they could then sit down and get caught up on what had happened either that week or the week before. And that helped a lot with the messaging.

And I also say on the well-being and compassion side, something that was extremely well received is that we had weekly and monthly meetings at leadership team, manager, veterinarians, et cetera, and then every single one of those meetings, we asked to have a ten-minute well-being session and we did meditation. We did flexibility in the chairs. Everybody did it on their own. And when you came -- we did it at the end of the meeting so that they were sent out mindful. When you're mindful, you have clarity about the stress that you're under. It doesn't relieve the stress, but you have more clarity. So

I'll say that really - we have a lot of positives - we did a survey on what we could do more, and for the staff themselves, taking care of their needs was the most important thing for them. We were able to get donations for lunch and making sure the animal care staff were included in that, so the nurses weren't the only ones getting it.

They created parking opportunities so that people didn't have to take public transportation, in Boston, as you can imagine, that's a very scary situation, and for those who could not drive in, we actually provided them PPE to wear home and come to work. When we tried to decrease these benefits, they reacted very strongly. They knew they were hanging on to that.

What Bill said about making sure you use your employee assistance program (EAP). I had a ton of people who were stressed up, at any phase of this, and they needed somebody to talk to. And so we really, really, really encouraged - going back to - please use the employee assistance program. The hospital put out a lot of well-being information based on the overwhelming contacts to EAP. I would say that's something I'll share.

Stokes: Thank you very much, Donna. Really appreciate you sharing what you've done to support your employees. We have a couple of comments. Most of you should be able to see them on your chat box.

Wayne Barbee mentioned that if libraries are open, that resource could be used, if they have computers within the library.

And then Carolyn McKinnie said to also consider sending texts to encourage staff. Do Faceime, assign strong team members with those struggling as extra support or someone to call. So those are really good suggestions.
I think just frequent communications can be really, really important to people that are working in jobs where they don't or can't have those frequent interactions anymore, and certainly, I like the comments that we've heard about that our employees are animal research heroes; it's important for them to know how important their role is, particularly in finding and testing the therapeutics and vaccines needed to solve this pandemic.

Jackson: [Tanise Jackson, ICARE faculty member] Some of the comments that were made about the Black Lives Matter movement and race relations - we do have another webinar similar to this one coming up on August 12th. I believe it is full, but please get on the waiting list for that, because we're going to have some amazing conversations concerning those and how we engage our IACUC animal care and use programs in those conversations.

Silk: We have scheduled another series. We have been approved for the dates, and so there will be more of these sessions coming. We will give first priority to those on the wait list, so if you would like to join us please get your name on the wait list.

Stokes: Well that's good news. Susan, and thank you, Tanise, for bringing that up. I believe you're leading those sessions.

I think we'll move on to our second major issue. This related to post approval monitoring related issues. And these included challenges with maintaining post approval monitoring programs due to restrictions associated with COVID-19. Obviously, a lack of PPE and the amount of PPE that would be required to go into multiple different laboratories could also impact that.

One issue was how to reestablish and sustain better animal welfare practices by researchers, and that's assuming that there was some decrease in the level of animal welfare practices that needed to be improved that either might have been detected by previous PAM and then somehow worked its way back to the animal care and use community.

Another issue is how to ensure compliance among researchers during a time of less monitoring. There are institutions where there was regular monitoring and a person that went around and interacted with the researchers, and now that interaction is no longer occurring. Many times those post approval folks would provide helpful advice and encouragement to researchers, and that is no longer being provided in many cases.

And then there was an issue brought up about not providing protocol-related treatments, such as analgesics, that could be related to a logistics issue where the analgesics might not be available, or staff may not be able to be present when those analgesics need to be administered.

And then lastly, the impact of postponed or modified semi annual facility inspections on animal welfare, where, again, normally there's that sequence every six months of a review, a walk through the facility, and oftentimes aspects that impact animals and their welfare are detected that need to be corrected. So that self-correction process is either being postponed or
modified, such as with remote video used for inspections as we talked about in the previous session. I think there has to be consideration by the IACUC about whether postponed or modified inspections could be having impacts, and discussion and a plan to make sure that those delayed or different processes are not resulting in adverse impacts.

Prentice: You know, COVID-19 is a moving target. We know that. Consequently, institutions have to adapt on the fly to what is happening in terms of the numbers in the community, state requirements, et cetera. So I think it’s extremely important that all of the researchers, as well as the animal care staff, be on the same page. They need to understand what’s going on. What the requirements are at the time. I know that some institutions have these weekly rather detailed bulletins, that basically go ahead and articulate exactly what the requirements are at that particular time, because some institutions have phases, depending upon the virus counts in the community and in the state. There might be a Phase I, a Phase II, and a Phase III, and, depending upon what phase you’re in, that determines exactly what the requirements are going to be. So I think that everybody has to be on the same page. So that would be my first point.

But my second point is we’re all on the same team. We want to ensure human safety and also animal welfare. We need to make the requirements unequivocal so that all investigators, all research technicians, all animal care staff understand exactly what those requirements are. You can’t take advantage of a situation that we’re facing now to cut corners, and I would hope that there are no investigators out there that have done so. If you have noncompliance, it’s got to be addressed immediately with appropriate education. But again, I think that the requirements have to be supported by the senior administration at the highest level. Everybody needs to understand that we’re all in this together, this is a very, very difficult time, and we’ve got to work together. There’s no time to cut corners in any way.

Stokes: Okay, thank you, Ernie. I like your comment about the Institutional Official being involved and making sure that they’re putting out communications to the research staff, just as friendly reminders, shall we say.

Morgan: Issues relating to not providing protocol-related treatments such as analgesics, so failure to provide scheduled post-op analgesia, or some other necessary treatment that is in an approved protocol may be considered noncompliance. There’s certainly an animal welfare issue, and if that appropriate veterinary support was not provided, that may be a reportable incident to OLAW. So a better occurrence would be to not start an activity that would require those things during this time if you’re not sure that there’s going to be personnel available to do that, so that way you can ensure the animal welfare.

If you have any concern about this happening at your facility, you can always contact the OLAW Division of Compliance Oversight [olawdco@mail.nih.gov or (301) 496-7163] and ask, just have a question, have a conversation with them, or discussion, discussing what occurred. And they will be happy to tell you whether or not that will be a reportable incident. But in general, it’s best if you just avoid that, and there’s also an FAQ on this - on the OLAW pandemic page.
Thompson: I’d like to weigh in on that as well in that this is a great opportunity. We knew that when the door shut on folks having access to facilities and research maybe moving forward even because of the restrictions and the issues around COVID, this is a perfect time to get the attending veterinarian or another veterinarian on staff involved with these researchers that have ongoing experiments or that have animals that might require oversight for pain and distress and looking at what's approved in the protocol versus what might need to be adjusted that could still provide what is best for those animals to relieve pain and distress, and being able to submit an amendment to the IACUC to say we’re going to modify and give this range of options that will help us address what staff access, what training, and what appropriate treatments are available to help with this without impacting the research, but with putting animal welfare at the forefront. So, having those conversations as early in that process when either research starts back up again, or there’s a recognition that there’s a need for these types of time treatments that might require staff that may not be as available as they were, getting the attending veterinarian, and then getting that information approved through the IACUC as soon as possible so that you’re minimizing the risk for not only pain and distress, but for noncompliance as Eileen pointed out.

Stokes: Certainly, by providing a reminder to the research staff and a facility, I like what you said, Eileen and Tracy, about making sure, reminding them that they make sure that they have all the reagents including analgesics, as well as staff support, before they start a procedure or a new round of experiments.

This also might be a good time for the researchers to check with their attending veterinarian about the use of sustained release analgesics that might be able to decrease the number or the amount of staff involvement in giving those, and they can be given less often. These longer acting analgesics are becoming increasingly available and there’s considerable literature out there about their efficacy.

McKinney: All great comments. Just from a USDA perspective as well, adding on to what Eileen said - we would consider not giving analgesia a noncompliance. Addressing all of their basic needs including husbandry, alleviating pain and distress, these are crucial. At the same time, we understand how challenging everything is right now, in addition to trying to take care of your staff and so on.

Silk: I guess they should also, when they’re checking, do they have the supplies and the medicines they need on board, they should be checking dates too, shouldn’t they? Because time has been sliding by.

McKinnie: Yes, that's a really good idea.

Prentice: Yeah, to add to that, you know, and the unfortunate circumstances where some institutions have actually had to shut down a lot of the research projects, and as they recover from the pandemic, they've got a phased-in approach to what they're going to allow to be reactivated, and clearly, you've got to look at the complexity of the protocol. For example, you know, post-op care, analgesics, the species, et cetera, and decide which projects you can
activate during various phases of reopening. So that’s just another thing to throw into the mix here when we’re talking about this.

Participant: Hi, Bill. What we did, at University of Texas Southwestern, was the university started a website, some of it was public, and some of it was behind a firewall, that accumulated all of the COVID-related information and guidance, and what we did was - they had one link for researchers for human research, and another link for researchers for basic research, and we actually directed that link to the IACUC web page, and so we kept all of the guidelines for what people can and cannot do in the labs and the animal facilities, and we also were able to keep up to date our announcements on what we were doing on the IACUC, some things regarding our inspection schedule. Also genotyping was another thing affected, rodent genotyping for people who couldn’t get into the facilities for an extended period of time. So, we had to work with several groups on that. We made sure people were being redirected to the IACUC website to get information on what we were doing to make sure that there was compliance as much as possible during this time.

Stokes: Stacy, do you all have a program of regular communications with your researchers just to remind them of their responsibilities and obligations?--

Participant: Yes, we do. We have a list serve, it’s monthly. So, once a month, we send out updates to everybody involved in the animal care and use program, all the researchers, everybody - for us, that's a few thousand people. And the animal facility group, they maintain lists specific to the individual facilities as well as PIs, but the IACUC one is much broader because we include administrators, other people in other departments.

One thing that I got feedback from some PIs, depending on the campus where you’re at, some folks felt like they were being given all of these guidelines, and same time didn't feel very helpful, so we made sure, the IACUC is here to help you be successful with your research. We want to partner with you. We want to be helpful. And we want to get the best outcomes possible. And really putting forth a positive message really helped us on that.

Stokes: Thank you. I think that can’t be stated often enough, that it's a team effort, and the IACUC is an integral part of the research enterprise and ensuring the success of animal research.

Silk: We have a comment from Jyoti. I think this is going to be relevant to our regulators. If your quality assurance department is performing regular audits on GLP studies, could the IACUC utilize those audits as PAM activity? And then focus on the non GLP studies for PAM by the IACUC. This could reduce the volume significantly while ensuring that some sort of post approval monitoring is being performed throughout the whole animal care and use program.

Stokes: I think that's a very useful comment. Those of you that are not involved in GLP studies, GLP studies are audited to make sure that they comply with very detailed standard operating procedures, and obviously those would specify any humane endpoints or the use of analgesics
or other interventions that would be provided to ensure animal welfare. Eileen or Carolyn, do you have any comments on that?

Morgan: Well, that would be a yes from OLAW. That would be a good thing to do. It might be something that you would also want to document in your emergency preparedness plan as part of your program for your disaster plan, so in other words, you may not be using this measure regularly, but I’d also say why not? Why not include it in your flexibility and count these people in as part of your continuing review, or post approval monitoring? Sounds like a win-win situation from my perspective.

McKinnie: I concur with Eileen/OLAW.

Silk: Gayle had a comment, from UW Madison. Would you like to talk to the group?

Participant: Sure. In these times of limited staffing and only a few people being allowed back on campus, we have had some cases where some of the tasks have been done by whoever is available, for example, if the PI is the only one who is allowed in the lab, they may be doing the animal work, and it may have been a few years since they've actually done the procedures. And so maybe just as part of that reminder is make sure that people are current on how things are supposed to be done. For example, we had one instance where a PI brought a frog into a procedure room, didn’t have everything he needed, so he left the room to go get some instruments, and then came back and the frog had disappeared from the uncovered container. So, you know, some of our PIs don’t normally do a lot of hands-on work, but they may be doing more of that for example, we don’t have a lot of undergraduate workers that are allowed back on campus yet. So just be aware.

Stokes: Thank you for bringing up that point and example.

Jarrell: Can I ask a question? I wanted to ask Gayle a question. Gayle, we also had a lot of PIs being asked to come in and do work that they hadn't done in a while, and we had to hold their hands. So, I agree with you. But did you have people like I was sharing in the chat, because of the restrictions of who can be in, did you have people being shared across protocols that they weren’t on?

Participant: I'm not sure. I would expect that we probably did have some of that. Our process for adding people to a protocol is just a nonreviewed change, and so I don’t monitor that very closely, but I know people have been helping one another out like crazy. So yeah, I would expect that's happening, and if we looked extremely closely, we might find some instances of that, where the protocols haven’t been updated to include the helpers.

Participant: Yeah, when you talk about adding staff, and making sure that everybody is captured, and we had people who may not be familiar, that was the time to make sure that they had the skill set and they were familiar with the protocol, and not just doing a procedure because they knew the procedure. So there was a lot of back and forth when that started, and it made the PIs back off from just trying to pursue who has somebody coming in and let's have them do everything. That's a lot of pressure on that person.
Stokes: Those are really good ideas, so thank you, Gayle, and Donna. I think we'll move on to the third category of animal welfare related issues. This had to do with ensuring adequate supplies, such as food, bedding, veterinary drugs, such as analgesics, but also euthanasia drugs and agents, such as CO2, if that’s being used. And certainly PPE. We mentioned that a condition of protocol approval and/or animal ordering could be an assurance that all of these things are already available, or some other assurance that they will be available when they are needed.

We have seen that the supply chain has been interrupted from the manufacturer through distributors and transporters, and that has resulted in further delays from what we’re normally used to, so I think there needs to be awareness of this impact on creating and dealing with shortages. It’s also important to assess the animal welfare impact of IACUC approved departures from the Guide, such as decreasing the frequency of bedding changes to conserve bedding and address staff shortages. Certainly, we’ve had discussion about that already, but if anyone else has comments about that or any other departures that you have made and how you have assured animal welfare in light of that departure, we certainly like to hear from you.

Morgan: I'll just make a note that we've had, I've heard of several institutions that offered help to some smaller ones, with some supplies, but it's not -- I haven't heard of that widespread, but that is somebody other facilities, if you ever get in a certain spot or that you're having issues.

Stokes: That's a great suggestion and having a good network with other nearby facilities where you could share if you got into a pinch would be a really good way to address that. And that's another key area for your disaster plan to include networking with other organizations to have agreements to share supplies or other equipment, or to house or to transport animals as necessary.

Stokes: We talked about adequate supplies and staff as a condition for a protocol approval. I know of some IACUCs who accept all protocols for review. They complete the review, but they're not allowed to be implemented until the IACUC can be assured that there are adequate supplies relative to what they need to do, we’re talking about analgesics or euthanasia drugs, et cetera. So that way you're not backlogging the IACUC in the future because they've already performed the review, and with conditions approved, it's a lot easier then to implement the protocol when all the other conditions are met.

Thompson: Right. And I also think this goes to ensuring that there's some flexibility in some of what's approved in a protocol, for instance, the choices of analgesics, euthanasia, drugs, options that can be assured that they're appropriate and approved by the IACUC before they would be instituted, but to give flexibility, so for instance, anesthesia protocols that we use for wildlife, knowing that there's sometimes drugs that are going to be a little bit harder to get, or utilize in certain situations, for instance, the opioids, because of restrictions and concerns around human health and safety, having a backup plan for alpha 2s, and combinations that would allow you to still have an effective anesthesia protocol available to conduct that research without having to deal with the shortages or the other hoops that would need to be jumped
through, so part of the condition of that protocol approval ordering again having some flexibility that the veterinarians have consulted with the PIs to allow for different types of options for treatment to relieve pain and distress.

Stokes: Thank you, Tracy. Any other comments? Participants? Wayne, would you like to talk about your comment?

Barbee: Sure. You can use your PAM program via vets or others in your program to look at these stockpiles immediately after approval, but before ordering animals or before you do certain procedures which are supply intensive to make sure that this is current.

Stokes: Excellent reinforcement of that point. Thank you, Wayne.

Participant: Hi, this is Susan, from Indiana University, Bloomington. I would add something fortuitous that has come out of these times which is watching how many undergrads have stepped up to help our intergenerational workforce. So, we have several PIs that are not as familiar with the technologies that are facilitating these activities that we've been describing, and it's just been very heartwarming to see them set up Zoom meetings to show their PIs and senior lab member, how to operate things, how to make things more efficient. That is something I've witnessed in the last few months that brings a smile.

Stokes: That's wonderful. Thank you for sharing that.

Participant: Sadly, we had an older caretaker die recently. The infection went through his whole family, but he was hospitalized for about four months on a ventilator before he died due to COVID-19 complications. So, everybody is mourning that. We have had some online events, trying to serve the family, do things for the family, but we also have COVID-19 research going on, and we have care staff that are afraid to go in that room. So it's just a tough time, and it seems like a lot of places don't know people that have died of COVID-19, but it's definitely out there and really severe for specific groups of people. I didn't know if any other programs have dealt with loss due to the virus and how you might have handled that.

Stokes: We're certainly sorry for your loss, and also recognize the really important work that you're doing there at the FDA Center for Biologics Evaluation and Research. We are really, really appreciative of the work that they're doing, and please convey that to your workers that are exposing themselves.

Silk: I think all of us increasingly, whether in our professional or our personal lives, are familiar with the sadness of this situation, and have lost people that we love during this time. That's a very solemn note to end on, so I would like to mention how happy and joyful I feel to see all of you and to hear from you, and to talk to you, and to have the opportunity to thank you for doing what you've always done, which is promote good science and take good care of the animals and now you are also taking care of each other, and we hope that we can be available to help you do that.
We were overwhelmed that these sessions filled up within an hour after we opened registration, and so we had to seek approval to have more sessions. We have been given that approval, and as I mentioned in the beginning, we're finding our way, and I feel like I know so much more after this one session about how to do that. Bill Stokes and Bill Greer, don't you guys agree? To all of the faculty and participants who spoke and wrote, thank you. We are going to offer another session of three ICARE Dialogues. During our session of three Zoom calls, we’re discussing five topics, and we do plan to repeat those with our next series in September, and then we will take stock and see about adding additional topics for our October series. So we ask you, please, fill out your post call survey, and please do let us know by e-mail what questions you still have. You can write to me at ICARE.SERO@gmail with questions, and I’ll get those to the right people. Thanks to the ICARE faculty who spoke so eloquently for today, for all the preparation they did to bring you this program, to OLAW for continuing support, to USDA, for their support, FDA, NSF. All of the agencies that work together with us, National Park Service, VA, BARDA, our private sector partners - all of you, thank you. Good job, everyone.