

Want to comment? Your input is important. OLAW welcomes [questions and comments](#) from viewers of this recording. OLAW will post the comments, questions, and answers on the OLAW website. Please go to the [OLAW Webinars and Podcasts](#) page and click on the seminar title for further information.

Note: Text has been edited for clarity.

MOUs for Collaborating Institutions: New Template from the Federal Demonstration Partnership (FDP)

Speakers:

- Axel Wolff, DVM, MS Deputy Director, Office of Laboratory Animal Welfare, NIH
- Amanda Humphrey, MBA Chief Research Operations, Northeastern University

Broadcast Date: January 19, 2023

View Recording: <https://youtu.be/EEHcRYkm6pE>

Slide 1: MOUs for Collaborating Institutions: New Template from the Federal Demonstration Partnership (FDP)

>> *Cate Pritchard:* Good afternoon. I'm Cate Pritchard, part of the Office of Laboratory Animal Welfare. Today is Thursday, January 19th, 2023, and I'm pleased to welcome you and our speakers to our webinar today. The webinar is titled "MOUs for Collaborating Institutions: New Template from the Federal Demonstration Partnership," otherwise known as FDP.

There are a few housekeeping details. If you have questions throughout the webinar, please try and enter them in the Q&A box. If a question is a little bit more nuanced, or context specific, we'll forward the question to our speakers after the webinar, and then we will append the answers to the transcript. We will also be monitoring the chat the best that we can, and we encourage you to use it to interact with us and our other participants. So, with that, let's get started with introductions for our speakers.

Dr. Axel Wolff currently serves as the Deputy Director at OLAW and previously served as the Director of the Division of Compliance Oversight and as a Senior Assurance Officer. Prior to joining OLAW, Dr. Wolff was the director of the Veterinary Resources Program in the National Institutes of Health's Intramural Biomedical Research Support Program. His interest in unique research animals has involved him in work with armadillos, chimpanzees, and fruit bats as well as more common species.

Amanda R. Humphrey is the Chief Research Operations Officer for Northeastern University across the campus network. Amanda oversees the efficiency of research operations and contributes to compliance objectives for the University. Externally, she contributes to various professional associations, including as a member of the National Council of University Research Administrators Select Committee on Global Affairs, and various initiatives to reduce administrative burden for institutions and faculty nationwide through the Federal Demonstration Partnership. Amanda is passionate about advocating for thorough and thoughtful compliance measures across the research enterprise. Amanda has degrees from Smith College and University College London, and recently received her MBA from Northeastern University.

And although he was unable to join us today, we'd also like to acknowledge the important contributions of Ara Tahmassian, PhD, to the FDP MOU template effort. Dr. Tahmassian is the Chief Research Compliance Officer at Harvard University and serves as the Director of the Broader Middle East-North African Bioethics forum. And with that, I will hand it over to our first speaker, Dr. Axel Wolff.

Slide 2: Agenda

>> *Axel Wolff*: Thank you, Dr. Pritchard. And hello, everybody. This is what we will cover today. First, what is the Federal Demonstration Partnership, or FDP? This is being addressed because it is the entity in which the template form was developed. We'll also go over OLAW's regulatory or oversight context, why FDP created these templates, the memorandum of understanding, the user manual overview, and then we'll answer some questions. So, let's get started.

Slide 3: What is the Federal Demonstration Partnership?

What is the Federal Demonstration Partnership? The FDP mission states that it is an association of federal agencies, academic, and nonprofit research institutions, and research policy organizations that work together to streamline the administration of federally sponsored research, and foster collaboration to enhance the national research enterprise, while maintaining high standards of stewardship and accountability. So, in a nutshell, it focuses on researchers doing research rather than administration.

Slide 4: What is the Federal Demonstration Partnership? (2)

The FDP is a long-standing partnership between federal funding agencies and research institutions that works to reduce administrative burden associated with research grants and contracts. Currently, there are ten federal agency members and more than 200 research institutions. It was a program that was originally convened by the Government University Industry Research Roundtable of the National Academy. It is a unique forum for individuals from universities and nonprofits to work collaboratively with federal agency officials to improve the national research enterprise.

Slide 5: OLAW Jurisdictional Oversight

So, what is OLAW's jurisdictional oversight? OLAW oversees the Public Health Service-funded animal activities. The Public Health Service agencies involved in funding are the National Institutes of Health, which is the primary one, the Centers for Disease Control and Prevention, the Food and Drug Administration, and also the Biomedical Advanced Research and Development Authority. Through a memorandum of understanding, OLAW's authorities have expanded and now cover also the National Aeronautics and Space Administration (NASA), the National Science Foundation (NSF), and the Department of Veterans Affairs (or VA).

Slide 6: Ground Rules for Institutions

Ground rules for institutions. For projects that are subject to the PHS Policy, or those of the other agencies that I've mentioned, these entities are required to use the *Guide for the Care and Use of Laboratory Animals* as a basis for developing and implementing an institutional program for activities involving animals. All performance sites must also be covered by an Assurance which OLAW issues. Collaborative agreements serve to ensure that the requirements of the PHS Policy are met at all performance sites, and therefore it assists in preventing reportable non-compliances. Next.

Slide 7: Collaborations: *Guide*, p. 15

So the *Guide* states that these collaborations— inter-institutional collaborations— have the potential to create ambiguities. In cases of animal use collaboration beyond just animal transport, the participating institutions should have a formal written understanding that addresses the responsibility for off-site animal care and use, animal ownership, and IACUC review and oversight. IACUCs from participating institutions may choose to review protocols.

Slide 8: Collaborations: *Guide*, p. 15 (2)

The participating institutions should have a formal written understanding such as a contract, memorandum of understanding, or agreement. The *Guide* offers flexibility in development, provided the outcomes listed on the previous slide are met.

Slide 9: OLAW's Regulatory Context

So OLAW's oversight or regulatory context— when we visit institutions, we'll check on the MOUs that are in place, or the equivalent documents that are being used when collaborations are in place. And these should address how the oversight and care of the vertebrate animals will be handled. Support does not always mean money; support can mean, for instance, unfunded collaboration such as providing expertise, or contributing or interpreting datasets. I will now turn the microphone over to my colleague Amanda Humphrey, and she will continue. Amanda?

Slide 10: FDP Created These Tools Because of...

>> *Amanda Humphrey*. Thank you, Axel. So, I wanted to talk a little bit about why did FDP even dive into this space? You know, most of the people that participate in FDP are not those in the office of the IACUC at an academic institution or medical center. So why did we even come to this? So, we created these tools, because we were observing a number of areas of administrative burden that were surfacing. We noticed that there was variable interpretation of the requirements of the *Guide*, which was creating variable business processes or operational gaps. And, you know, every institution strives to ensure the best possible care for animals, and that is really paramount.

So, what we did is we considered a number of different documents, vehicles, ways of clarifying the obligations set forth in the *Guide* as Axel set forth for everyone here earlier. And we ultimately discussed an MOU as the most appropriate type of agreement because we often issue subawards between collaborating institutions. While that document is a really wonderful mechanism for conveying information between two institutions, we heard from a lot of our members that the office of the IACUC and oftentimes the sponsored programs office, really weren't in the same work stream. They didn't have access to each other's systems. They weren't really clear on how to get that information from one side to the other so that the information was flowing correctly, as required by the *Guide* related to the information contained in an MOU.

And so what we wanted to do was create an MOU sample that could be used in the cases where institutions did not have that nice ability to have work streaming between a sponsored programs office that might be executing contracts, and an office of the IACUC that would actually be overseeing the care and welfare of vertebrate animals. We wanted to have a sample that would address that, and also just something that we were sure would not have conflicting terms between the standard FDP subaward template that we use all the time between academic institutions and this MOU document. So that was also part of our remit as we looked at this process. We also wanted to think about ways to help reduce the burden around review and signature time and creating samples that institutions can go and say, "Oh, this is a pretty good basic sample, we are going to use this sample and we are going to give this sample to other institutions" makes it a lot easier, because then when you receive that sample and it's not been altered, the review and signature processes are much more streamlined.

One of the key reasons that we dove into this in the first place is that we wanted to make sure that the reporting practices across institutions were clear and consistent. We wanted to make sure that institutions knew who was going to do the reporting, because we didn't want institutions, in some cases,

to be both notifying OLAW that there had been an event at one institution and maybe double reporting something. At the same time, we also didn't want neither institution to report something because they didn't know who should be doing the reporting. So, we wanted to make some of those understandings explicit between the parties. Also, just things like whether or not the collaborating institution should be notified if there is a notification forwarded to OLAW. That's something that was a very variable practice. And I will talk a little bit more about that in just a second. Next slide, please.

Slide 11: Development of the MOU

So, the first thing that we did is we started thinking about an MOU. We created a working group to develop a generic MOU template or sample that would be applicable across collaborating institutions that were using vertebrate animals. We wanted to use this MOU to reduce burden and also provide enough flexibility that- you know- everyone has that institution or two institutions where you do a lot of volume with that organization. So, as we'll talk about later, there are ways to modify the MOU sample so that you can use it more broadly across your institution with another institution, if that makes more sense for you. But you can also use it for a one-off situation with an institution you maybe don't collaborate with that frequently.

And of course, we wanted to create something that institutions have the opportunity to learn from, but not necessarily to implement at their home institution. We do have some institutions through FDP that use the subaward, and they have language in there that covers the obligations of the MOU as outlined by Axel earlier, and kind of articulated within the *Guide*. We didn't want to prevent institutions from doing that, but we wanted to provide some real clarity around what should be covered in an MOU so that if an institution does want to go down that road, they know what that looks like. And really, we wanted to focus in on preventing problems and misunderstandings which could negatively impact the care of a vertebrate animal. We just want to really emphasize and underline here that the MOU template or sample that we have generated is not required by OLAW; it is just one tool of many that institutions have at their disposal to help them navigate these collaborations and inter-institutional collaborations. Next slide, please.

Slide 12: FDP Tools Designed to Answer...

So, when we designed the tools, we designed actually two tools which we will walk through today. One is the MOU sample, and the other part is a user manual which I will talk a little bit more about in a second. Here were some of the things that we wanted to answer. Some of the questions that we wanted to answer:

- We wanted to make sure that we were providing pathways for institutions to define roles and responsibilities clearly, whether the work is funded or unfunded by NIH.
- How do we do that in a really clear, easy, concise document that doesn't have a lot of legalese in it and makes those roles and responsibilities crystal clear?
- How do we do this in a way that is not burdensome, in a way that the language is clear and easy to understand?

So that's really what we went through when we went through this process. We actually had people from the administrative side of the house like myself; I've never been in an office of the IACUC. I've sat on our IACUC meetings at various institutions I've been at and found them deeply interesting, but I've never actually served on an IACUC or worked in an office of the IACUC. And then we also had experts from

offices of the IACUC, as well as several wonderful participants from federal agencies giving us feedback and guidance, including the USDA, OLAW, and the Office of Veterans Affairs. So, we really appreciated all of the hard work that went into this from a variety of stakeholders. Next slide, please.

Slide 13: FDP's 2019 Survey on MOUs

So how did this all start? How did we decide what road we were going to start down, and how did we even narrow down some of these pathways that I've talked about of understanding the ways that institutions were interpreting the requirements, or executing the requirements at their own institution? This all started with a webinar that we hosted back in 2019. During that webinar, which is available on the FDP website (and I will provide a link as well as walking you to that website when we run through the tools). We asked a couple of questions of our community, and these were ones that really helped us define our direction.

So, the first question we asked is: Does your institution issue MOUs when multiple institutions are working with vertebrate animals on the same research project? And a majority, a slight majority (34%) said that "Always, even if there is a subaward" they will always issue an MOU. And then 86 respondents out of 262 (or 33%) of the respondents said, "I don't know. I don't know what we do." And 25 respondents (or 10%) said, "Only if there is not a subaward." And then 62 respondents (or 24%) said, "We do not issue MOUs; we consider the OLAW Assurance of the subrecipient collaborator to be sufficient."

I will just briefly touch on that to say that as of today, the FDP subaward template that is available does not specifically address reporting requirements related to OLAW. And I think that that is really, definitely, a consideration that I wanted to highlight because it was something that I was really not clear about when we started this whole process that we went through. So next slide, please.

Slide 14: FDP's 2019 Survey on MOUs (2)

The next question we asked is: When you are a subrecipient on an NIH-funded project, where do you report any animal welfare issues? Do you report them directly to OLAW and not tell the pass-through entity? That may actually have impact on data quality and [have] data integrity issues. Do you send it directly to OLAW but also send a copy to the pass-through entity or your collaborator institution, either as a CC or under separate notice. Or do you send it to the pass-through entity and have them send it to OLAW— ask them to send it forward to OLAW? Or do you not know what the process is?

So, 44% of the institutions said that they do send it directly to OLAW, but they also send a notification to the collaborating or pass-through entity. But 35% said that they were not sure what the process was. Part of the reason that so many of these respondents probably are not aware of what the process is, is that probably a majority of the individuals that were on this call were from the administrative office (the office of sponsored programs) and not from the office of the IACUC. So, they may not have been quite as familiar with some of the business processes that the office of the IACUC has in place. Next slide, please.

Slide 15: FDP's 2019 Survey on MOUs (3)

And the last question that we asked is: How is operational alignment between your institution's IACUC office when issuing MOUs, and the office that issues subawards? And by that I generally mean the office of sponsored programs that I've been referring to as we've been talking. It can be called a lot of different things at different institutions. It might be called a Research Management Office, etc.

So, we had 271 responses to this. All of our questions throughout the webinar were voluntary responses; we didn't get responses from everyone every time. So, only 18% of the institutions that responded to this question said that the MOU process and the subaward processes are closely aligned. So, there is somehow a communication between the IACUC office and the subaward office that says, "Hey, we have a subaward that also indicates that the subrecipient will be doing work with vertebrate animals. Office of the IACUC, are you guys going to issue an MOU? Or, you know, are we going to incorporate this language?" And actually 10% of the institutions that responded to this said that the MOU language is actually included in the subaward, and that just that the office of sponsored programs deals with all of it. But 42% of the respondents said that the MOU process and the subaward processes are mutually exclusive and not tied together at all.

And often we were finding that the reason for that is because those offices likely have different reporting chains or lines of command. They may not have systems that talk to each other or work streams that talk to each other in any other format. So, we wanted to bridge that gap through our tools. Next slide, please.

Slide 16: What Did We Learn?

So, when this initially came to us, it had actually come in as a request to the subaward subcommittee, which I at the time was a co-chair of. It was asking us: "Just put some language into the subaward, and that way we don't have to issue separate MOUs." And what this whole webinar that we did, as well as some other feedback mechanisms that we had with recipient institutions, told us is that we were not ready to leverage a subaward as a final solution just yet; although, that could be a future tool that we work toward. Putting the MOU language in there may actually inhibit some of the adoption, because an MOU is generically like a pretty informal document. It's maybe not as legally formal as a contract or agreement in another form or format; it doesn't include anything like "I represent and certify, I warrant to you"— things that have legal implications. We were pretty careful about trying to avoid such terms when we were actually drafting the MOU. Ultimately, we wanted to develop consensus among institutions and reduce confusion and burden in either issuing and/or reviewing those MOUs. One of the ways that we felt that we could do that would be by creating some tools. Next slide, please.

Slide 17: Two-Pronged Approach

And so what we ultimately came up with was this two-pronged approach - what we'll call today a user manual, which clarifies our interpretation of the requirements. It gives them tools and resources for getting institutional offices on the same page. We found when we started these conversations that there were terms that an office of the IACUC might use that would mean something completely different over in research administration land and vice versa. And then also understanding institutional practices around MOUs and what might your peer institutions be doing, and how might they be using MOUs and subawards.

And then we also wanted to create an MOU sample to initially identify what makes a good memorandum of understanding, what needs to be in there that helps us and informs the way that we talk about things in what we'll call the user manual (or the guidance). We wanted to have a sample product for institutions to be able to use across a variety of funding agencies, including OLAW, USDA, VA, etc. And as I mentioned before, we had great contributions from our colleagues at those agencies, and that really helped us to create a document that I think is more universally useful than if we had worked with one agency alone. Next slide, please.

Slide 18: Where to Find These Resources (FDP)

I will actually take you to the website for this in just a second, but I wanted to show you that there is a slide in the slide deck that will get you started with this. So if you forget what I'm showing you on the website in a second when I take over screenshare. At the top, [if you look at] the first red bounded block there, you will kind of see a breadcrumb trail of where you need to go when you get into the FDP website. On the right-hand side, you will see a link to the FDP website, and then down below, you will notice a second bounded box under the "Resources" section. These are all of the materials related to the IACUC MOU project. There is the webinar that I referenced, including the second bullet which is the slides to the webinar. And then you will notice our FDP MOU sample, as well as the MOU guidance document.

One thing I want to make clear here is that I know that when you are in an Office of the IACUC, anything that's issued by OLAW or another animal welfare regulatory agency such as USDA, if it is called "Guidance," it is not *guidance*— it is a rule that you really need to follow. In research administrator land everything is guidance, you know: all best practices, all user manuals, all things that have that title or that name. We don't really make a distinction and say, "Oh guidance is something that I need to pay attention to in a different way than I pay attention to perhaps a document that outlines best practices or a user manual." So just want to make that really clear. We did change the title on the MOU guidance on our website recently to try and harmonize a little bit more so that it was more clear that this is just *information* that we want you to have as resources at your fingertips, and not something that is mandated to follow. But it is helpful to understand if you do see some places in the document that still say "guidance" that we are not trying to put that on the same level playing field with guidance that you might receive from a federal agency. So, I just wanted to make that clear. I'm going to take over screenshare, just so you know.

Okay, so I'm going to start with the FDP website. This is the landing page of the FDP website. When you come to visit us, this is what you will see. One thing that most institutions are familiar with is our subaward forms, and you are certainly welcome to go in and click through those. But if you were looking specifically for the MOU guidance or user manual, as well as the MOU sample, where you want to go is actually down here under "FDP Committees". And then here's another wacky thing about administrators: We call it the "Animal Subjects Subcommittee" instead of the "Vertebrate Animals Subcommittee" or "Office of the IACUC Subcommittee," but that's what it means. And it's just because we have a lot more administrators than IACUC individuals affiliated with the FDP. So, we wanted to make, we are kind of using our own parlance instead of maybe what the formal parlance is in an office of the IACUC. Here are those resources that I was talking about and I am just going to pretend to click on (I have these documents pulled up on my computer already), but I am going to click on this user manual and walk you guys through that.

This user manual has a couple of different sections, and this document really looked at the *Guide*; it listened to our experts in the room from the federal agencies and the various offices across the United States, including large and small animal welfare programs, as well as folks from sponsored programs offices. We always have our nice little disclaimer in here, in that nothing in this document is legal advice; so you know, if you are using this, or you are relying on it or anything like that, I always recommend please make sure that you have pulled in your general counsel's office as you go to implement these documents *in addition* to working between your office of sponsored programs and your office of the IACUC.

We have a section in here that just lays out some definitions. I'm not going to go through all of these in detail, especially because some of them will be answered in the Q&A, or we can dive into them during that section later.

But then we try and walk through:

- Why is an MOU important?
- What is its purpose?
- How is it different to the purpose of a subaward?" Real quick, high level: the subaward is really putting it into the context of the overall collaborative project, whereas an MOU is really focused on the care of any vertebrate animals utilized in the conduct of that project.

And then this, again, gives a few specific bullets on what is an MOU versus a subaward:

- Who is required to have an MOU or agreement
- Who should see it?

Then we get into some recommendations for planning and institutional communication regarding the MOU just to get an institution started. If you haven't started this already at your institution, this can help be a conduit or a starting point for that.

And then we go through some FAQs about what an MOU is, how to use it, and what institutions may or may not require it, and what does that mean?

So those documents are there and available for your guidance. I think if you download it, it looks a little bit neater, that the headers get a little bit strange in the web view. I'm just going to pause my share and do a new share. And I'm going to actually show you the other important document, which is the actual FDP MOU sample.

And this sample, as you can see, is a Word document. I'm just going to make a couple of quick statements here about this before we dive into the actual MOU itself. Whenever FDP puts its name on something, we try and have— our name means consistency, which allows institutions to reduce administrative burden. So, if your institution wants to use the MOU but you feel you need to change language within the MOU for any reason— I have no judgment about that, but please remove these three letters “FDP.” That is a signal to other institutions that this document has been modified from its original format and terms and conditions. They need to read it in a different way than if it just says “FDP” at the top because then, you know, maybe it's more of a skim read, or skim review than if you have got something. For a more substantive change, we want to really dive into that and see what you have changed in the document. So, we've got, kind of sets forth the purpose here and then this applicability statement. You know, you could change this if you are — for example, I work and live in Boston, and so I am within arm's length of multiple other research institutions; [I] can think of a couple of research hospitals where...

[Moderator and speaker pause to work through technical issue. Correct file appears onscreen.]

So here are those three little FDP words that I mentioned; here's our kind of general opening salvo of the purpose of an MOU. And then here, this goes to the applicability— this is a great place to highlight where institutions may need to change this. For example, if you are one of the many Boston Longwood hospitals down the street from me, you may be having animals on the same floor that actually belong to

two different hospitals, and you might have that happening throughout. And so you want to have a kind of generic MOU that covers the relationship between the two institutions, and not necessarily dig into protocol after protocol after protocol. If you are in that kind of situation, I would recommend that you modify this and take out the phrase “protocol” and maybe just reframe that how you want to, to document that this is really the default position for how your institutions will move forward unless otherwise indicated by a specific MOU if you have a special situation. But if you are using this for one or a small number of projects that you are trying to document, it provides all the relevant information of institution A and institution B.

We've tried to define who should be institution A and who should be institution B. In the Sponsored Program Research Administration world, typically institution A would be what we call the pass-through entity; this is the institution that is typically receiving the bucket of federal funding and is then passing it to institution B, maybe through a subaward. Or maybe there isn't a subaward, but they are kind of the programmatic lead of the project and they are working with institution B, who is feeding information to them that will then kind of roll up into the final deliverables (the final report) that is going back to that funding agency. And so, institution B, sometimes called the subrecipient, receiving institution, etc., fills that role of rolling that information back up to the other institution.

We provide some basic demographic information here, as well as some project-specific information that you can either fill out in line here by removing this text and typing in, or like we indicate, providing a table if there is more than one protocol covered there. And we provide all the regulatory references for everything that we talk about. These were the documents that we really used when we were going through everything.

I will have you notice that this is only three pages long. In the first page, there is not a lot of information that you have got to do; there are not a lot of terms and conditions, and the same is true throughout this document. And even on the last page, you will notice half of it is a signature block, which is pretty great. So, this is not a legalese-heavy document that institutions have to go through. We started by breaking this down into components such as, “What is it that you are really going to want to understand about your collaborator when you are entering into an MOU?” So, we just have some generic program-wide acknowledgments:

- Information about whether or not transportation needs to be covered, either in this or a separate document
- Information about ownership and oversight of the animals. Being in Boston, I can say that you might have animals that are owned by hospital A but are being housed at hospital B, but they ultimately are still owned by Hospital A. And so you might have some interesting permutations on the theme. But I think for most institutions, the default is going to be if it's happening on your campus or your institution, that those animals are typically owned by you.
- Investigation and reporting: just covering some of those really important areas that really assure that animals are being properly cared for in the conduct of research.

We also have a very broad category for other requirements not addressed above. So, if there are any special situations that you encounter, this is a great place to add those; we know that sometimes there are state-specific laws that are different, and you can document those there.

So, I wanted to just bring back to how do you fill this out if you are an institution? We try and just give some instructions here in this top part. So, if you are e filling this out, you'd probably want both institutions to fill out this program-wide acknowledgement, so you'd put an X, or a checkmark, or whatever you wanted, to indicate your concurrence with that. If maybe institution A does not have any information to share, (maybe they are not doing the animal work) they might click "N/A," but institution B might click "yes." So, you just go through this. In the instances where we think that in most cases, it's *either "A" or "B,"* we will actually indicate this in the instructions, like "Choose One." And that, we find, is pretty helpful. So, we try and be pretty prescriptive about when you would want to have that latitude or that flexibility to select "yes" or "non-applicable" for each of those institutions, or when would you really want to be prescriptive.

I just want to draw attention to the language here, because I talked a little bit earlier about the fact that we don't have a lot of legalese in this agreement. We don't ask institutions to "represent," "certify," "warrant..." We didn't want to get into that because some institutions are comfortable with this, some institutions are comfortable with that... at the end of the day, a lot of that type of language is covered typically under a subaward agreement or subaward situation. So, we wanted to focus on just the parties, documenting understandings in this document. And so that's where are; we have the parties *acknowledge*, the parties *agree*, and it's really just about that formalizing and documenting for the institution.

And then there is some USDA information. In keeping with the fact that we do have some USDA input here, we do reference some USDA things within this document. So, you may want to add, you know, if you are working with another species, we've got a USDA animal report here that may only be relevant in some situations or some cases. So, you just look at your specific use case and see if it's relevant to you; if you don't find it, that is what the "Other Requirements Not Addressed Above" is.

We try and make it really clear: who are the people that your institution might have as the appropriate signatory for this? There could be a range of individuals, and we have tried to list them out there so that if it does get somehow to the hands of a faculty member before it gets to the office of the IACUC or the attending veterinarian or an IACUC administrator, that it's really clear where does it need to go so that it gets to the right place and that chain of command is followed.

I think that is everything that I had to share about those. Axel, did I miss anything that you wanted me to go back through?

>> *Axel Wolff*: Well, we have time. Why don't you just walk through it a little more and just show what some of these examples are? Because I think we still have time here to do that.

>> *Amanda Humphrey*: Okay, so I will give an example that I have come across, and this is a pretty rare example. But let's just say institution A has a grant from the NIH and they are not conducting vertebrate animal studies or work at institution A. They have no sub-recipients on the project, but there is an institution B that is conducting vertebrate animal work under maybe another funding source, and then actually providing that data over to institution A for use in the grant funded by the NIH. That is a perfect situation where you will not have a subaward to document your understandings, and where an MOU can be particularly useful. So, if we are thinking about that, let's just say these two institutions do not work together very frequently. If I'm pretending that I work at institution A, I would fill this information out on behalf of my known faculty member and document what grant does this tie to. And then, if I'm

sending this over to institution B and asking them to document their understandings with me, this is where I will put their relevant information related to the project as far as I know or understand it.

In some cases, I might have to ask them to fill in specific things like maybe their protocol approval dates, or their protocol numbers if I'm not aware of those when I send this over. I might not even have a protocol approval date and a protocol title, because there may not be a congruency review of my institution if the vertebrate animal work is not being conducted at my institution. So this would be a place where hopefully faculty members are asking those questions and saying, "Hey, do I need a congruency review?" And we would probably say, "Yes, you should just go through one. It's a really, if nothing else, we want to know that vertebrate animal work is related to this project, and that something is happening so that we can make sure that we have the right understandings in place."

And so, you come down here, still with that understanding. And we know that institution A is not going to be doing any vertebrate animal work, but they still have a program of animal care and use qualified to perform animal care and use activities, and the other institution may still be interested in knowing that about the other institution. So maybe both institutions say "yes" because this is pretty generic; we are not asking anything specific about this project or this collaboration. So, we both might say "yes" to that. We both still might choose to say "yes" to this first understanding here. But at the end of the day, both institutions are checking "yes" under that program-wide acknowledgement.

Based, on the information I've already provided about the context here, it's unlikely that animals will be transported from point A to point B. But, you know, this does say "applicable," but you could say, "Hey, it's not applicable in this case." So we are both going to check "N/A," because no animals are going to be transported during the course of this project; we don't need to worry about that.

Ownership and oversight. You know, if institution A is not seeing these animals, and all of the work being done with them is totally being done over at institution B, there is a pretty good chance that those animals are going to be owned by, as well as overseen by, institution B. So, we'll assume that that is the case, and would click "yes" for institution B, but "not applicable" for institution A. And then the parties acknowledge— well, since we don't have any animals in our possession related to this project over at institution A, we might click "not applicable." And over here on B, we might— we will— click "yes" because they are really going to be ensuring this. And then how are we going to review and approve prior to the initiation of the activities? This might be a congruency review, or it might be a full protocol approval. Institution B is definitely going to have that, but this might vary depending on what institution A's policies and practices are around this. Let's just say that the office of the IACUC [at institution A] still wants to do some sort of congruency review; they want to do some sort of check on this to understand the work that is being done over at that other institution. So maybe we'll just say A here, but I wouldn't look at it askance if this came in and it said "not applicable" instead of "yes". And then the parties acknowledge that in this case, institution B is going to do that core kind of check.

Then for monitoring on their property— again it's up to institution A whether you would click "N/A," or if you would click "yes." I think if you are doing a specific project-by-project one [MOU], you might want to be more specific to what is happening, or what your expectations are related to that specific project, whereas if you are doing a broad MOU that's covering a lot of activities, you might just click "yes" for both institutions on that one.

And then for notification directly to OLAW— in this case, since institution A is not handling any vertebrate animals, I would probably recommend that you just have institution B do a direct report, and that it's not applicable for institution A. And then this one should probably also say choose one, A or B, but you could probably change this to institution B and just make sure that they know that they are responsible for making those disclosures.

And then we've also got institution B agrees to promptly notify institution A of any reportable event. So you would say “yes.” And then if you are going to have that— because sometimes data and information is flowing both ways, as I said earlier, if there is an animal welfare issue that occurs during the life of a grant, if one institution is not aware of that event that happened, it could change the amount of data that's going between the two institutions. It could change what that data means, do you want to remove— you know, if you had something happen halfway through a protocol, would you want to remove a certain amount of data because the protocol wasn't finished for a particular one individual or subgroup? You would want to know about that, so you might actually have this be “yes” for both institutions. In this case, institution A isn't handling any animals, so we'll say “not applicable” for them. And we'd probably then say “not applicable” for institution B as well, because they, in this case, are not doing the action. They are not providing the notification; they are the recipient of the notification.

And then here, which institution is responsible for reporting USDA-regulated animal activities? Again, I would assume that this would be institution B; institution A would say “no.” And same with this one. And then I would route this to somebody—the appropriate party— at my institution for review, (likely the IACUC administrator) and they would review and sign off on it. Anything else you want me to go through?

>> *Cate Pritchard*: This is great, Amanda. Thank you so much.

>> *Axel Wolff*: Yep. Thank you.

>> *Amanda Humphrey*: Sure.

>>*Cate Pritchard*: I have a ton of questions in the chat and coming in through the Q&A box. So, whenever you are ready to move on to those, just let us know.

>> *Amanda Humphrey*: Please, go ahead.

Slide 22: Questions (slides 19-22 skipped)

>> *Cate Pritchard*: Okay. Well, let's first— Nicolette, do you want to start sharing again? The question slides— we are first going to tackle some questions that we received in advance of the webinar. And while Nicolette is working on that, I will just bring up my version.

Slide 23: Question 1

Okay, so the first question is going to be for you, Amanda: “Is using the MOU sample mandatory? The *Guide* only states that a formal written understanding is required and should be used.”

Slide 24: Question 1: Is using the MOU sample document mandatory?

>> *Amanda Humphrey*: It is not mandatory. Institutions have and continue to have latitude to choose the mechanism that is most appropriate for their business processes and procedures. So we really want to underline that and want to make sure that institutions understand that that is totally okay. OLAW is not prescribing it; even FDP amongst its members is not prescribing that you need to use the MOU

sample. We do in fact have members that use the subaward. We have members that might use other methodologies, so we don't want to stop those. But we wanted to provide a tool or a resource that could help institutions start to get toward consistency that is helpful.

Slide 25: Question 2a: What is the difference between an MOU and an Interinstitutional Assurance (IIA)?

>> *Cate Pritchard*: Awesome, thank you. Alright, our next question is, "What is the difference between an MOU and an Inter-institutional Assurance?" And Axel, this one is for you.

Slide 26: Question 2a: What is the difference between an MOU and an Interinstitutional Assurance (IIA)? (2)

>> *Axel Wolff*: Okay, thanks. So, I just want to stress that the MOU is specifically to ensure animal welfare; there are lots of other documents that come into play when institutions collaborate. And so that's the whole reason why FDP took on this project, because there is so much confusion and there are lots of different documents involved. But the MOU is recommended specifically in the *Guide* for collaborating institutions to address the responsibilities for animal care and use and to avoid ambiguities. The IIA is the Inter-institutional Assurance which is issued by OLAW to an awardee institution that does not have its own animal program and instead uses an Assured institution to conduct the animal activities.

These documents do not substitute for one another. They don't— you can't use one instead of the other. It's just that they are totally different. One is to ensure animal welfare, and the other one is a legal requirement if you are getting funding from any of the agencies I mentioned but your institution does not have an animal program, but you are getting the funding and you are performing the work at another institution that does have an animal program, and that's where the IIA comes into play.

Slide 27: Question 2b: How does an MOU and an Interinstitutional Assurance (IIA) relate to an institution's Assurance?

>> *Cate Pritchard*: Thanks. And there is a follow-up question for that. How does an MOU and an Inter-institutional Assurance relate to an institution's Assurance?

>> *Axel Wolff*: Okay, so the MOU is independent of any Assurance. The IIA is a type of Assurance.

Slide 28: Question 2b: How does an MOU and an Interinstitutional Assurance (IIA) relate to an institution's Assurance? (2)

It's an Inter-institutional Assurance, like I said, for an institution that does not have its own animal program but depends on another performance site with an animal Assurance that has been issued by OLAW.

>> *Cate Pritchard*: Great. We do have a ton of questions that are coming in both through the Q&A box and through the chat box. Our speakers have a hard stop today at 2:00pm. So, we are not going to be able to get to all of these, but I promise you that we will ask them to answer these offline, and then we'll append these to the transcript. So, in the chat box, you are going to see a link to our listserv; please subscribe to that. And then we'll send out a notification when the transcript and the slides and the webinar recording come out. But we'll go until 2:00pm with some of the questions that are received; [keep] entering them in the chat box or the Q&A box as they come up.

Okay. So the first question that we have: "Is this template intended to be used as a component of or attached to the FDP subaward template, or separately?" You want to take this one, Amanda?

>> *Amanda Humphrey*: Sure, I would recommend that it be used separately. I would guess, if you are using the MOU sample, a lot of the information that is there isn't necessarily relevant to the other parts of the collaboration, or it might not get over to the office of the IACUC. So, I would probably handle them separately. But if you wanted to incorporate them, and that is what both parties wanted to do, I would say go for it. I think it's totally fine.

>> *Cate Pritchard*: Okay. The next one, let's see, was a little bit unclear to me, but I will read it anyway. "When a grant recipient has a subaward to a collaborating institution for all the live animal work in the grant, the IACUC at the recipient institution may not be aware that an MOU is needed (not aware of the grant, in other words). The FDP subaward template language that includes reliance language has helped bridge this gap. Will the MOU be linked to that template so the grant recipient and collaborating institution can complete the MOU, or at least trigger a discussion if one is desired?"

>> *Amanda Humphrey*: I think if I am understanding the question, is it's kind of, "What is the difference between those two documents, and how do we relate them to each other?" The way that the subaward language is currently written is that it documents if there is vertebrate animal work being performed by the subrecipient under the project, and is that properly approved by the subrecipient institution and then billed in accordance with the dates of the appropriate applicable approvals? In other words, when it is an allowable cost? That is what the language in the FDP subaward is intended to cover. The language in the MOU itself is intended to cover questions about the care and use of the animals themselves, including those issues that we talked about like transportation, ownership, oversight, etc.

And so they are kind of two very different areas. We did not put a direct link from one over to the other, just because of the fact that there are a lot of institutions where those are very separated work streams, and we weren't really at a point when we started this process to tie those work streams together in any way for our membership. It's an open question as to whether now that we have this document, if the subaward subcommittee will take another look at the language and incorporate more MOU things now that we have kind of defined what needs to be defined in an MOU, or if those things are just so different that we want to keep those things separated to the maximum extent possible, if that makes sense?

>> *Cate Pritchard*: Okay, thank you. And if that didn't answer the question, if the questioner wants to put something else in the chat box, go ahead and then we'll talk to Amanda again offline and get back to you. The next question: "Is the intention to use the template for collaborations with US entities only? How can the MOU be adapted for use with foreign collaborators?"

>> *Amanda Humphrey*: Great question.

>> *Axel Wolff*: It would be the same. I mean, it really doesn't matter because the MOU specifically only addresses animal issues. So, if the domestic entity is dealing with animals in a foreign site, it would pretty much be the same information. Although, again, you can adapt it to your own needs. It wouldn't necessarily have all of the boxes that are applicable here, but as far as who is responsible for animal care, who is responsible for reporting problems, those items would be the same regardless of whether it's domestic or foreign. Amanda, please jump in.

>> *Amanda Humphrey*: I think that is absolutely true, Axel, and you are spot on. When we wrote this, though, we did write this to be used between two OLAW-Assured institutions. So, if your foreign collaborator does not have an OLAW Assurance, you might want to think about, you know, making some changes or looking into that further. But if they have an OLAW Assurance, which they do not have to be a domestic entity to have an OLAW Assurance, then this is absolutely an appropriate document, because it's not going into the rules of a specific animal care and use as governed by any one specific, you know, government, it's just what is applicable under your OLAW Assurance.

>> *Axel Wolff*: And just to add, somebody asked about a foreign Assurance. Yes of course, if PHS funds are being used abroad, a foreign Assurance is needed. Again, that's separate from the MOU. If your institution is subject to the *Guide*, that's when you will be using the MOU. If you are subject to the PHS Policy, then a foreign Assurance is needed. Yes.

>> *Amanda Humphrey*: I think we have time for one more question. There is a great question in the chat, or in the Q&A, that I can see. "Would it be acceptable to update the MOU title to "agreement" as our (possibly others as well) institution is very specific about using the word "MOU" for very particular cases— with the understanding that "FDP" will be removed as Amanda has requested." I think that that's okay. I think you have to understand, though, that on the other side of that, other institutions may say, "Well, it says the word agreement, that implies something different than an MOU to our institution, so it might have to go through a different legal channel at the recipient institution." So, know that changing those words might have an impact on how the other institution receives that document. Axel, did you have anything else that you wanted to add to that?

>> *Axel Wolff*: No, that's perfectly fine.

Slide 29: Next Webinar: Spring 2023, Topic TBD

>> *Nicolette Petervary*: Thanks, everyone. This is Nicolette. We are up at 2:00 pm. We just want to tell you about the next webinar with a topic to be determined in Spring 2023. Thank you all, and we will see you at the next one. As Cate mentioned, we will be appending answers to the questions we weren't able to answer live on the webinar transcript. Thanks so much for coming.

Additional Questions Received During the Webinar

Question A: If an institution changes the language used to identify a protocol (e.g., instead of "protocol", say "study" or "project"), would that require the removal of the FDP nomenclature at the top of the form?

- **OLAW:** The nomenclature regarding the definition of the animal activity is up to the institution.
- **FDP:** No, it would not, when we talk about the prompt for removing the FDP moniker, we are speaking to changing substantive text, like the introductory section on the relevant regulatory text and the acknowledgements that each party agrees to in the body of the MOU.

Question B: Would it be acceptable to update the "MOU" title to "Agreement" as our institution is very specific about using the word MOU for very particular cases? With the understanding that FDP will be removed as Amanda has requested.

- **OLAW:** Yes, it is acceptable to use other terms. As outlined in the *Guide for the Care and Use of Laboratory Animals*, examples of nomenclature for this tool are provided for the use of this formal written understanding (e.g., contract, memorandum of understanding, or agreement). The term “agreement” is specifically mentioned and is acceptable.
- **FDP:** That is an institutional decision, but if you change it from “MOU” to “Agreement,” please remove the FDP moniker. Institutional operational decisions around signature authority and implementation should drive what an institution calls the relevant document. If your institution requires this be called an “agreement,” that is acceptable, but please recognize that for other institutions, an “MOU” is viewed as having a substantive legal difference to an “agreement” and thus they may prefer to call it an “MOU.” Thus, you may find that you receive pushback if calling it an “agreement.”

Question C: Would using this template as a "blanket" MOU (removing protocol-specific references) or adding other conditions at the bottom require removing the FDP designation at the top? Or is that only expected if wording of pre-populated agreement language is altered?

- **FDP:** If you are using this as a “blanket” MOU with no modified or added terms and conditions (aside from changing the box that identifies the specific research project information), then you are free to leave the FDP moniker on the top of the MOU.

Question D: May institutions have an umbrella MOU covering many different institutions?

- **OLAW:** Yes, if the circumstances warrant this type of arrangement. If the same procedures, animals, reporting requirements, etc. are in place, then the same instrument may be used. If the collaborations at different institutions constitute different parameters, then the MOU should be tailored to specifically address them.
- **FDP:** Yes, umbrella MOUs are appropriate. I am not sure if you are asking about having a multi-party MOU for a specific consortium or having several umbrella MOUs, so I will respond to each.
 - The MOU sample was designed for two-party collaborations. You would need to modify the sample, including removing the FDP moniker, if you would like to create a multi-party resource. I would recommend that you use multi-party MOUs only for specific consortium projects/collaborations and not as an umbrella MOU.
 - If you are asking about having multiple umbrella MOUs with several institutions, that is not an uncommon situation. You can have as many separate umbrella MOUs as makes sense for your institution.

Question E: Can you have a 3-way MOU and use the FDP template?

- **FDP:** The MOU sample was designed for two-party collaborations. You would need to modify the sample, including removing the FDP moniker, if you would like to create a multi-party resource. I would recommend that you use multi-party MOUs only for specific consortium projects/collaborations and not as an umbrella MOU.

Question F: Interinstitutional Assurances are directly requested by OLAW when a funding component informs them that an award is being issued...

- **OLAW:** That is correct. The Assurance is a different document from the MOU and one does not replace the other. There are many other types of documents that may come into play during collaborations between institutions such as contracts, subawards, cooperative agreements, etc. Coordination with the institutional sponsored programs office and the funding component's grants management offices is strongly advised.

Question G: For foreign work, is an OLAW Foreign Assurance required?

- **OLAW:** Yes. If activities are conducted at a foreign site and are sponsored by PHS or the other entities mentioned over which OLAW has jurisdiction, a Foreign Assurance is required.

Question H: Is this template intended to be used as a component of/attachment to the FDP subaward template or separately?

- **FDP:** This is intended to be utilized separate from the FDP subaward template. If both parties are amenable to incorporating it as part of the document, that is acceptable practice, but it is designed to be a stand-alone agreement.

Question I: Can the FDP MOU be used as an alternative to an interinstitutional agreement? The user manual says the MOU can "supplement" an interinstitutional agreement, but it isn't clear how the agreements differ.

- **OLAW:** This webinar was presented to introduce the MOU template but also to clarify the confusion about the many documents that may come into play during collaborations. The Interinstitutional Assurance is a completely separate document required by OLAW when one institution is relying on another Assured site as the entity at which the animal work will be conducted. The MOU supplements and clarifies the animal specific issues that may be encountered in a collaboration involving animals.

Question J: What is the difference between an off-site waiver and an MOU?

- **OLAW:** These are separate instruments. The MOU is a formal written understanding between two collaborating institutions which addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight. It is not clear what is being referred to as an off-site waiver but it is not the same as the MOU.
- **FDP:** Concur.

Question K: Is the intention to use the template for collaborations with US entities only? How can the MOU be adapted for use with foreign collaborators?

- **OLAW:** The information outlined in the MOU is the same whether foreign or domestic. As with a domestic site, information about the foreign entity at which the work is performed is to include responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight. For entities over which OLAW has jurisdictional oversight, a Foreign Assurance is also required.
- **FDP:** If the foreign site in question has an OLAW Assurance, you may utilize the MOU sample.

Question L: Our institution requires that the Chief Financial Officer also sign any MOUs. Is it acceptable to have two institutional signatures on the form?

- **OLAW:** Yes. There is flexibility in how the document is used and modified to fit the specific circumstances involved in the collaboration.
- **FDP:** Yes, you are welcome to modify your signature block as required by your institutional process. That does not require removal of the FDP moniker.

Question M: Is it acceptable to have an IACUC administrator sign these?

- **OLAW:** Yes, if this individual has the authority to actually bind the two entities to the terms and conditions of the MOU.
- **FDP:** Concur.

Question N: Who should sign this document? The IO [Institutional Official], or the IACUC administrator?

- **OLAW:** It is up to the institution as to who should sign.
- **FDP:** Concur.

Question O: Why is the effective date is 5-years or throughout the funding related to the MOU and not associated with the protocol lifespan?

- **OLAW:** The institution can set the dates. Most NIH grants are for 5 years but different time periods may be used.
- **FDP:** Concur.

Question P: Would you require a new MOU when the IACUC protocol associated with the MOU meets its 3-year lifespan?

- **OLAW:** Not necessarily if there are no changes upon renewal of the protocol. The MOU dates can be adjusted to fit the length of the project.
- **FDP:** No, the MOU has a 5-year lifespan, but you can amend that to fit the expected duration of the project, including a broad phrase about the MOU continuing for the duration of the project.

Question Q: Let's say the MOU highlights a specific protocol number and the MOU is good for 5 years, but protocols are approved for 3 years. Once the protocol is resubmitted after 3 years, it is given a new protocol number and approval date. Does the MOU then need to be reestablished at this time or is this something that can be updated between IACUC Offices?

- **FDP:** No, the MOU has a 5-year lifespan, but you can amend that to fit the expected duration of the project, including a broad phrase about the MOU continuing for the duration of the project.

Question R: Question: Is this MOU template better suited for single projects for PIs rather than for hospitals or institutes, as it does not cover fee structures for collaborations? Also, if involving "broad MOUs" [an MOU covering more than 2 institutions or protocols], what happens when one project is canceled - is the MOU void? Is it more complicated if covering multiple protocols since linking it to the protocol numbers etc., and rather for 3 years than 5 years - since numbers change?

- **OLAW:** The MOU may either be project specific or institution specific (such as recurring procedures at an imaging facility). Fee structures should not be in the MOU as this needs to be addressed in other instruments. The MOU is specific to animal activities and can be used by any entity involved in collaborative work. Specific changes over time such as protocol cancellations need to be handled on a case-by-case basis as they arise.
- **FDP:** As the MOU user manual highlights, MOUs and subawards are complementary. If you are exchanging funding on a collaboration, you may need a subaward or another legal document to solidify the terms of that part of the partnership. The MOU is really specifically about animal care expectations, not funding. I would also note that any type of entity with an OLAW assurance can utilize the MOU, whether a hospital, institute, company, or university.
 - The question also asked about voiding the MOU if a collaboration is cancelled. I would say yes, you don't need to formally void or terminate the MOU since there is no funding contemplated, but it might be nice to make sure the other party is aware that a collaboration listed in the MOU will not take place.
 - I would also offer that yes, protocol numbers are updated every 3 years, but institutions should have records that link each iteration of the protocol together so I don't think it is critical to notify when a protocol number has changed because the institutions should be able to use any iteration of the protocol number to initiate discussion about a protocol.

Question S: For the transportation section, should this section address regulatory responsibility during transport? We are seeing more institutions relying on the transporter for responsibility and not wanting to address ownership or responsibility during transport.

- **OLAW:** The *Guide* specifically states that the MOU is to address animal activities “beyond animal transport”. The sending institution is responsible for the animal preparation prior to shipment and for employing a reputable shipper that will safely transport the animals. Ownership is not relinquished during transport. The receiving institution is to notify appropriate entities when animals arrive dead or in distress. OLAW and/or USDA will address the specifics of animal transport noncompliance as it occurs and will work with the shipping institution, the receiving institution, and the transporter as necessary.
- **FDP:** Concur.

Question T: Animals go from institution A to institution B. Research protocol is with institution A. A professional courier takes animals from A to B. A ships them. Who is owner when animals in transit? Institution A, Courier, or Institution B?

- **OLAW:** (See OLAW FAQ F.12 and *Guide* pp 107-109.) Ownership remains with institution A until the animals are safely received at institution B, unless other arrangements are made in the MOU. “When animals are shipped from an institution, that institution should consider and address all relevant factors to ensure safe transport of the animals”.
- **FDP:** Concur.

Question U: The manual states "Staff/employees of Party 1 will visit the facility of Party 2 to care for/use animals in research; OR Party 1 purchases and retains ownership of the animals while Party 2 cares for/uses the animals in research...." will an MOU be needed if the individual is a grad student at Institution A but interning at Institution B? In other words, if there is no funding involved?

- **OLAW:** Funding is not the determining factor, rather it is whether the institution is subject to the provisions of the *Guide*. The items outlined in the question are exactly the types of stipulations to include in the MOU.
- **FDP:** Concur.

Question V: With the example provided, is the IACUC office expected to know that there is a collaboration not being funded by institution A, that involves work with animals at the collaborating institution? If yes, are there suggestions about how this information would be provided to the IACUC office? For example, if a chemist at institution A is working with a collaborator at institution B to generate a drug and this drug will be administered to an animal at institution B but there is no grant, no funding from A to B or vice versa, how does the IACUC office fit into this scenario?

- **OLAW:** The IACUC office needs to be aware of this proposed collaboration and apply the MOU where applicable. The PHS Policy is applicable to all PHS-conducted or supported activities involving animals, therefore funding is not the only consideration.
- **FDP:** In the situations I have seen, in the NIH grant application, there was information about the unfunded animal related work referenced in the scope of work. I would recommend that the

IACUC discuss with the office of sponsored programs how they can help identify these situations because it should be documented in the grant application. I would recommend utilizing the award set up stage to initiate contact so you don't see every project, just the ones that move forward.

Question W: When a grant recipient has a subaward to a collaborating institution for all the live animal work in the grant, the IACUC at the recipient institution may not be aware that an MOU is needed (not aware of the grant). The FDP subaward template language that includes reliance language has helped bridge this gap. Will the MOU be linked to that template so the grant recipient and collaborating institution can complete the MOU or at least trigger a discussion if one is desired?

- **OLAW:** It is up to the institution to determine how to apply the MOU. It is important to have communication between the sponsored programs office and the IACUC office to ensure that all entities that have a "need to know" are apprised of the arrangements.
- **FDP:** I am unsure what you mean that the recipient institution may not be aware of the grant. I think you are asking how to connect the dots between the IACUC and the sponsored programs office so you can more easily identify when MOUs are necessary and/or which MOU goes with which subaward.
 - On the connecting the dots piece, I would look at the user manual, there information there about jump starting those conversations and identifying where pathways between offices need to be created.
 - On the identifying the MOU/Subaward connection: if you have a subaward that you know has vertebrate animals connected to it, I suggest sending the grant number to the IACUC. The IACUC protocol often identifies all associated grants. Many IACUCs are therefore able to search their databases and identify which grant goes to which protocol, which then will identify the relevant MOU.

Question X: Should you still use an MOU when the institutions do not have the same registrations, like AAALAC International Accreditation, for example?

- **OLAW:** The MOU is applicable to all entities using the *Guide*, which includes Assured sites and AALAC Accredited ones. The MOU is applicable when there is any form of interinstitutional collaboration involving animals.
- **FDP:** Concur.

Question Y: Do you know if the VA will accept this MOU when collaborating with Affiliate (Assured) institutions?

- **OLAW:** The VA MOU form is to be used in this situation.
- **FDP:** Concur.

Question Z: We're seeing more and more instances where subaward institutions do not want to share their IACUC protocol with an awarded institution due to privacy policies. Instead, they want to give a truncated form describing the animal work. How does the awarded institution conduct a congruency review when they cannot view the entire program from the sub?

- **OLAW:** This is a perfect example of why the MOU should be used and why these types of responsibilities (i.e., congruence review) are to be spelled out in advance.
- **FDP:** You can document the responsibility for congruency review in the MOU. I think that might be the best way to manage this concern.

Question AA: Would it be appropriate to say N/A for the USDA when no USDA species is involved? This is a tricky question - suggestions or thoughts are welcome. For wild animals being captured, who owns the animals?

- **OLAW:** If USDA species are not involved, then check N/A. Wild animals are usually owned by the state. Check the permit for details.
- **FDP:** Yes, N/A would be appropriate.

Question BB: Would there be guidance on creating an MOU for an institution like ours who has a few remote Field Stations and offers PIs from other universities to perform research or teaching with vertebrate animals there? There seems to be many specific details to be worked out to delineate the responsibilities for animal work in those locations.

- **OLAW:** Yes, this would be a great use of the MOU to avoid problems and blame when things go wrong.
- **FDP:** I can certainly bring the idea of another type of sample up to the committee. In the meantime, you may want to consider modifying the sample specifically for your field stations.