**TRANSCRIPT**

**Webinar:** Subaward Requirements: Domestic & Foreign

**Event Date**: Tuesday, October 17, 2023

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Cynthia Dwyer: Welcome to today's webinar on NIH Subaward Agreements: Domestic and Foreign. We are expecting potentially thousands of you attending today, so we're going to delay the start just for a moment to allow, for those logging in, the opportunity to catch the entire presentation. While we are waiting, we want you to be sure and check out the top, right corner of your screen with today's webinar tips. This virtual platform is very engaging, very customizable to fit your needs. So, in the corner of each of the feature boxes that you see on your console or screen, you have the option to minimize or maximize each of those boxes. You can even grab a corner and make it small or larger. If you minimize it because you don't want too much on your screen, don't worry. All it has done is moved down to the bottom navigation bar where you see other icons. You can easily click it, and it will show right back up on your screen. In that feature bar, you'll also see other items that are not on your console, such as the "Share a topic" box where if there are webinars or events you would like the NIH to provide, you can share a potential topic, as well as the all-important feedback form, we really would like you to fill out before you leave today. During the registration process, we received hundreds of questions and topics of interest, which were used to help develop this presentation. The Q and A box should be used for questions that can help us with FAQs, but we also have technical staff. If you're having any kind of difficulty, you can put those issues in the Q and A box, and we'll be happy to help. So please explore, learn, interact. We hope you enjoy the opportunities today. The National Institutes of Health and you play important roles in advancing scientific research and discovery. And this often means collaboration between various institutes, institutions, universities and organizations. Subaward agreements are a fundamental component of this collaborative approach, and in just a moment, NIH policy leaders will be walking you through the intricacies of NIH subaward agreements. They'll also be discussing the purpose, key elements, compliance requirements and best practices. Their objective is to provide you with vital knowledge and valuable insights for navigating and managing subaward agreements. This is not focused solely on the foreign policy information that was recently published. Their objective is to provide you that knowledge in a format that includes a presentation, followed by a deeper dive to answer many of those questions that you've already asked as well. I'm Cynthia Dwyer, the Outreach Coordinator for the NIH Office of Extramural Research. I would like to extend a very warm welcome to all of you joining us from around the globe and introduce you to our presenters today. From the NIH Office of Policy for Extramural Research Administration, also known as OPERA, I'd like to introduce the Director, Ms. Michelle Bulls, and Deputy Director, Ms. Kristin Ta. Without further delay, let's begin our exploration into NIH Subaward Agreements: Domestic and Foreign. Michelle and Kristin, over to you.

Michelle Bulls: Thank you so much, Cynthia, and thank you and a warm welcome to our participants. We are really excited to be here today to talk to you about some key elements of subaward requirements. We know how important it is for prime recipients to collaborate and maximize the scientific outcomes of projects, and in some cases, it does require a subrecipient. So in those cases, we want to make sure that you understand the need to highlight the scope of work that will be outlined in those sub agreements and outline the need for the collaboration and making sure that that scope of work and the deliverables are clear, both to the recipient institution, which is the prime, as well as the subrecipient, and outlining those key elements in those agreements are extremely important. So, without further ado, I'm going to start down the slide deck row. So, what is the role of the prime versus the sub? I talk a little bit about the fact that we want to make sure that within our scientific world, we are able to continue to collaborate and maximize the opportunity for research outcomes. So, when that is at play, there are times where the prime might need to reach out and have a third-party collaboration with the sub, whether it's domestic or foreign. And in those cases, we try to outline a few areas that NIH is very much willing to have our recipient community be accountable for. That is, the performance of the project, the appropriate expenditure of the grant funds by all parties, as well as the applicable reporting requirements and then other obligations of the recipients as outlined in the NIH Grants Policy Statement. The main message here, really, is that the recipient cannot be a conduit. So, the prime recipient must perform a substantive role in the conduct of that planned research. We cannot funnel money through the prime to a sub because that's not a collaboration. That's a conduit, and so we want to make sure that, at the very least, that the recipient where the application has come from was peer reviewed and that that main science is taking place in that recipient institution, the prime. And then, we want to make sure that all of the other areas, including the appropriate oversight, scientific and programmatic specifically, as well as the financials and the administrative requirements are related to the grant. That information and that accountability is shared, but the only way that's going to be shared in real time is to have that in the written agreement, so the other piece of this is that while the grant is made to the prime recipient, the prime recipient when it enters into a collaborative space, those terms and conditions that are placed on the prime flow down to the sub. Kristin, did you have anything you wanted to add?

Kristin Ta: No, I think you really hit on the key points in that the flowing down is really one of the biggest ones, right? The prime is the one that we work with, that's responsible for the award, and their terms flow down to all of the subs.

Michelle Bulls: So, when you're setting up your subaward agreement, it's really that partnership and that collaborative space, again, between the prime and the sub. And when you enter into that formal written agreement, with each subrecipient we have to address the key requirements because back on the first slide where we talked about making sure that we have appropriate oversight and that those terms and conditions flow down, we want to make sure that written agreement highlights all of those pieces. And so, with that being said, in the written agreement, we must make sure that discussions are taking place between the prime and the sub and that the prime clearly articulates what those terms and conditions are to the sub. There are scientific, administrative and financial reporting requirements that are placed on the prime, so where those requirements, those ... Again, we talked about the fact that they flow down. That same bit of information flows down to the sub. The sub takes on a portion of that project because it's an overarching success, right? So, making sure that that sub has an understanding of what the compliance is with ... or the rules are with complying with those federal regulations and policies to facilitate an efficient, collaborative venture, is critical. There is no way around not understanding from the sub what the prime is being held accountable to by the NIH, because if the prime does not give and have those discussions about what the terms and conditions are, going through both the programmatic, scientific, financial and administrative requirements, the sub will be at a disadvantage. So that's why setting up those subaward agreements and having those discussions between the AORs, which is the Authorized Organization Representatives, at both institution is going to be critical. Kristin, did you want to add anything to that piece?

Kristin Ta: Yeah. I think the partnership is really the important thing to emphasize, like you were saying, right? Setting those expectations up-front in the written agreement so that everyone knows exactly what's expected throughout the whole life of that project.

Michelle Bulls: The only other thing that I would add to that, though, is that I want to make sure that folks understand that each of the subaward agreements are very nuanced. So, while you have a standard set of elements that you want to cover, each project is specific, and we need to make sure that while we cover those standard elements, the projects and the information that goes in those standard elements are specific to the project. Otherwise, you just have a standard, and what we see often times, Kristin, really, is that folks continue to just cut and paste an old subaward agreement into their new subaward agreement, and they don't take under advisement the nuances of the terms and conditions of that specific award. And that is a dangerous place to go. We need to make sure that those ... each element is very clear and very nuanced and very specific to each project, and that is really critical. Where there are questions, though, I think we need to make sure that we contact our funding ICs, so we do encourage you to reach out to your IC to ask questions and also offer comments, where that's at play. So, in setting up your subaward agreements, we want to make sure, again, that ... Oh, wait. Written agreement elements. Sorry, guys. In the key elements for the written agreement, we want to make sure that you provide the detailed requirements for each subaward agreement. We need to know who is going to be the subaward lead and why ... the lead investigator, and why that's important is because we have to have a lead in order to make sure that the scientific oversight of these subawards are at play. We also recognize that there needs to be procedures for how and where the direction and monitoring of the research effort is coming from. We need to be sure that those procedures are followed in terms of reimbursing for each subrecipient for its efforts. We need to make sure that there are financial management systems in place, at the subrecipient site, that will accommodate accounting structures and a lot of different areas that is important for us to be able to make sure that you can pass an audit as well as NIH. Kristin, I know that sometimes we have scenarios, really, where you might have the prime that has a strong financial management system in place, but then you have the prime that might not have such a strong system in place. And I think we have to make sure that as these collaborations are developing and crystallizing, that the sub is able to manage and support the funds and the research that's coming their way from the sub ... I mean from the prime. Did you want to add anything before I go through the rest of the bullets, because I think this is really a huge area where we find a lot of noncompliance?

Kristin Ta: Absolutely, and I think you really hit the nail on the head when you talked about just copying and pasting and using the same language over and over, right? We're providing these key elements, but you really have to think through, "Okay, for this project, what procedures do I need to put in place to monitor this research? How often do I need updates from my subrecipient? What information do they need to be sharing with me?" And really laying that out from the outset, right? You can't just paste in, "I will provide" ... "They will provide me with reports," right?

Michelle Bulls: Right.

Kristin Ta: What does that look like? You need to be specific.

Michelle Bulls: Very specific. And I do think where ... A lot of times at NIH, we talk about consortium agreements too, right, in the Grants Policy Statement under 15.2.1. And I think we really need to make sure that all of our participants here understand that the subaward agreement and the consortium agreement is the same. We use those terms interchangeably depending on the type of project. And I think you hit the nail on the head in terms of those details, because we do need to make sure that the policies, such as travel, reimbursement and fringe benefits, financial conflict of interest. While that might be a bit different at the sub site, it needs to map to the requirements in the NIH Grants Policy Statement. The other piece of that too, and the reason why that is extremely important, is because having that discussion and those collaborative discussions between the prime and the recipient are critical because NIH does not deal directly with subrecipients. We only deal with our prime recipients because that is where the legal relationship lies, and I think we just need to be very clear that when subs have concerns or subs have questions, you really need to go back to that prime, talk to the prime about what's in these written agreements and make sure all those critical pieces are laid out. If there are any questions, I think we need to make sure that we empower the primes to say that the agreements cannot be signed until all of these details, like you just said, are crystallized, and that's very, very important. Another area is making sure that ... and I don't know why my slide is doing this, but anyway ... making sure that another area that is really clear is intellectual property and addressing ownership and disposition of data produced under the subawards. It's extremely important that those inventions and patents and co-authorships and authorships are laid out in that subaward agreement key elements, and those discussions need, again, to take place between the two institutions, the prime and the sub. Where there are questions about IP and data sharing, please be sure to reach out to your institute or center because, Kristin, I think a lot of times what we see is that folks will highlight the fact that, "Oh, well, it wasn't very clear what IP requirements were." And while they look at the terms and conditions of the award, and they look at the standard terms and conditions in the Grants Policy Statement, there may be some nuances that the prime recipient wants to see, or there may be nuances in the terms and conditions of the award. So, I think it's really critical for us to at least let our participants here know that if there are any changes, any details related to IP, that has to be explicitly laid out, and it needs to be done so sooner rather than later. And I know that you've seen some challenges as well with public policy requirement provisions, if you want to highlight those, because I think that's another area where we see differences that are not crystallized or, at least, understood before the agreements are signed.

Kristin Ta: Right, and I think that's where some folks get themselves into trouble when they just use really general language in their subaward agreements. Because like you mentioned earlier, some of the prime recipients may be institution that have a lot of NIH grants. They're very experienced. They know all of the requirements and how to follow them, and so they may make assumptions that their subrecipients have those same understandings.

Michelle Bulls: Yeah.

Kristin Ta: And if you're not laying out all of the specific requirements in that agreement, folks might not be aware of some of the requirements that need to apply and need to be complied with. So, it is really worth everybody's time up-front to lay out all of those specific requirements. It'll prevent compliance issues, IP disputes and all that type of stuff down the road.

Michelle Bulls: Yeah, and I think, also, one of the areas that we talked about on our previous slide was the administrative piece, like financials and performance and progress reports. You need to have timelines outlined in your written agreements. You can't expect that when a progress report is due to NIH, that you're going to be sending ... the sub is going to be sending their progress report or financials to the prime, at the time that that report is due. We oftentimes see a lot of lag time with subrecipients providing details of progress and financials to the primes, which has created a challenge, especially for closeout.

Kristin Ta: Mm-hmm.

Michelle Bulls: Because we're waiting for details and invoices and final financials, and the prime is on hold and cannot close these awards out because they don't have the details from the sub. And so, in these cases, we need to make sure that you all understand that it is critically and vitally important for you to even include dates. I think that's the piece. You include the dates for your performance reports. When do you want your subs to submit those reports, or when can the subs submit it? Put it in your written agreement. When do you want your financials? Put that in the written agreement. And the reason why that's really important is because NIH has a requirement, and that's a standard term and condition. When the prime, who has the legal relationship with NIH, is delayed, that looks bad on the prime. That causes the prime to be out of compliance, and so we want to make sure that we keep this collaborative space very sacred, and having those details in the written agreement is going to be critical. You agree?

Kristin Ta: Absolutely, and to your point about closeout, right, it's the prime who's going to be the one that's getting reported in SAM.gov for not complying and going into unilateral closeout, right, so you have to make sure ...

Michelle Bulls: That's right.

Kristin Ta: ... that you, as the prime, are keeping everything in order and getting stuff on time so that you can be on time and in compliance.

Michelle Bulls: That's a very good point. Thank you, Kristin. Let's hope I can get this right this time. So, for prior approval for subaward agreements, for the domestic subs, we generally do not require prior approval for each agreement. Now, there might be a term or a clause in your term and condition that might be different, or it might be something in the Notice of Funding Opportunity that might be different. Those are nuances. Those are very anomalies, but for the most part, NIH does not require prior approval for domestic subs. Where you have a foreign sub, that is always going to require prior approval. You will rarely, if ever, see a change in the NOFO or in the terms and conditions. And then, of course, for a change in performance site with a foreign entity or foreign country, the addition of a new performance site in a country other than what was specified in the approved application does require the awarding IC's approval. And of course, if you're transferring the work by a domestic recipient to a foreign component, that will also require IC prior approval, and that goes along with the principles up top, where we talk about the fact that foreign subawards will require prior approval. We do note that there are sometimes where that is not always clear. Kristin and I answer a lot of questions, including our staff members answer a lot of questions about that kind of thing. And so, this is really about the subaward agreements and the foreign subs, not necessarily foreign components, which is a separate policy. So, for our foreign subaward agreements, this is one where we provide a clarification not too long ago, and I know many of you probably said, "Oh, we are joining this because they're going to be talking strictly about the foreign subaward agreements and this updated policy". But this is really not a new policy. This is really a clarification and pulling out the existing requirements that we already talked about up-front, and that is that any time that you are providing a collaboration to maximize the scientific outcomes, you need to provide the written agreement in a ... Well, you need to provide any details that would inform the progress report. And so, in this case where we talk about the foreign subs and the written agreement must include provisions for requiring subrecipients to provide access, whether electronically or otherwise, to copies of all lab notebooks and data and any documentation that supports the research outcomes as described in the progress report. Remember, this is a collaboration. So, every part of that collaboration is important to inform NIH's progress reports. It's an overarching review of the scientific outcomes, both successful or otherwise. And of course, we talk about the fact that it may be entirely electronic. What we don't talk about on this slide, that I think is extremely important, and that is that NIH responded to an OIG recommendation, so this is not something that NIH decided that we were going to clarify. The OIG was very clear that NIH needed to make sure that we highlighted the fact that any kind of written agreement must include a provision that provides access to any documentation that informs that progress report. And so, we pulled that out because we wanted to make sure for our foreign subrecipients that that was very clear. We also want to make sure that our primes understand that if there are any needs ... if there's a need to update any existing subaward agreements to address this requirement, it must be done so within 60 days of the effective date of the notice that was issued. So that means that that would be March 1, and that is extremely critical, because the date that it starts is January. So, we didn't put that in the slide, but that's when it starts. We got a lot of feedback about the need for us to give folks time, so the effective date is January, and the existing agreements need to be updated within 60 days. If you need additional time, we want to make sure that you know that NIH is open, and you need to contact us, and we will work with you to provide you with that additional time. That's extremely important to note as well. And then, of course, we all know that our recipients must retain the records in accordance to the record retention policy in the uniform regulations and as implemented by the NIH Grants Policy Statement. And that is that it must be pertinent to the entire competitive segment for 3 years from the date of the final FFR and when that is submitted to the NIH. So, if there's an extension on the grant, and then the final FFR comes later, again, these principles apply. And I think, Kristin, I think one of the things that we want to make sure of, as folks are walking away, is to make sure that they understand that January timeline ... or the effective date is critical because we worked really, really hard, wouldn't you say, to just try to make sure that we heard the concerns of the community?

Kristin Ta: Yeah, absolutely, and I think, too, I just want to point out when we have links on the slides as well, but there are some really detailed FAQs and a blog post and a whole video that you, Michelle, did with your colleagues here at NIH. So, I think if folks want to learn more about this, that would be a great place to start.

Michelle Bulls: Agreed. I don't know if you want to kind of talk about the compliance component, because when we say recipients must provide access to NIH upon request. I think we've been very clear even in some of the presentations and the FAQs that NIH will be conducting a audit or not an audit, but a compliance review.

Kristin Ta: Mm-hmm.

Michelle Bulls: Compliance review, not audit. So, I want to make sure that folks understand that that is really critical because we assumed that many of our prime recipients and others understood that requiring lab notebooks and data that documents and informs the progress report was already at play. But seeing that recommendation from OIG, I think we were kind of stunned that that was something that was kind of missing, wouldn't you say?

Kristin Ta: Yeah, for sure, because that's a regulatory citation that we have bookmarked, and we put that in all the time, right, recipients and subrecipients have to make things available to NIH so that we can review and answer questions that we might have about a project. So, it definitely was a surprise when we had those specific cases where we weren't able to get access and realized that maybe it wasn't being implemented as we thought.

Michelle Bulls: Agreed. So, we have, as a result of just making sure that we communicate outwardly our Grants Policy compliance requirements with regard to subaward requirements and agreements, we work with our Division of Communications to stand up a subaward website, and they did a very good job of highlighting all of the resources. And they're outlined here and linked here. And also, we included FAQs on NIH subawards, which does include the latest clarification. And then, I think, like Kristin said, we have this open mic blog that provides the further clarifying information regarding the subaward and the fact that we truly did make sure that we acknowledged and addressed the community's feedback. I think that NIH leadership did an amazing job in making sure that these ... the comments that we received were thoroughly vetted, thought through and addressed in a very collaborative way. So, then, of course, we have the NIH Grants Policy Statement in Chapter 15, which will be updated soon to have and include all of these various changes that you see here. So, Kristin and I are excited to test your knowledge, and so we have this test your knowledge slide deck that we want to walk you through. So, Kristin, I'm going to turn it over to you while we test the knowledge and go from there.

Kristin Ta: All right. So, we've got some questions that kind of go over some of the things we've covered today and build upon those a little bit, so we're going to use some polls, hopefully successfully here, to see if you guys have all been paying attention and have been picking up on what we've been sharing. So, our first question here, and you can go ahead and plug in the answer that you think is correct. We have a couple of examples. These are just examples of agreement language, and we're going to ask you which one you think would be the better example of what kind of language should be in an agreement. So, answer A: "Subcontractor A agrees to report progress to Prime Recipient B. Prime Recipient B will review the work performed and may conduct site visits as appropriate." So that's your first choice. And the second choice: "Subcontractor A will submit quarterly progress reports to Prime Recipient B and will provide all relevant supporting documentation, upon request. Prime recipient B will review the quarterly reports and provide feedback on work performed. Prime recipient B may conduct site visits to assess progress as needed." So, we'll give you guys a second to plug in your thoughts. All right. And I'm going to move forward in just a second, so we got about a third of folks in. All right, so let's see what everybody thought. Oh, fantastic. You guys ... Most of you guys went with the right answer there. So, what we were really trying ...

Michelle Bulls: Yes.

Kristin Ta: ... to get at here, and we've been kind of hammering home the whole presentation, is details, details, details, right?

Michelle Bulls: Yeah.

Kristin Ta: It's important to include those details on the timing of report submission, the requirements to make available all the supporting documentation that goes with progress reports. And this is really important because if you use kind of that general language that just says, "They'll give us reports. We'll look at them, and we might do site visits," something really high-level and general like that. If down the line a compliance issue comes up and folks ask, "Hey, how often did you get reports? What was in them? Did they tell you what was going on?" You're not going to be ... You, as the prime, are not going to be supported in what you need to provide, and it's also going to make challenges for the subrecipient as well. So, it's really important to get all those key details up-front in your agreement.

Michelle Bulls: I agree. What I think the one thing that we want to highlight, Kristin, is the fact that if you don't put those details in, and there's a compliance challenge, NIH can't support you, right?

Kristin Ta: Mm-hmm.

Michelle Bulls: Because if you say, "We asked them to put the ... We asked for this ... the documentation," but you don't highlight when you're going to get the documentation or how you're going to get the documentation and what's going to happen as a result with the subrecipient that they don't have the ... they don't provide it to the prime. That's a challenge, and those are the key, critical details. NIH cannot support the prime if we don't have those details, and so we want to keep everybody compliant. The goal is not to come out and be the compliance police of the NIH, but the goal is to make sure that you have all of the necessary information that you need to maintain compliance both at the recipient institution, which is the prime, and the sub.

Kristin Ta: Exactly, right. Everyone wants to think that agreements are always going to go well, and everyone is going to submit stuff timely, and it's going to be great. But then when challenges come up, it really is important to have that strong written agreement to support you.

Michelle Bulls: Exactly.

Kristin Ta: All right. On to our next question. It's a little bit hard to read here. So, which of the elements below should be outlined in a subaward agreement? And so, you're going to pick all of the ones that apply. So, A: "Schedule and method of reimbursement." B: "Statement of work and schedule for any required deliverables." C: "Policies for travel reimbursement and salary and fringe benefit costs." And D: "Requirements for providing any supporting documentation." So, we'll give folks just a second to fill in your answers there before we move on. All right. So, looks like we've got about a third of folks responding, so I'm going to move forward to the answer. Okay, so looks like most folks chose the majority of these items, so let's see. The answer is ...

Michelle Bulls: All.

Kristin Ta: .. all of the above.

Michelle Bulls: That was a trick question, guys.

Kristin Ta: The more information, the better, right? And I also ... I see some folks putting their answers into the Q and A, so make sure you're answering in the poll section so that we can get your answers as part of the poll responses.

Michelle Bulls: Mm-hmm.

Kristin Ta: So, like we've been saying, laying out the timing and documentation requirements for invoicing is critical. You need to know the expectations, and your subrecipient needs to know when things are due to you, as the prime. Setting up expectations about how frequently invoices will be submitted, how payment will be provided. And like Michelle was saying, consider your responsibilities to report to us when you're setting deadlines for your subrecipients, right? So, if NIH needs your closeout reports within 120 days, you need your subrecipient's reports 90 days after, or even sooner if you need time to get your stuff together and time to get it to NIH. So, think about those timelines up-front. It's also really important ...

Michelle Bulls: Especially if there are multiple subs, right?

Kristin Ta: Mm-hmm, right. For really complex projects, you might need to do ...

Michelle Bulls: Yes.

Kristin Ta: ... less than 90 days so that you have time to get everything in order as well. That's huge. And I saw a few folks didn't pick this last piece here about things like travel reimbursement and salary and fringe. But it is really important to outline what the expectations are for travel policies, salary and fringe benefits, especially because policies might differ between the prime and the sub. And so, you don't want to, as the prime, assume that they're going to be submitting costs in a way that aligns with your policies if that's not how they normally do business, so you really need to lay out what those requirements are from the outset.

Michelle Bulls: And if there are differences, those need to be ... I'm sorry, Kristin. Go ahead.

Kristin Ta: Oh, I was just going to hit on this reminder about the requirements flowing down from the prime to the sub.

Michelle Bulls: Yeah, because where there are differences, I think those need to be reconciled before these written agreements are signed and put into place. I find ... So, Kristin and I have talked a bit about this closeout challenge that we've seen over the years. And a large part of what we've seen is that there are some different policies across the various recipient communities, right? And so, where those differences are, you need to outline those and reconcile those before you sign that written agreement, because one of the things that happens is that the prime is held accountable for the delays. And so, where there are differences, those pieces need to be pulled out, addressed up-front, and if there can't be ... If you can't reach an agreement, that needs to be made clear, too. And I think one of the things we didn't say, Kristin, which is really critical, is where you can't get that clarification and that additional information in terms of the lab notes and making sure that that documentation supports the Research Performance Progress Report, which also informs the Federal Financial Report, which is the FFR ...

Kristin Ta: Mm-hmm.

Michelle Bulls: ... the agreement should not be signed. We have to have a open discussion among our primes and our subs that these are elements that need to be broken down, and there is no way around it. It has to be very clear or the agreements cannot be signed. And I don't know that we said that, but I think that's something that we needed to go back to, so my apologies.

Kristin Ta: Yup, that's huge, for sure. All right. So we've got another question here for you guys to take a look at. If NIH asks a recipient to provide supporting documentation related to a foreign subaward research outcomes described in the RPPR, and the recipient can't provide them, what will happen? So A: "Nothing. Supporting documentation is not required." B: "NIH may take one of more enforcement actions on the prime recipient." And C: "NIH will request the documents directly from the subrecipient." And I hope you all get this one right because we've been talking about this the whole time, so we'll give everyone ...

Michelle Bulls: They will.

Kristin Ta: ... a second to put in their answers. All right. It looks like we've got most folks, so I'm going to move forward. Okay, so 98 percent of you got that right answer, and we are going to talk about why that last bullet is not correct as well, but let me just move forward. So as we've said a few times, NIH needs to have access to any documents, papers or other records that are pertinent to that federal award, so that includes any support for the progress reports that you are submitting to us as the prime recipient. And as that primary recipient of the NIH funds, the prime recipient is accountable to NIH for providing the requested documentation. As Michelle said, I think I said it too, we don't have a direct relationship with those subrecipients, so if we ask the prime for it, and they can't provide it to us, we can't go ask the sub for that information. It's the prime's responsibility to give us any requested supporting documentation. And if the prime isn't able to do that, that's a violation of the terms and conditions of the award and can lead to enforcement actions or other remedies for noncompliance with the terms and conditions. Do you want to add anything to that one, Michelle?

Michelle Bulls: I think we hit that one home a couple of times.

Kristin Ta: All right. So let's move on to our next question here. So when a subrecipient needs prior approval for a change to the project, what should they do? So A: "Prior approval requirements do not apply to subrecipients." B: "Subrecipients may contact the NIH Awarding Institute or Center to request prior approval." Or C: "Subrecipients must contact the prime, who will coordinate with NIH." Give you guys a couple seconds to answer that one. All right. I'm going to move forward here. Let's see. Ah, you guys were almost 100 percent correct on this one. So prior approval requirements for change in scope, other significant changes to the project, like a change of PI, that type of thing, those do apply to subrecipients. However, NIH's legal relationship is with the prime, subs should not be reaching out to NIH directly. They need to go through their prime recipient, who will work with NIH to get the appropriate prior approvals. So, if subs start emailing NIH Institutes and Centers, don't be surprised when they come back to you and say, "I can't help you with this. You need to go through your prime, and then we will have a conversation with the prime recipient." Okay, we've got a couple more questions here. So, this one is, Are prime recipients required to review a subrecipient's single audit report? So, A: "If a subrecipient meets the audit threshold, the prime recipient must review the audit report to ensure that all findings are resolved." B: "If a subrecipient meets the audit threshold, the prime recipient must review the audit report and take appropriate action to resolve any findings that relate to the subaward agreement." Or C: "The prime recipient is not required to obtain a copy of the subrecipient's single audit." We'll give you guys a couple seconds to take a stab at that one. All right. Let's see how folks answered here. Oh, okay, so we might need to talk about this one a little bit more. Most of you picked B, but there was a fair amount of you who picked A, so let's talk a little bit more about this one. Okay, so the answer is B. If a nonprofit subrecipient meets the regulatory requirements, the annual expenditures of 750 or more under federal awards, the recipient must receive a copy of the audit report, so I think everybody's on the same page about that, but they're only responsible for resolving findings that relate to that subaward agreement. They're not responsible for resolving cross-cutting findings in that audit report. And I know, Michelle, you wrote the language that's in the regulation for this requirement, so I don't know if you wanted to add to that one at all.

Michelle Bulls: Well, I think it's just really important for folks to understand that while you have oversight and management of your award with NIH, you don't have oversight and management of a sub's audit findings, and I think that's just the simplest way to put it. It really does need to ... The need to have a copy and to be informed is critical. The need to make sure that those appropriate actions are taken to resolve any findings related to that sub, because now what that puts ... what that does is it puts the sub ... If the audit findings are not resolved that are related to the sub, it puts the prime at risk, right? But anything outside of that, any cross-cutting findings, anything that does not relate to that sub, it's not the prime's responsibility at all. I think that is very important, and that's one that folks should truly put a pin in and document because folks do not have that kind of responsibility to regulate and monitor all of the sub's audit findings, that are not linked to this subaward agreement. Yeah.

Kristin Ta: All right. Now, I'm going to move to our last question here. What is the threshold for reporting data on subawards under the FFATA requirements? So this is the Federal Financial Accountability and Transparency Act requirements. I didn't spell out the whole thing on the slide here, and your options are A: 25,000, B: 30,000 and C: 50,000. So at what point do you have to report on your subawards under FFATA? All right. Let's see. We got a good number of folks. I'm going to move forward here. Oh. Looks like we need to update some folks on the FFATA thresholds, Michelle, but we got a pretty interesting split here. A lot of you thought it was 25,000, fair amount, 30, and a few, 50. So let's take a look at the correct answer. The correct answer is B, so it looked like a lot of you were going off of the old threshold of 25,000, but it was actually increased a couple of years ago to 30,000. And so when you have a subaward that's equal to or greater than 30,000, you are required to report on that subaward in the FFATA Subaward Reporting System, or FSRS. And so what that's going to do, is it's going to take your subaward data, and it's going to push it forward to USASpending.gov, which is where we capture all of our grant award information. So recipients are required ...

Michelle Bulls: And that's very critical.

Kristin Ta: Mm-hmm.

Michelle Bulls: Oh, I'm sorry. Go ahead, Kristin.

Kristin Ta: Oh, you're fine. Go ahead.

Michelle Bulls: Yeah, just I was going to say ... And I don't want to interrupt you because they are required to do that, but I think that the challenge here is that we have had some instances where folks have not reported, and I hope it's not because they don't think they have to. But the bottom line is, is that at the $30,000 mark, it is required, and that's an OMB regulatory requirement. That's not an NIH requirement. We're implementing it through our Grants Policy Statement, but you really, really have to pay close attention to that because, honestly, if there is ... If you don't report in FSRS, that can cause an enforcement action to ensue, and we don't want to see you guys out of compliance and us have to take an enforcement action because you've not reported in FSRS.

Kristin Ta: Right. This is a pretty simple one to check the box, right? There are some data elements that you have to collect from the sub and submit, but this is an easy one to make sure that you're in compliance with as long as you're tracking it. And in addition to providing some basic information on the subaward itself, there are some specific cases when folks are getting into the really high dollar values of their awards, where you will have to report on the most highly compensated people at that subrecipient. So it's really important to review those requirements as well and make sure that you're not just reporting in FSRS, but that you're reporting all of the information that's required because, again, we do see that folks ...

Michelle Bulls: Same for compensations.

Kristin Ta: ... miss that. Yup. All right. I think I said that was the last one, but I lied. We have one more.

Michelle Bulls: You didn't lie. You just tricked us.

Kristin Ta: Bonus question. All right. Each subrecipient on an NIH grant application is responsible for submitting a separate DMS plan as part ...

Michelle Bulls: Oh, that's a good one.

Kristin Ta: ... of the grant application. So bonus policy discussion here about DMS. If you have 10 subs, do you need 10 different DMS plans for each of them? So this is a true or false. We'll let you guys take a stab at it. All right. Looks like we've got a good chunk, so let's take a look here. Oh, okay, so about a quarter of you said true. Seventy-five percent said false, so let's take a look at the correct answer. So the correct answer is false. You do not need a separate Data Management and Sharing plan for every single subrecipient or subaward that you have on your project that you are proposing in your application. So the DMS policy expects only one Data Management and Sharing plan to be submitted with each application, so what does that mean? It basically means you and your subrecipients all need to talk at the application stage about what data management and sharing is going to look like for your project as a whole, and that needs to be covered in the one overall plan that's submitted to NIH. And then, for any costs that are associated with data management and sharing, you're going to outline that in your budget justification under your subaward budget form in a data management and sharing justification section. And if you're up-to-date with all of our DMS policies, your DMS costs will all be in the correct cost category. We're no longer doing the single line item for DMS costs. Do you want to add to that one at all, Michelle?

Michelle Bulls: So, I think it's important, honestly, that you guys always remember ... So, in some cases, some might say administrative burden. And I think what we want to make sure of is that in these cases, it's the overarching policies. It's the overarching plan that feeds into each and, again, the direct relationship with the prime, and in this case, it definitely would be burdensome for everyone to submit, especially for some of these complex grants. So just to make sure that you guys understand that while there are areas where we can manage administrative burden, where we have some level of control and understanding with the relationships. There are times with folks feel that the lab notes is an administrative burden, and that came down, of course, from OIG, and NIH needed to be responsive. And so those are the differences. But I think we're good. We have a lot of questions?

Kristin Ta: We do, so I think with that, maybe we can turn to some of the questions here in the Q and A. And I just saw one ...

Michelle Bull: So we ... Cynthia ...

Kristin Ta: Go ahead.

Michelle Bulls: Just want to see how long we have to answer these questions.

Kristin Ta: It looks like we have about 5 minutes left.

Michelle Bulls: Okay.

Kristin Ta: So here is one for FFATA. "Do foreign subs have to be reported in FFATA?" You want to take that one, Michelle?

Michelle Bulls: You said what? I'm sorry. I was trying to send her the notes.

Kristin Ta: Oh, sorry.

Michelle Bulls: Okay.

Kristin Ta: Someone asked if foreign subs need to be reported in FSRS under FFATA.

Michelle Bulls: No, they do not.

Kristin Ta: Are you sure? I think they do. I'm pretty sure they do. Any subaward that crosses that threshold has to ...

Michelle Bulls: At that threshold, the 30,000, yeah.

Kristin Ta: Yes, so if it's over 30,000, it's got to be in there regardless of who the subaward is with. And then, I see one in here about the question we just talked about related to data management and sharing, so I'll take a stab at that one. So we have a question: "If the subrecipient has no data management and sharing costs requested, do they need to include that they are not requesting money in the budget justification and applications?" So yes, even though we don't have the single line item anymore, right, so you no longer have to put a single line item with zero, but you do still have to address data management and sharing in your budget justification. So you would outline that you don't anticipate any data management and sharing costs.

Cynthia Dwyer: I'm going to jump in ...

Michelle Bulls: Yeah, I think ...

Cynthia Dwyer: Hi, Michelle and Kristin, you have about 4 minutes before we need to wrap up for our hour.

Kristin Ta: All right.

Michelle Bulls: Okay, thank you. So we have a easy question here. "What is DMS?" It's data management and sharing.

Kristin Ta: Yup, data management and sharing.

Michelle Bulls: I think this was the question where it asked whether or not FFATA was required for foreign or just domestic, and it's required for all.

Kristin Ta: Mm-hmm. So here is a good one that I think we can address. So prime institution are required to maintain documentation for 3 years after grant closeout. And someone's asking, "What's the requirement for an institution when their grant is transferred from another institution halfway through the grant? Is the new prime required to get all the past data from the first institution, or are they only required to hold data from when they were the prime institution?" And so ...

Michelle Bulls: So where's ... Go ahead.

Kristin Ta: I was going to say ...

Michelle Bulls: I was going to try to look at it myself.

Kristin Ta: Oh, I know. It's hard to in this Q and A to see all the questions. But so you, as a prime, your agreement starts with NIH when we issue you a Notice of Award, right?

Michelle Bulls: Right.

Kristin Ta: So you are responsible for everything from the point that you enter into an agreement with NIH going forth ...

Michelle Bulls: Yeah.

Kristin Ta: ... through the end of that records retention period. And so for the original recipient, they're going to have to maintain all of the records from their end through the 3 years from when their project ended at their institution, so the same requirements apply to all ...

Michelle Bulls: Because they still have to ... That's right, because they still have to commit ... submit the final reports.

Kristin Ta: Mm-hmm, and so they would maintain.

Michelle Bulls: So that's key.

Kristin Ta: Exactly.

Michelle Bulls: So this ... There was one question that was really, really good, and I was trying to find it again. Oh, man, it was a really good question about, would NIH consider ... it was about the ... I think it was about the subaward costs that ... Oh, no, it was about the lab notebooks, and it was about whether or not NIH would consider obtaining that information on an as-needed basis. Why does the prime have to get this information from ... And I think the real response to that is the fact that the challenges that NIH would need you to retain that information and make that information available because, again, it informs the progress report that you're submitting to NIH. And so, any information that goes into the reporting of progress needs to be retained by the prime. NIH will likely ask for that information, but one of the questions was, why ... If you need it, then you can ask for it at that time, and they can receive it. But anything that informs that progress report needs to be retained by the prime because that's where the relationship is. The minute that we are not able to access it at that prime site, it requires us to then go outside of the normal legal relationships, and we cannot do that safely, so I think that's just ... Unfortunately, that's just the way the regulations are written, and we have to follow that.

Kristin Ta: Yup, and with that ...

Michelle Bulls: It says, "Does a foreign prime" ...

Kristin Ta: ... it looks like we're done.

Michelle Bulls: Oh, we're done?

Cynthia Dwyer: Okay.

Kristin Ta: I think we're about to hit time, so I don't want you to start another question ...

Michelle Bulls: Okay.

Kristin Ta: ... we don't have time to answer.

Michelle Bulls: Oh, I was going to start another question. I feel horrible. There's a lot of questions we didn't get to.

Cynthia Dwyer: I was just about to tell you, you have 1 minute, but now we're down to about 30 seconds, so ...

Michelle Bulls: Okay.

Cynthia Dwyer: So, since it does look like we don't have enough time for another question, I do want to say thank you, Michelle and Kristin. This was a very informative presentation, and your polling, your knowledge tests and your Q and A, we greatly appreciate it. So, on behalf of the NIH of Office of Extramural Research, I'd like to thank all of you. We had over 3,800 live attendees for today's event. We hope this webinar answered many of your questions, and you can always go to the grants.nih.gov website for policy updates, policy information, the Grants Policy Statement, many of the resources that were discussed today. And so, we hope that you can also find what you need on this page. We mentioned it a few times in the chat, but you can return to the URL that you logged in to this event, and it will ... we will have there. We'll be updating it with the actual final PowerPoint slides and the recording as well. So, we thank you and have a great day.

Michelle Bulls: Thank you. Take care, everyone.