International Collaborations: Policies, Processes, & Partnerships

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Kasima Garst: Thank you for joining this presentation on Understanding International Collaborations. During the next 45 minutes, our presenters will be covering some important policies, processes and systems topics including common registration issues related to foreign applicants and recipients, foreign subawards and foreign components. This time frame will also include a Q and A with our attendees of the live event. My name is Kasima Garst. I am a Systems Policy Analyst in the NIH Office of Policy for Extramural Research Administration, or OPERA. I am happy to be your moderator for this presentation. Now, let me introduce you to our experts for this presentation, Michelle Bulls, the Director of the NIH Office of Policy for Extramural Research Administration, or OPERA, Emily Linde, the Director of the Grants Program at the National Institute of Allergy and Infectious Diseases, also known as NIAID, and Kristin Ta, a Senior Advisor in OPERA. Michelle, I'm going to turn it over to you to kick-start our presentation.

Michelle Bulls: Thank you, Kasima, and welcome to all of our colleagues and partners across the world. I had a nice polling, and it looks like we are very well-represented across the world. So, Kristin, you're going to get started and kick it off to me.

Kristin Ta: Yes, so today, we're going to be doing a presentation that's going to go over some policies, procedures and requirements related to international collaborations. We've broken it down into pre-award requirements and considerations as well as post-award, and then we're going to leave lots of time for Q and A at the end so that we can talk about your questions. All right. Do you want to get us started, Michelle?

Michelle Bulls: Absolutely, and so it's really exciting to be a part of this international collaboration conference. It really does speak to the vast portfolio that NIH provides, as we are probably the national leaders within the biomedical workforce, offering up to upwards, $32 billion annually in this space. And so we wanted to at least talk to you guys about the types of international research we are looking at. And we had broken it out here for direct foreign awards, health care are directly relationships with NIH, as well as domestic awards that have foreign components. And so if you see here from 2020, FY 2020 to FY 2022, we have a fair number of direct foreign awards with the domestic and foreign components. It's really shocking because though we make a lot of awards, and this might look a bit small, I will say that this is significant in terms of that international collaboration, especially with the domestic awards and the foreign components. It really does show NIH's commitment to international research and making a healthy world across the globe. Next slide. So what is a foreign component? And what we try to do is, we try to outline what we believe are activities that may meet the definition of foreign components. And it's included but not limited to the involvement of human subjects and animals. We also talk about the extensive travel by which a recipient and project staff, for the purposes of collecting data, making surveys, sampling and similar activities. We also include the activity of the recipient and the environment of making sure that the impact is on the US's foreign policy through the involvement and the affairs of the environment of a foreign country. And other examples are collaborations with foreign investigators at foreign sites where there is an anticipated result in co-authorship and the use of facilities and instrumentation at a foreign site and then recipients of the receipt of financial support or resources from foreign entities. Next slide. I'm going to move into the pre-awards phase just or us to go through what this looks like for our foreign collaborations. As you know, NIH has the NIH Guide for Grants and Contracts. NIH is very proud of our funding opportunity announcement and the breadth and depth of the number of announcements that you are able to attain through the NIH Guide for Grants and Contracts. We also had an opportunity you'll see below for you to subscribe to the NIH Guide and to obtain weekly table of contents for all of the fund activities and announcements that are going out from the NIH. This does not just mean for your funding opportunity announcements, but it also includes policy changes and that sort of thing, and that's our way of connecting to our public-facing partners and making sure that the NIH guide for grants and contracts is always up to date with the latest and greatest funding opportunity announcements, policy changes, revisions to funding opportunity announcements and that sort of thing. Reviewing the funding opportunity announcements, it's very important for our applicants because this is where you identify eligibility and where we would identify whether or not a foreign institution may or not be eligible or where we would allow for a foreign component in a certain program along with the fact that there may be a requirement for foreign components. But all of those sorts of details are going to be very critical for you to identify, and you're going to be able to find those in the funding opportunity announcements that linked to the NIH Guide for Grants and Contracts. We also want to make sure that our foreign applicants understand when and how the applicants must submit the detailed budget and who you need to contact if you have questions about any part of the funding opportunity announcement. Next slide. In continuing with determining eligibility, generally our foreign organizations are not eligible to apply for certain programs, and they're listed here on the slide. We try to be very clear in our funding opportunity announcements even though we state clearly in the policy that these programs generally do not allow for foreign organizations. If there is a change or if there is a deviation from that, you would see it in a funding opportunity announcement or a notice of special interest. Some of our funding activity codes may support projects that are awarded to domestic recipients with a foreign component, which, you will always need to review that funding opportunity announcement in order to obtain those critical details. Understanding eligibility is key to being successful in submitting an application to the NIH. Next slide. And so applying for funding and required registrations, one of the things that we tell not just our foreign organizations, but we also tell our domestic organizations, start early. It can take up to 6 weeks or more to complete registration process. We've had an interesting time with the system for award management lately, and so we are really encouraging our applicants to start prior to 6 weeks if possible. We want to make sure that you are in a position that you can submit your application successfully. And so in doing so, we want to make sure that you have all of the information you need up front, early and often. If you have questions or if you don't know what you don't know, feel free to reach out to the program official or to the contacts that are outlined in the funding opportunity announcement. For the systems for award management, that is a requirement in order for any organization or entity to do business with the federal government, and it's renewed annually. And so we recognize that while you might have done business with the federal government in the past, and you are in a renewal state, I'm cautioning you to please make sure that you reach out to the SAM to make sure that you know when your registrations are and when they expire so that you can obtain the assistance you need to get your 12-digit, unique entity identifier in a timely manner. Foreign organizations must also obtain what they call a NATO Commercial and Government Entity Code in order to register in SAM, so you need to make sure that that is available to you. We also have a requirement, of course, for eRA Commons and Grants.gov. Those are requirements that must be in order or must be in place in order to submit an application to the NIH. And then, of course, if you are funded, which, we wish you well in your application process, you have to have an HHS Payment Management System account. So make sure that you keep that as a checklist nearby so that you can have your registrations and know what you need to do, when you need to do it and which systems would require them. Next slide. In developing your budget, as I stated in a previous slide, the applications from foreign organizations must use a detailed budget. And for the domestic organizations or applications with a foreign subcontract, the modular budget is allowed, just not in a direct foreign organization relationship. We need you to review the NIH Grants Policy Statement, and we've included a link here for information on allowable cost. And we also kind of outlined here just to pull that out for specific exceptions for awards and foreign components. These are the costs that are not allowable or allowable in certain circumstances, and of course, the F&A costs for NIH grants are limited. And if you need to know additional information, we've included a link for your use beyond the presentation. Next slide. So for F&A, for foreign awards, it is at 8 percent of the modified total direct costs exclusive of the tuition and related fees, direct expenditures for equipment and subawards in excess of 25K. The bottom line really is that NIH provides a limited amount of F&A for our foreign organizations in order to support the cost of compliance, for example, the protection of human subjects, animal welfare, invention reporting and post-award requirements as well as the FCOI, financial conflict of interest and research misconduct. Next slide. So I've given you a bit of a walk-through for what's required in eligibility and successfully completing an application for your pre-award policies as it relates to direct foreign organizations as well as foreign components and subs. I'm going to turn it over to my colleague, Kristin Ta, who will walk you through the post-award administration and take you through that step. Thank you for your time.

Kristin Ta: Great. So once you actually successfully completed and received your NIH award, what comes next, right? So this is what you call the post-award phase. So once you receive that notice of award, the notice of award is going to contain all of your terms and conditions for that grant agreement. So that is the official legal document between NIH and you as the recipient that outlines the expectation for the grant award. And this includes a reference to our NIH Grants Policy Statement, which is a term and condition of all grant awards issued by the NIH and has all of the requirements, administrative requirements reporting and all the things that you need to know in order to administer your award appropriately. So on your notice of award, you're going to see terms and conditions related to things like Streamlined Non-Competing Award Process, so some of our awards fall under this, which we call SNAP, and it provides a little bit more flexibility in terms of reporting so you have to submit. Things like your federal financial report would be required only at the end of your competitive segment instead of annually. So it's important to look at those things in your notice of award and make sure that you're aware of all of those requirements. In addition to the notice of award for that prime award that's issued, it's also important to set up your subaward agreements in accordance with the grants policy statement. And Michelle and I are going to be doing a little bit more of a detailed presentation about those subaward requirements following this part of the presentation. Also, most of the public policy requirements in the NIH GPS also apply to foreign grants, so not only to our domestic recipients but also to foreign recipients. So it's important to review those requirements for things like animal welfare assurances, safety requirements and other areas to make sure that your organization is compliant. In addition, financial conflict of interest requirements apply to foreign awards, and recipients are required to submit their publicly accessible FCOI policy to NIH via the eRA Commons. So if your organization is receiving an NIH award for the first time, you'll need to upload this policy before that award can be issued, so it's very important to pay attention to those requirements. And you can see more information about financial conflict of interest policies on our OER website, which is linked here for you on the slide. In addition to looking over those general terms and conditions, you'll see that there are also specific scenarios that require you to ask NIH for prior approval. So in your initial grant application, you outlined the work that was going to be done and how you plan to do that. But of course, once the award is made, there are always going to be changes along the way, and some of those require us at NIH to review and approve before you proceed with those changes. So it's important to reach out to your grants management specialists and your program officer listed on your notice of award before proceeding with any major changes. And the types of things that you'll need to reach out for prior approval include adding a foreign component or changing one of the foreign components as part of your grant award, changes in scope. And some indicators that your scope may be changing include things like significant rebudgeting, changes to the specific aims of the project, substitution of one animal model for another or a change from the originally approved use of vertebrate animals that was in your application. You're also required to reach out for prior approval for changes of the principal investigator or other senior key personnel effort on the project. So if there is a reduction of 25 percent or more, you're required to reach out to NIH for prior approval. And as part of that requirement, it's also important to note that if the reason that the person is being removed from the award is due to issues related to workplace safety or other issues similar to that, you're required to notify NIH of that, as well, as part of this prior approval process. We also have several reporting requirements that are required throughout the life cycle of your NIH grant award. The first is the research performance progress report, so that's reporting on the scientific progress of your grant as well as other areas, and that's due annually in order to receive your next noncompeting continuation of your grant award. We also require the federal financial report, and there's going to be another presentation later today that will go through that in detail. The FFR is due annually for non-SNAP awards, and if you have a SNAP award, the final FFR is due at the end of your competitive segment. These FFRs are submitted in the HHS Payment Management System. That was a change that went into effect a year or 2 ago now. And when you're submitting those reports in PMS, the PMS drawdowns that you have made must reconcile with what you are reporting in your expenditure FFRs, so it's very important to make sure that information is all up to date and accurate. You're also required to do invention reporting, so at the end of your project period, that includes submitting a financial invention statement to NIH, and all inventions that are resulting from NIH-funded research also need to be reported in the iEdison system, and there's a link here that takes you to that system. Lastly, just a couple of additional reporting requirements that we wanted to highlight specifically to foreign, so the single-audit requirement applies to all recipients including foreign recipients if the recipient has expended a total of $750,000 or more in HHS award funds in a year. So if you hit that threshold, a single audit is required. An additional requirement that we wanted to highlight, especially for domestic organizations that are working with foreign sub recipients, is that the FFATA Subaward Reporting System, or FSRS, reporting requirement. So FFATA was a law passed several years ago which requires recipients to report on all of their subawards, subcontracts and consortiums that are equal to or greater than $30,000. And the way that that reporting is done is through the FSRS system. So it's the recipient's responsibility to collect the necessary data from all of their subaward recipients and file that information in the FSRS system so that NIH can have accurate data on our subaward recipients. And with that, we can open it up to Q and A. I think, Kasima, you're going to help us with some of that.

Kasima Garst: Yes, so we've been getting some questions in. Let's start out with, let's see, a registration-related question. Does a foreign university need to register on SAM.gov, also if it participates as a foreign component versus having a co-or-multiple PI from a foreign country?

Emily Linde: [Indistinct].

Michelle Bulls: Oh, go ahead, Kristin.

Kristin Ta: Oh, that was Emily, but I'm happy to answer the question, if you want.

Michelle Bulls: Okay. Go ahead.

Emily Linde: Thank you so much for the question. So a SAM registration is required if you're submitting an application to the NIH. It's also required for you to maintain that so that it's a current SAM registration if u are to receive continuing awards. If, however, you are a subaward, and you're not submitting a direct application, at that point you are not required to have a SAM registration. But just to repeat, if you are applying for an award, or you want to continue to receive funding, you must have and maintain a current SAM registration. And as Michelle mentioned, that can take a little while, so be sure you're working on that.

Kasima Garst: Thank you, Emily. Just a reminder for our folks that the Q and A questions need to be entered into the Q and A feature in Zoom. We will not be taking questions for our presenters through the chat feature in Zoom. So use the Q and A functionality. The next question going into some of the continued vein of subawards, and we may also address some of these as we get into the later presentations today on subawards, as well, Michelle, there was a question for you about if a foreign organization is the prime recipient of an award with a US-based subaward. Is the US-based subaward required to use an R and R detailed budget template in this instance?

Michelle Bulls: Yes, unfortunately. If the prime uses a detailed budget, the sub will have to do so, as well.

Kasima Garst: Great, thank you. All right. Let's see what's next. We have a question related to F&A, a couple of questions related to F&A, actually. There was a question about, are F&A allowed on equipment rental fees?

Michelle Bulls: For subs ... for foreign entities?

Kasima Garst: The question was ... I believe that is the intent. The question just read as, "Are F&A allowed on equipment rental fees?'

Michelle Bulls: F&A, in the case of a foreign organization, is limited to 8 percent for the cost of compliance.

Kristin Ta: And that excludes expenditures.

Michelle Bulls: That does exclude ... Yeah. Mm-hmm, and I think we put that on the slide, as well.

Kasima Garst: And echoing on the covering the cost of compliance, does that include the single audit for foreign organizations if they exceed more than 750,000 per year in total cost across all NIH projects? Or, can this be claimed as a direct cost?

Michelle Bulls: So, Emily, I'm going to tell you that in my tenure, this could be claimed as a direct cost if, in fact, this is how they claim it across the board consistently, regardless of the source of funds. If, in fact, this is something that they are using for the cost of compliance, and it goes toward the 8 percent, I have always thought that they could use the funding for the single audit. The challenge then there becomes that this 8 percent is limited. And so it's limited for the compliance with human subjects. It's limited for compliance with animal welfare. And so we want to make sure that folks understand the single audit cost can be pretty significant, depending, so just keep that in mind.

Emily Linde: And if you don't mind, Michelle, can I follow up on that? I want to underscore where she started with that, which is really that it needs to be consistently applied regardless of source, right? So just you could potentially charge that as a direct cost or request to charge that as a direct cost as an NIH award, if you're not doing that for all awards, you shouldn't do that. And then there was another thing that I wanted to add besides that. I'll remember it later. I'll remember it later, but I did want to underscore that you need to be consistent with that. And we definitely see different things across NIH. Oh, I remember what the other point was. It's not just NIH awards. It's across all HHS funding agencies, so that includes, for example, our sister agencies like the Centers for Disease Control and the FDA and a few others like those. But it's HHS funding thresholds of 750,000.

Kasima Garst: Great. Thank you both. So we have a couple more registration-related questions. Do organizations need to register in both ERA Commons and Grants.gov, or do they only need to do these two registrations?

Michelle Bulls: So, Kasima, I know you're tempted to answer this because this is right up your alley. But I'll leave you with moderator status at this point. They need to register in both.

Kasima Garst: Thank you so much, Michelle. You read my mind with that.

Michelle Bulls: I know you attempted.

Kasima Garst: All right. This is also going kind of high-level, as well. We have a question here about, how does NIH decide whether an award is under SNAP or non-SNAP?

Emily Linde: Michelle, do you want me to go with that one, or ...

Michelle Bulls: Yeah, sure. You can, and I'll add on if I need to.

Emily Linde: So that's actually decided at the IC level, right, especially for direct foreign awards. ICs may differ in their use of the Streamlined Noncompeting Award process or not. I can tell you for NIAID we do not use the SNAP process for foreign awards because we really do want to be sure that we're monitoring, especially the financial expenditures, and requiring that annual FFR and the rest of that. There are some ICs that may feel that the risk associated with that award itself is lower risk, and they may choose to put that award under SNAP. So you will see both, and I highly suggest that you always consult section three of your notice of award to make that determination for that award.

Michelle Bulls: I think that's a very good point, Emily, because the angle that I was going to come from is from the central NIH, which is ... SNAP is allowed but at the discretion of the ICs. And I think we have to be very clear about that, and ICs handle their foreign organizations quite differently. And I think Emily said it nicely and that in order for you to know what's happening under that specific award, you need to consult with the section three of the notice of award. Even though the NIH grants policy statement is the standard term and condition, the ICs do have the discretion of placing their own IC-specific or programmatic-specific terms in those awards.

Kasima Garst: That's great. Thank you both. Continuing on with that sort of SNAP-non-SNAP theme, in the process of transferring a grant to a foreign organization from a US organization, could that also change the status of SNAP from SNAP to non-SNAP? Emily, I think you and Michelle kind of will cover this in terms of the IC ...

Michelle Bulls: Yeah.

Kasima Garst: ... authority, but just want to give you the opportunity to respond.

Michelle Bulls: Yeah. I think what we said still stands, right, that if, in fact, you're changing institutions, and it's NIAID, Emily has clearly said that for any foreign award, she's going to need ... There will be no SNAP option, which might not be the same for another IC, so, again, making sure that you review that notice of award and those terms very carefully so that you can understand which IC you're working with and what their expectations or requirements are.

Kasima Garst: Thank you, Michelle. So going back a little bit, we see we've got some questions here again on the registration, and then that will lead into some of our reporting-related questions. So for foreign organizations participating as a subrecipient only, are they required to obtain a UEI if they do not need to register fully in SAM.gov?

Michelle Bulls: So, Kasima, I'm pulling you out of moderation level.

Kasima Garst: Absolutely, so because now the unique entity identifier is issued by SAM, even if you're not required to have the full SAM registration, you will have to go through SAM to obtain a UEI, as it is required for any subrecipient reporting requirements, and we'll kind of segue into some of those FFATA-related questions next. But the answer is, if you are going to be subject to any subrecipient reporting, you are required to obtain that UEI, and you have to go through SAM to get it. Even if you don't complete their full registration, they have a separate process for recipients or entities that are only obtaining a UEI but not completing the full registration. Thank you for that, Michelle. So a segue to that, the question in on following up on FFATA is, is the FFATA reporting for a sub for $30,000 a year or more, or is it more than 30,000 for the lifetime of the award?

Kristin Ta: So I'll jump in and take that one. The FFATA requirements apply to any subaward that crosses that $30,000 threshold. So it's not based on a single year, and it's ... Even if you start with an initial award that's under 30,000, as soon as you modify it and it crosses that 30,000 mark, it has to be reported.

Kasima Garst: Great. Thank you, Kristin. Continuing on on some of the other reporting matters, going back to the invention-related reporting, if they are a subaward, which institution actually needs to complete the reporting on an invention?

Michelle Bulls: The prime. The prime needs to report on the invention. It's the responsibility, and we'll get to that a little bit in terms of what's written in those subaward agreements. But it's the responsibility of the subs to provide the information needed to the prime. And then the prime has the direct relationship with NIH, and they do the reporting.

Kasima Garst: Thank you, Michelle. The next reporting and sort of follow-up question there, we have, is the single audit requirement to non-US-based organizations receiving $750,000 on federal funding or HHS funding? The presentation shows HHS funding. Thanks.

Michelle Bulls: It should be federal funding.

Emily Linde: I can double-check, but I'm pretty sure that the policy statement says HHS funding.

Michelle Bulls: It should be federal, but we should look it up.

Emily Linde: Okay.

Michelle Bulls: It's federal, yeah.

Kasima Garst: Thank you. Let's see. All right. Going to a question about the notice of award, on the notice of award, sometimes the amount of the subawards are listed. Are we bound by those amounts as opposed to if they were not listed?

Kristin Ta: So that kind of gets to the prior approval requirements that we were talking about. So recipients do have rebudgeting authority, but it's important as you're making those types of changes to keep the indicators of change in scope in mind. So significant rebudgeting is an indicator of change in scope, but of course, there could be changes that are smaller in dollar value. So you do have rebudgeting authority, but it's very important to be careful with how you use that and make sure you're communicating with the IC if you're making any substantial changes to the project.

Michelle Bulls: So I did look it up. It's 750K or more in federal funds in a single year, so we should probably modify the policy statement.

Kristin Ta: We'll make sure that's correct everywhere.

Kasima Garst: Thank you, Kristin and Michelle. Okay, so let's see. Our next question ... I'm going to look at some of the ones that we've gotten a lot of upvotes for. Does NIH have data on our success rates for direct foreign awards versus domestic awards with foreign components versus domestic-only awards?

Michelle Bulls: So I know we have success rates on direct recipients. I'm just not sure whether or not ... We can go back and take a look at that. I do believe we do have success rates on all. But we'll take a look and make sure that the response is clear and accurate.

Kasima Garst: Michelle, I think we have a question here related to the definition of a foreign component as it's defined in the grants policy statement. The question on ... Do NIH ICs have flexibility in interpreting the definition of a foreign component in the same way foreign consultants on projects have been deemed a foreign component in some instances but not in other instances?

Michelle Bulls: So I'm going to be quite honest with you. We've kind of heard that a bit, especially during COVID. And the consulting piece is very interesting. We have not considered it, considered foreign consultants foreign components. But it does depend on how the relationship is. Like, we've had situations where there have been foreign consultants that were lead and were generating data and were working with humans. And so you have to understand that it depends on the program and the project design, the science design and what that composition looks like. And so I don't want to say that it can't happen because it could, and I think it really does depend on the science and the composition of the science and the design that the ICs have put together for the programmatic outcomes. What I would ask, though, for institutions is, when you hear that, you know, there's a foreign consultant that is being considered as a foreign component, the question that you would ask the institute or center ... That's what the IC stands for, institute or center. You would ask them what deems this as a foreign component because then they can help you understand what the composition of that team looks like and why they have assessed it as a foreign component. The NIH grants policy statement provides guidelines, but those guidelines are very important to how they actually make some decisions. And just like that, for instance, if that foreign consultant is dealing with humans or generating data or co-author, some of those pieces then really does make it a foreign component, and those are the things that we ask our institutes and centers to work with the recipients on to help them understand why these cases are a bit different. But we really do leave it to the program officials in the institutes and centers to design their programs and their scientific outcomes, and the policy statement is a guideline for that.

Kristin Ta: Yeah, I would just piggyback on what Michelle is saying to add on. When you look at the actual language in the definition, it talks about a significant portion of the project being conducted outside the US. And as Michelle just explained, what is significant is really going to differ on a case-by-case basis, and that's the programmatic determination that the IC folks make.

Kasima Garst: Thank you both so much. We did have a couple of questions about that, scientifically significant, so I think that will help with the variety of questions that were asked on that line. The next question that I see here is related to indirect costs. I know, Michelle and Kristin, you guys had weighed in on that as well, earlier. But we did have someone ask, what if an international subaward does not request any F&A? Should it automatically be included anyway?

Michelle Bulls: So the uniform regulations state that if the entity does not ask, we're not required to provide F&A. But it goes back to something I said before. If it's not beneficial for the entity to request F&A, and they're direct-charging everything, they need to be direct-charging everything, again, consistently regardless of the source of funds. And it can't be, they do this this way with us, and then they change it with CDC, and then they do something different with HRSA. It needs to be consistently applied. And so I would say that if they're not requesting it because they don't believe that there's a real need to request it, and they're direct charging everything, those cost categories need to be consistently applied. There needs to be an organizational policy to support it. And I would like to think that even institutes and centers may even ask for the organization's policies to support the direct charging of all of those costs.

Kasima Garst: Great. Thank you, Michelle. Is there generally a limit of funds provided to a foreign collaborator if not specified on the notice of funding opportunity or NOFO?

Michelle Bulls: Emily, you want to take that one?

Emily Linde: So what I would say, definitely start with the funding opportunity announcement because that may have a limit. It may not have a limit. But generally speaking, if there is no limit on the FOA, the best thing to do is think about what's scientifically appropriate, right? You don't want to be requesting more funds than are scientifically appropriate, and you definitely want to be requesting funds not only that are scientifically appropriate but appropriate for the area in which you are, right? So the cost for a nurse, for example, in a clinical trial might not be the same in Sub-Saharan Africa as it would be in Canada as it would be in India, right? So they should be appropriate for the location and appropriate for the science.

Kasima Garst: Thank you, Emily. The next question that we have ... This goes in line with our prior approval requirements. Can they add, retroactively, a foreign component to a project? What is that process?

Kristin Ta: So prior approval means approval before the change is made, and that is the requirement. If somehow foreign work has been added without obtaining that prior approval, you need to reach out to NIH immediately and start working with your grants management officer and program officer to resolve that.

Michelle Bulls: And I would encourage foreign organizations or domestic organizations that are adding foreign components, I would strongly encourage you to be very careful about that because if, in fact, the institute or center determines that the prior approval justification is not acceptable, any costs that have been added toward or charged on the grant could be disallowed. So I just want to make that very clear. Pre award cost is the risk to the organization, and we want to be very careful about that.

Kasima Garst: Great. Thank you. So the next question we have is related to, again, back to the audit question and the responsibilities of a prime versus a subrecipient. And I know you may be referring to these in some of our follow-up presentations. But does the audit for foreign organization subrecipients fall on the prime recipient if it is a US entity. Maybe that question is a bit worded funny, but can we talk a little bit about what the expectations are for the prime responsibility for subrecipient audits?

Michelle Bulls: So I think we talked a little bit about it in the question that you asked before, Kasima, where we stated that the prime recipient is responsible, of course, for making sure that they have an audit. And the sub, if, in fact, they are receiving 750,000 or more in federal funds, if they are receiving that, they have a responsibility of having the audit. So it's not just the prime. It's both, right? And I think we want to make that very clear, what the responsibility of the subrecipient to the domestic institution or the prime institution is, to make sure that the sub's audit is up to date, right, because those are the kinds of things that they want to make sure of in the agreement. We want to make sure that we have an eligible sub or foreign component that is attached to the prime. And so I think that that needs to be very clear. But it's independent, and the trigger is 750, not whether or not they are a sub to a prime.

Kasima Garst: Thank you, Michelle. So we only have a couple minutes left. I think we have the time for one more question. I'm going to ask the one with the most upvotes. They would like to know how to consider variable local currency, inflation or fluctuations as they prepare financial reports in dollars. Do you have any regulation on that and any information you can provide?

Michelle Bulls: Okay, so I'm going to ask you to repeat that question.

Kasima Garst: Sure. The question reads, I would like to know how to consider variable local currency, inflation, and I think they mean also fluctuation in preparing financial reports in US dollars.

Michelle Bulls: So I'm going to say ... I'm going to address the inflation piece because I think that that's the first part of this where what we tell our recipients or our applicants is that you should request what you need in order to complete the project. And you have to account for in your budget whether there are inflation or currency that's going to be different. Those are the kinds of things that need to be considered as you are putting your budget together and submitting it to NIH. But you should be submitting a budget that requests the funding that it takes to complete the scientific project. And, Emily, I don't know if you had anything you want to add, but I just think from a standard appropriations piece from on the NIH side, we would only pay for that which was requested, and we do ask that the recipients consider all of those kind of the factors as they're putting the budgets together.

Emily Linde: So I would completely agree with that. I do think that there is two sections in a grants policy statement that help address this for foreign organizations or those domestic organizations collaborating with foreign organizations. I suggest you read chapter 16 of the grants policy statement, specifically 16.5, which is on the funding and payment. And also on 16.7.5, which is on reporting record retention, easy for me to say, reporting and record retention. And that specifically talks about PMS and the draws and the rate of currency in effect at the time of the draw. So I think there's actually a lot that's in that question itself, so one has to do with fluctuation, and you can talk to the IC. NIAID has a very strong policy regarding requesting inflation, and we ordinarily don't provide it, but other ICs may have more flexibility or more availability of funds, and then just a reminder that when you're pulling those funds out, you're using the currency rate in effect at that time because you're always reporting and talking to NIH in US dollars.

Kasima Garst: Thank you both. We are going to have to start wrapping up, and thank you to our experts and those who joined us for this presentation. Thank you for joining today's presentation focused on subaward agreements, requirements and case studies. During the next 25 minutes, our presenters will be highlighting some important information for you followed by case studies and Q and A if there is time. For those participating in the live event, we invite you to get involved by using the polling features when prompted and to use the chat for any comments related to the props from the presenters if needed. Otherwise, Q and A can be entered into the Q and A function in the chat. My name is Kasima Garst. I'm a Systems Policy Analyst in the NIH Office of Policy For Extramural Research Administration, otherwise known as OPERA. Now, let me introduce you ... Oh, excuse me. Now, let me introduce you to our experts for this presentation. We will be joined by Michelle Bulls, the director of the NIH Office of Policy For Extramural Research Administration, or OPERA, and Kristin Ta, a senior advisor in OPERA, as well. I'm going to turn it over to our presenters to start us off.

Kristin Ta: Great. Thank you, Kasima. So today, we're going to be talking about some of our NIH requirements for subawards, specifically the roles of the prime and the sub. We're going to talk a little bit about setting up your subaward agreement, what that should look like, and then we're going to have some Q and A to talk about the requirements for subaward agreements. So, Michelle, I'll turn it over to you to get us started.

Michelle Bulls: Thank you so much. Thank you so much, Kristin. We are so happy to be here with you guys today to talk you through this. It's very important to us that we provide as much guidance as we can to our applicants and our recipient community in order to ensure compliance with NIH grants policy requirements. So we're going to go into a little bit about what the role is of the prime versus the sub, the parent entity versus the sub recipient entity. And one of the things that I think we all know is that the primary recipient, which I call the prime, and most people refer to it as that, is accountable to NIH, has the relationship with NIH, and it's a direct relationship with NIH. And one way that we secure how this looks is to designate the primary recipient as the recipient that will provide us and be accountable to us for the performance of the project, how the funds are expended for the proper and applicable reporting requirements and making sure that those are adhered to and, of course, all of the other obligations, programmatic and otherwise, that are outlined either in your notice of award or in the NIH grants policy statement, which serves as the term and condition standard, term and condition of the award. One of the things that is very clear is that NIH holds the prime recipient as having the substantive role in conducting and planning the research and leading it. NIH is not going to allow for recipients to be a conduit to merely just have the funds flow through to a sub for all of the work to be done at that sub level. That is inappropriate because the primary recipient has to be able to provide that programmatic oversight and that financial and administrative oversight. And so the requirements for the primary to perform a substantive role is critical. We also want to remind our colleagues here that terms and conditions from the primary recipient flow down to the subrecipient. And what does that mean? That means that all of the standard terms and conditions in the NIH grants policy statement, while we have that direct relationship with the primary recipient, it still does flow down to the subrecipient, and the subrecipient is responsible for making sure that performance at that site ... that the appropriate expenditures that are authorized for the sub to expend as well as reporting requirements and other programmatic and administrative areas are complied with, as well. Next slide. So Kristin and I are going to talk to you a little bit about how to set up your subaward agreement in order for the subs to be protected as well as the primary recipient to be protected because we all know that, at the end of the day, compliance begins and ends with the prime. But we also want to make sure that when the prime is setting up these subaward agreements that all of the factors, the critical factors that need to be considered, are in place. It must be done in partnership between the prime and the subrecipient. It should not be heavy-handed. The partnership needs to be strong starting with the written agreement, flowing down in between the prime recipient and the sub. It needs to be a formal written agreement, not just a gentlemen's handshake. It has to be formal. It has to be written. And all of the critical elements of that subaward agreement must be addressed. It needs to identify the fact that there's going to be scientific need, who's going to be leading the sub. Agreement and partnership between the prime and the sub have to understand who's going to lead the subrecipient, right? Who's going to be the lead of that consortium? Who's going to be the lead of the subrecipients' activities? We also want to make sure that you have procedures for how ... if changes take place, making sure that information in there. So negotiating these arrangements from a scientific, administrative and financial is really, really critical. And then the other piece is, while we say it's a partnership, it still needs to be approved by the authorized organizational representative at both institutions or both organizations. And where there is a question or where there are concerns and where agreement cannot be made, we do ask that you engage the institute or center for support. Next slide. And so we have a few critical and key elements here that we've identified, and it's laid out when filling out the NIH grants policy statement. And I was talking a little bit about this in my previous slide here where we want to make sure that we identify the individuals that will lead the consortium or lead the sub. And why is that important? Because that individual needs to be able to report the scientific and direct the scientific areas of that project at that sublevel. The procedures for how the direction and the monitoring for the research effort needs to be very clearly laid out. If there are changes in the sub's leadership, how is that going to be communicated? How will that be addressed? All of these things need to be in the written agreement. Procedures on ways to file the reimbursement, how do we reimburse? What does that look like? That needs to be identified and spelled out in the agreement, not just that the individuals will reimburse, but the individuals will reimburse for this amount at this time. It really needs to be clear because I'm going to tell you that having that strong procedure for how it's going to be directed and strong procedures for the reimbursements and the policies is going to be critical to closeout. And so we want to make sure that those written agreements are in place and strong and sound and agreed to by both parties. A determination of policies to be followed such as travel, reimbursement and salary and fringe benefits, all of those things need to be laid out. If the foreign organization has a different travel policy or travel reimbursement policy and salaries and fringes, you need to make sure that the prime recipient understands that, and that's included in the written agreement and signed by both parties. Next slide. Terms that establish whether or not financial conflict of interest policies will apply to the subrecipients and making sure that the requirements of those foreign organizations are clear in the written agreement is very important. FCOI, as we know, does apply, but we want to make sure that how that is communicated and when compliance is obtained and how that looks within the project period or the period of performance for this project ... It needs to be laid out. The addressing ownership and disposition of data produced under this consortium agreement ... Those are the things that need to be really laid out as to when the data will be shared, how it will be shared, the curation, the repositories. All those kinds of things need to be laid out if there are differences from what the primary recipient expects. We also want to make sure that intellectual property and the security and confidentiality thereof is laid out and outlined in the written agreement. Expectations for authorship and co-authorship on publications and provisions regarding the property needs to be fully vetted, and what the obligations are to NIH for the reporting is critical and laying out when the reports will be ... when the information for the reports will be provided to the prime so that the prime can actually report on time and maintain compliance with the terms and conditions of the award. And incorporate the applicable public policy requirements and provisions, are also critical. Next slide. So, Kristin, I've given you a lot of information, and we probably will have additional information as we put in the appendix just to lay it out for you. But Kristin is going to test your knowledge, and this is really where the case studies are going to come up, and this will be fun. So, Kristin, take it away.

Kristin Ta: All right. So we've got a couple questions, and I think we have some poll ability so that you guys can plug in your answers, and we can see what the group thinks. So we're going to start first with an example of a couple statements from a subaward agreement. So looking at these statements below, which one is the best example of providing appropriate agreement language, so A or B? I'll give you guys a second to answer the poll, and then we'll talk about the answer. All right. So let's see the responses. Oh, fantastic. So almost everybody got it, and let's talk a little bit about why B is the correct answer. So as you can see by looking at the language in the second bullet, we provided a lot more specific details about the reporting requirements. So it's not enough to simply say the subrecipient is going to report on their progress, and the prime recipient is going to monitor progress. You really have to be specific about what that's going to look like. So, for example, the subrecipient will submit their reports quarterly to the prime recipient. They'll maintain their supporting documentation, and the prime recipient will review this and may conduct site visits and will perform appropriate oversight. Those details are really important to include in the written agreement itself, first off, because the requirement to provide supporting documentation is in the regulations. And so that's a reporting requirement for the prime. They need to be able to provide us, NIH, the supporting documentation for all of their costs and all of the science. And so if the subrecipient hasn't agreed to give that to the prime, the prime isn't going to be able to give it to us at NIH when we ask for it. And we've actually seen that in several cases. So it's really important to protect yourself as the prime when you're writing up those agreements and include all of those details. Similarly, with the timing and content of reports, if you don't lay out those expectations up front, it's kind of setting you up for a scenario where you're not going to be getting reports when you want them or need them, and then you're not going to have the language in your agreement to point to when the subrecipient isn't complying. So it's really important to flesh out all of those details up-front for make for a successful subrecipient relationship. So the next question relates to invoicing and reimbursement, so I'll give you all a moment to read this one and identify which of the elements below should be outlined in the subaward agreement. We'll give everyone just a minute to read through that one. Uh-oh, it won't let you check more than one? All right. Well, then let's hop forward to the answer because you really do need to be able to check more than one of these because the answer is all of the above, which it sounds like from what I'm seeing in the chat, most of you have realized that more than one of these answers was correct. So as I mentioned in our previous question, laying out the timing of things and the documentation that's required is critical, so as Michelle was talking about before, you want to set up the timing for all of your invoices and payments because that's really important for the success of your agreement, setting those expectations for submitting monthly invoices along with supporting documentation, that kind of really specific language. And this is going to come into play when you're ready to close out your grant award at the end of the project because all of the close-out reports that are due to NIH are due within 120 days of the end of the project period, and that includes all of the draw-downs and all of the reporting for your subaward agreements, so you need to make sure that you've set that expectation up-front that invoices and all information is going to come in well ahead of that deadline. It's also important in your agreement to outline what policies are going to be followed, so a subrecipient may have different policies for travel reimbursement, for salary and fringe benefits than the prime recipient, and that's okay, but you need to outline in your agreement which policy they'll be using. You can outline that they will be required to follow the prime's policy, or they can follow their own as long as it aligns with the NIH requirements, but that expectation needs to be captured in the written agreement. Okay, let's look at one more question. This one is about prior approval, so when a subrecipient needs prior approval for a change to the project, what should they do? I'll give you guys a second to read those options and give your answer. All right. And it looks like just about everybody figured this one out, and I know Michelle talked a little bit about this one before. So the prior approval requirements for a change in scope and other significant changes to the project do apply to subrecipients. However, our NIH relationship is with the prime, so subrecipients should not reach out to NIH directly. They need to contact the prime recipient to request prior approval, and that prime recipient in turn will work with NIH to obtain the appropriate approvals from grants management and program, and we have one last question before we run out of time here, and this one relates to single audit. So are prime recipients required to review the subrecipient single audit? If you were on our first presentation, you probably know the answer to this one, so we'll give folks just a second to answer before we discuss this one a little bit as our time runs out. All right. So let's see those responses. Oh, so this one is a little bit closer, so let's talk a bit more about the answer. So the answer is B. If a nonprofit consortium meets the threshold ... I'm sorry. I started reading, and I confused myself. So if the subrecipient meets the threshold that's outlined in the regulations, they are required to complete their single audit, and they are required to provide that single audit to their prime recipient for review. The prime recipient, however, is not responsible for looking at every single audit finding that's in that subrecipient's audit report. They are only responsible for looking at audit issues that are identified related to their consortium agreement, so they are not responsible for resolving any crosscutting findings or overall findings on behalf of the subrecipient, so that's a really important distinction for subrecipient monitoring. Along with that, I just wanted to highlight that if the consortium does not reach the expenditure threshold, the recipient still has to monitor their activities to ensure compliance with the NIH requirements, but they may not require consortium participants to have an audit and charge that audit to NIH. That single audit is only required if the subrecipient is meeting the thresholds outlined in the regulations in the NIH grants policy statement. So that was our last question, and it looks like we've just come up to the end of our time.

Kasima Garst: Thank you, Kristen and Michelle, and to those joining us for this quick presentation and case study, the PowerPoint and the related resources will be made available soon in the NIH Grants Conference Center on the International Collaboration PreCon page, and as we've mentioned earlier, the current PowerPoint slides did not contain the case study, so they will be available soon. Okay, moving on, thank you for joining today's 25-minute walk-through of the Federal Financial Report, FFR. During our time together, our presenters will be highlighting some key components of the FFR, and then we'll address as many of your questions as possible coming into our Q and A box for the live event. I am Kasima Garst, a systems policy analytics in the NIH Office of Policy for Extramural Research Administration or OPERA, and I will be your moderator for this discussion. Our experts for this presentation are Emily Linde, the Director of the Grants Management Program at the National Institute of Allergy and Infectious Diseases or NIAID and Alan Whatley, the Lead Grants Financial Analytics in the NIH Office of Policy for Extramural Research Administration, also known as OPERA's FFR and financial closeout support service center. Alan, I'm going to turn it over to you to start us off.

Alan Whatley: Well, thank you, Kasima, and good afternoon, everybody. We appreciate everybody joining for this FFR presentation, and we'll get right on into the presentation, a definition of the FFR. What is an FFR? A Federal Financial Report, better known as an FFR/SF-425 is a statement of expenditures reported against funds awarded to a recipient, and so in short you guys as recipients are awarded funds. Then you're required to report the expenditure activity back to the awarding institute either annually or at the end of the project period depending upon whether or not the grant is under the Streamlined Noncompeting Award Process otherwise known as SNAP. So as was discussed earlier, if a grant is under SNAP, an FFR is not due until the end of the project period, and if a grant is not under SNAP, an FFR is due annually at the end of each individual budget period. FFRs can only be submitted electronically, so we do not accept hard copy of FFRs. They can only be submitted electronically in the Payment Management system better known as PMS, and the URL at the bottom is how an FFR can be submitted, and the PMS link will take you directly into the payment management system, which is where your FFR can be submitted. And so many of you may remember when FFRs were submitted in eRA, eRA Commons, but as of January 2021, the Department of Health and Human Services directed all agencies to make a transition, and that transition is to have FFR submitted in PMS. And so certainly was a transition period for some. Some are still going through that transition period, which is absolutely understandable, but the fact remains is that all FFRs are now submitted in the Payment Management System. All right. So now we'll actually get into a demo of an FFR. We're going to go through all of the individual fields and explain them all, and I'm going to move through it as briskly as possible because I want to be very respectful to the agenda today. We have until 12:45, and so while I want to demo the FFR, I want to be sure and leave time of questions, and I want to make sure that I'm able to field as many questions as possible for FFR once I'm complete with my presentation. And so let's get right on into the FFR starting with field 1 would be the agency, or of course it's NIH from our perspective. It would be the actual institute that made the award, and so the NIH institute that issued the award would be in field 1. In field 2 would be the actual PMS subaccount or document number that the funds were awarded under, and so that would be in field 2. Slightly different from the grant number but PMS document number would be in field 2. Field 3 would be you guys, the recipient organization and your address information. Field 4 would be the DUNS and EIN. Field 5 would be the PMS account number. Field 6 would be ... Only the last two would apply for the FFR. It would either be annual or final. Field 7, the basis of accounting that you use in your own internal accounting system whether it's a cash basis or accrual basis of accounting. Field 8, the project period from and to, in the from field would be the start date of year one of the grant award, and so that represents the start date when the grant was first awarded in year one. The project period to date represents the project period end date in the current competitive segment. In field 9 represents the budget period end date within the current competitive segment, and so now we'll move on into the financial information that starts in section 10, transactions and so field 10a, cash receipts. Cash receipts is a prepopulated field, and it will represent what you have drawn down in PMS for that particular subaccount slash document number, and so when you pull up the FFR, that field will already be prepopulated. It'll be prepopulated with what you drew, and so the first field that would actually be entered would be field 10b, cash disbursements, and that represents the amount that you've actually paid out, the amount that you've actually disbursed compared to what you have drawn. And then field 10c is also a prepopulated field. It's a calculation cash on hand, and it simply represents your cash receipts minus your cash disbursements, and an extremely important rule for final FFRs: Cash on hand must be zero. Your cash receipts and cash disbursements must agree on all final FFRs, and so if cash receipts and cash disbursements do not agree on the final FFR, they won't even be able to be submitted. You will get an error right there in PMS, so that's a very important point to remember and be aware of. Next, field 10d, amount of total federal funds authorized, again, field 10d will be prepopulated, and it will be prepopulated with the amount that's currently authorized in PMS at the time of FFR submission, and of course the amount of funds authorized should agree with what you receive on your notice of award, and so you should have received notice of awards letting you know the exact amount that you have to spend, and that exact amount should be represented in both PMS and on field 10d of the FFR. Next is 10e, federal share of expenditures, and that represents your cumulative expenditures, what you have spent compared to what you are awarded, and another important point is that your federal share of expenditures, it is a cumulative field. And so it should represent cumulative expenditures, and what I mean by that is that in year one of your grant, of course you would put your expenditure amount for year one, but then in year two you would be reporting expenditures for both year one and year two combined. And so it wouldn't just be single expenditures for year two. It would always be cumulative for all years awarded just as field 10d would be a cumulative field representing all awards money. Field 10f is unliquidated obligations, and so the definition of an unliquidated obligation would be funds that you have obligated associated with the award, but they have not physically been paid out. You haven't physically spent them yet to the point where you were able to classify it as an expenditure, but you know that those funds will be paid out. They will be paid out shortly, but they can't be classified as an expenditure. That's when you have the opportunity to report it as an unliquidated obligation, and so an example of an unliquidated obligation would be subcontract costs. You have a subcontractor on your grant, and those costs have been performed, but they've not yet been physically paid out by your organization. That will be a perfect example of something that you would classify as an unliquidated obligation. Next field, 10g, is the total federal share, and that is a calculation of 10e and 10f, your expenditures, plus your unliquidated obligations. In other words, it's your total expenditures, and then 10h is also a calculation, and that's total federal funds authorized minus your total federal share, in other words, everything you were awarded minus what you spent, and that leaves the unobligated balance of federal funds, and the unobligated balance, again, represents the unspent portion of the award. And that's a prepopulated field. It's a calculation. The next section of the FFR is for recipient's share and program income, extremely rarely used fields on the FFR. It's only used in the rare circumstances when the NoA requires cost sharing and so very rarely used, but those fields are necessary when those rare cases come up, but for foreign awards there's not anything that you would really deal with, next, section 11, indirect expenses. All right. And so the indirect expenses, the box will fill 11a, which is the indirect expense type. There are four types of indirect expense types of predetermined, provisional, fixed and final. For NIH foreign recipients it is always fixed. The indirect expense rate goes in the next field. Again, as previously discussed in the earlier in the presentation today, the indirect expense rate for foreign recipients cannot exceed 8 percent, and so it's important when entering that field to realize that the FFR is set up for that percentage to be entered as a whole dollar, and so you would just simply enter eight if your indirect expense rate was eight. There would be no need to enter 0.08. I understand what you're trying to do when you do that. You're trying to represent that 0.08 as a percentage, but since the percentage is already calculated into the FFR, it just makes your indirect expenses way understated, and so there's no need to enter indirect expense rate as a decibel, just enter it as a single, thank you. Next, the period from and to is the same thing as represented on the top part of the form. It is the current competitive segment, start date and end date, and, again, it should be cumulative. Your indirect expenses should be cumulative just as your expenditures in 10e are cumulative because these indirect expenses are a representation of a portion of those expenditures, and so they should always be cumulative when you're entering your period from and to as well as the amount that you're putting in. Your indirect expense base, next slide, the indirect expense base, field 11b, it is ... You should use your modified total direct costs, so in simple terms it's your direct costs plus equipment, tuition, subaward agreements excess of $25,000. That is your indirect expense base. The amount charged, field 11e, is a calculation of the rate, your indirect expense rate times your indirect expense base, 11b times 11d. And then field 11f, federal share, should agree with 11e because it's the amount of cost charged to the federal portion of the award, and so it shouldn't really differ from 11e. The only time it would, would be for a cost sharing, which again is extremely rare for foreign awards. All right. Doing good on time, looks like we still have about 10 minutes for questions, and so I want to provide everybody with the shared mailbox that you can send any FFR-related inquiries to if you have any questions related to this presentation, if you just had kind of questions about FFR over the years, if you have questions about a specific FFR, please reach out to us using this mailbox, very eager to hear from you, want to provide support. I don't want any questions out there where anybody is just kind of out there and don't know where to turn to. You can turn to us using this mailbox, and we'll be sure to get back to you and provide you with a good response and a sufficient answer. So we're at 12:35, and so it looks like we have about 10 minutes for questions. And, Kasima, what are we looking like in the Q and A?

Kasima Garst: Thank you so much, Alan. That was very helpful. The first question, and I did respond in the Q and A as well, but for everybody's awareness, will the DUNS be replaced with the UEI on the form in PMS?

Alan Whatley: You said you already responded to that one, Kasima?

Kasima Garst: Yes, so, Alan, did you want to just speak to the update for everybody that regarding the Unique Entity Identifier?

Alan Whatley: Kasima, I think you will be better than me to give an update on the UEI actually.

Kasima Garst: Oh, no problem at all.

Alan Whatley: Yeah.

Kasima Garst: So for everybody's awareness, the Payment Management System has updated to reflect the new Unique Entity Identifier in their systems, and eRA is sending the UEI for all NIH FFRs, so that information should already be displayed. If you have any technical questions there, you could reach out to the eRA service staff.

Alan Whatley: That was someone? So are you fielding the Q and A? Or should I take a look?

Kasima Garst: No, I got it right here. Sorry, my computer accidentally ...

Alan Whatley: [Indistinct]

Kasima Garst: ... Muted on me.

Alan Whatley: Mm-hmm.

Kasima Garst: So the next question, when it comes to a new competitive segment of grants, for example, year six, does the cumulative reporting cover year one onward from the awarding of the previous competitive segment? Or does cumulative reporting simply cover year six onward due to the fact that it's a new segment?

Alan Whatley: Great question, and the answer is, is that it would only cover year six onward if the FFR starts ... The expenditures start with each competitive segment, and with each competitive segment is a new document number in PMS, and so the document number would be right on top of the FFR, and those would be expenditures that you should be reporting for each individual segment, very good question.

Kasima Garst: Thank you, Alan. The next question here: What are examples of scenarios in which you would need to revise the annual FFR after submission?

Alan Whatley: Scenarios where you may need to revise, it would kind of depend on each individual organization, but some reasons for revision may be subcontractor costs that came in after the FFR was submitted. We encourage not to even submit the FFR until expenditures are finalized because we would like to minimize revisions as much as possible, but we also understand the reality of working on these grants, and sometimes expenditures come in after the FFR has been accepted. Sometimes expenditures reduce. You may have a subcontractor where your expenditures actually reduce, and you may need to refund HHS on a grant where the FFR has been accepted. And so different scenarios happen where expenditures are adjusted after the fact, and that's where revised FFRs will be allowed.

Kasima Garst: Great, thank you. All right. Let's see. Our next question here, how should carryover be addressed on an annual FFR?

Alan Whatley: All right. It'll be in the notice of award whether or not carryover, automatic carryover authority if this is active or not within the award, and so it's just a matter of going to your notice of award. If you do not have automated carryover authority, you're not allowed to spend any unspent balance from the previous year without first reaching out to the awarding IC to gain that approval. If the award has automatic carryover approval, then you're allowed to spend any unspent balance from the previous budget period in the current budget period. It just depends upon whether your notice of award cites automatic carryover authority.

Karisa Garst: And, Emily, is there anything else you would like to add from the IC perspective on that?

Emily Linde: Sure, thank you so much, Kasima. So I would encourage you so once you've submitted an annual FFR, and you know you have an unobligated balance that you might wish to spend, that's the point at which that I would encourage you to submit your carryover request. At that point the IC does know that you have an unobligated balance that has been reviewed and reported on the FFR, and we know that balance is then available, and then just another reminder that the way that NIH approves carryover requests is via a revised notice of award which specifically reflects that we are approving that you've requested carryover and the amount that it is.

Karisa Garst: Great, thank you, Emily. The next question we have here: Where should recipients report the obligated but not yet performed cost? For example, for cost reimbursement base subaward or consultancy, should we report the total contracted amount? Or should we only report the annual performance costs amount regardless of invoiced or not?

Alan Whatley: Emily, do you want to take that one? Or you want me to tackle it?

Emily Linde: Well, so I think you can help me out. I would say this: The first thing I would be thinking about is your reporting period. Right? Because you may have ... You should only have the costs in there that are anticipated for that reporting period. Right? So if you have a subaward agreement, and you know that they've already performed work then by the end of that reporting period, but you have not yet been invoiced those costs would be included as unliquidated obligations. Right? Because you have incurred them by the subawardee performing that work, but you have not yet disbursed funds to reimburse those individuals. Alan, did you want to add something to that?

Alan Whatley: You said it really well. I truly couldn't add anything further than that. I hope that answers the question for whoever asks.

Kasima Garst: Great, thank you. Following up on some of the invoicing, there's a question. Do you need an invoice in hand to report it as unobligated?

Emily Linde: So I think I might ask that person to restate the question. Right? So if you have incurred the costs but not paid them, they're unliquidated. If you have not incurred those costs, then they are unobligated. Right? If you've incurred them, and you've paid them, then those are listed as expenditures.

Kasima Garst: Oh, the user said they meant unliquidated.

Emily Linde: Right, so as the cost has been incurred, and you haven't invoiced it, you haven't yet paid it, that is an unliquidated obligation. Right? Once you pay it, it becomes an expenditure.

Kasima Garst: Great, thank you, and I think we have time for one more question. If your institution tracks the NIH salary cap as cost-sharing, is it necessary to document on the FFR?

Emily Linde: So this is one that I think that I would like to get back to them. I can certainly explain what my understanding has always been is that you are reporting cost-sharing when it is required by the notice of award. It's very infrequent for NIH that we require cost-sharing on the notice of award. Alan, I wouldn't expect if we're not requiring that cost-sharing, and it's voluntary, committed cost-sharing that it would be reported on the FFR. Is my understanding correct?

Alan Whatley: Your understanding is correct.

Kasima Garst: And I think also we're going to have a surprise addition with Michelle Bulls, the Director of OPERA, is going to also jump in and provide some insight as well.

Emily Linde: Yay.

Kasima Garst: You are on mute, Michelle.

Michelle: My apologies. Alan stated it correctly. It is ... Typically, salary caps are not cost-shared, right? It's: You charge the grant, and if you hit the salary cap then, you have to only charge what the salary cap allows. And so since it's not cost-sharing, neither administrative nor required, it would not be reported in the FFR. So, Alan, you are correct. That's right.

Kasima Garst: Great, and I'm going to just go ahead and thank Alan and Emily and Michelle, again, and everybody who was able to join us for this quick but informative overview of the federal financial report. And the one last question that I get to help out with, from the Q&A, was about how you can find copies of your approved FFR. You will see it in the grant folder, in the ERA Commons, or you can also view it in PMS as well.

Hello, thank you for joining today's presentation on Collaborating and Partnering with Foreign Entities from a Scientific Perspective. During this 45-minute presentation, our presenters will be sharing some important information about the NIH as an organization, finding the right funding opportunity and how to use NIH resources to help find potential collaborators and important considerations along the way. A Q&A will follow. I am Kasima Garst, a Systems Policy Analyst in the NIH Office of Policy for Extra Research Administration, or OPERA. I will be your moderator for this discussion. Our experts for this presentation are Emily Linde, the Director of the Grants Management Program at the National Institute of Allergy and Infectious Diseases, or NIAID; and Dr. Glen McGugan Jr., a Program Officer of the Division of Microbiology and Infectious Diseases at NIAID. I'd like to now turn this over to Dr. McGugan to get us started.

Glen McGugan: All right. Thank you so much, Kasima, for that great introduction. So welcome, everyone, to the presentation today, and so I'd like to provide to you today just a brief overview of the NIH grants process, really focused on how it relates to international applicants and international collaborations. So with that, as I'm sure it will come as no surprise to this audience, the NIH is the largest public funder of biomedical research in the world, and our mission here is to seek fundamental knowledge to enhance health, length in life and reduce illness and disability, and that's accomplished, in large part, through the more than 50,000 research grants to more than 300,000 researchers at some 2,500 research institutions. The NIH also has a long and robust interest in international research. And so you may be wondering why does the NIH support international research? Well, international research really strengthens the overall science, so this provides special opportunities for furthering research programs, maybe using unusual talents, unusual resources, maybe patient populations that we don't have here in the US or environmental conditions that aren't here or maybe to augment the things we do have here in the US. And also, this may be of specific relevance to individual institutes and centers here at the NIH. So you may be asking yourself, "Where do I even begin to navigate this process?" Some of you in the audience may be more seasoned members of the research community. Some of you may be new to the process. So the next few minutes I would like to give you an overview, maybe answer some questions for you about the process and then leave time at the end for a discussion, and I'm really thankful that my colleague, Emily Linde, is here as well to answer any of those more technical budgetary questions that you may have. All right. So from the applicant's perspective, the whole process begins with a grant submission. And then on the other end, you'll get money for that or maybe you'll have to try again. Most people know that. But what happens here on the inside of the NIH during that process may be a bit of a black box or appear to be a black box to many people. So I think a good place to start would be looking at the overall NIH grants process. Now that's going to begin with you, with a scientific idea that you have. Based on that idea, you're going to write an application. You're going to submit that here to the NIH. And then once it's here, it's going to go through the NIH peer review process, and that's either going to be at our Center for Scientific Review. It will be assigned to a review group, a study section, or it may be reviewed at one of our institutes, so they have their own scientific review panels. In either case, these will be your scientific peers that are brought here by the NIH to review the science that you're proposing. In either case, it's going to go to our NIH Advisory Council of that particular institute, and then a decision to fund will be made, and then hopefully, you'll get a notice of award for your particular project. Now, from the time you submit the application to the time you get an award could be quite lengthy, more than 9 months, and that is if you're successful on the first try. You may have to resubmit to increase your chances of getting an award. And I say that not to discourage you, but rather to encourage you to submit early, plan early and then to be persistent in the process. The other thing I want to point out is that he NIH is actually not one institute, but it's actually 27 different institutes and centers. And that's important because they all have their own mission. They all have their own budgets, and so they all have their own priorities. And so because of that, they might have different grant programs that they offer. It also might affect the types of people in the organizations that are eligible to apply. So if you've not, I encourage you to really look at all of the institutes and centers here at the NIH, look at their missions and see which one might be of most relevance to your particular research program. Fortunately, on this side, there are a number of people who are happy to help you navigate the process. You've heard from several of them already today. There are people, program staff like myself, and I'll talk more about my role later. But we also have scientific review officers, and these folks are in charge of that review meeting that I mentioned earlier. We also have grants management specialists and officers, and these folks are a wealth of information for helping you monitor the budget, answering any policy or compliance questions that you may have, and I can tell you that I also reach out to them regularly to ask these kinds of questions as well. The other thing I want to point out is that grant awards from the NIH are issued to institutions by and large, not to investigators. So because of that, I think it's really crucial that you set up a dialogue with your organization's designated representative. Now this may be called your signing official or your authorized representative, and they're usually located in your institution's business office, sometimes your sponsored programs office depending on how your institution has this set up. The other thing to note is that you have to respond to a funding opportunity announcement, and so inside this FOA, you will see eligibility criteria, and you'll also see contact information for the person here or persons here at the NIH who you may want to contact for more information. All right. So whether you are a domestic institution or if you're an international institution, in either case, you're going to need to need to submit a competitive idea. So a scientific idea that's important for your field, because remember, eligibility for a program does not necessarily equal to competitiveness. So you want to make sure that you have a competitive idea. It also needs to align with the mission of the NIH and an institute. And it must be unique, and what I mean by that is, it can't be something that's already funded. So the NIH is not going to fund research that we're already funding. And so if you're new to the field or new to the NIH, maybe you're an international organization, how do you know what's unique and what's already being funded? Well, fortunately, there's an excellent tool called NIH RePORTER, and it's part of a suite of the NIH Research Portfolio Online Reporting Tools. And with this module, you can mine a really amazing wealth of information. I use this all the time myself. You can look at project numbers, PI names. You can find out success rates if you want to know how much money the NIH is spending on a particular topic, then you can find that out as well. I'd also encourage you to look at the advanced search site here. So by doing this advanced search, you can enter in your abstract, some key words, maybe a specific aims, and when you do that, you'll be given a hit list, and this will give you an overview of similarly funded projects. And the benefit of doing that, as an applicant, is that you'll be able to spot underrepresented areas. These are areas where you may want to target your particular project because this would be an area of interest. You'll also notice overrepresented areas. Now, this means that there's probably going to be more competition for those areas. It'll help you identify experts in the field, so you can see their publications, their grants and even the study sections that reviewed those grants, and that will help you as you target your particular application. It'll help you identify the most appropriate NIH institutes and the most appropriate program staff such as myself. So speaking of program staff, we are scientists and administrators here at the NIH. Sometimes, we're called program directors. Sometimes, we're called health science administrators. But regardless, we provide scientific expertise to our institute as well as to the NIH at large as needed. We oversee a portfolio of grants and sometimes cooperative agreements. We interact with the research community, just like I'm doing today, and we advise investors. Importantly, we are responsible for helping to develop research concepts and funding opportunity announcements. So if you've never contacted a program staff before, I really encourage you to consider doing that. I can promise you that myself and the program staff that I know, we're more than willing to offer our expertise and help you navigate the process. So when you reach out, you may want to ask questions like, is your project a good fit for our institute? Do we know of any special targeted funding opportunities on your topic? Do we know the most appropriate grant program for your project? And then after review, even though we don't assign the reviewers, we are present. And so after the review, we can kind of guide you into how to respond to those criticisms that end up in your summary statement and then alter it to increase your chances of being funded and then tell you what your chances of being funded are. So finding the most appropriate program officer will really depend on if you know the funding opportunity announcement you're looking at or not. And so if you do, there will likely be a contact person in that funding opportunity announcement. And you can respond directly to that person. But if you're not sure, I would recommend using the NIH Matchmaker Tool, and that is part of the same suite of the NIH RePORTER that I mentioned earlier. And here, again, you can enter your abstract, specific aims, key words, and you will receive a hit list not only of similar projects but also of program staff. And so when you get that hit list, you can pick out one or more of those program staff and then e-mail them directly and ask if you can set up a time to discuss your project. When you do that, I would suggest you develop a concept paper. Now, what I mean by a concept paper is not anything too elaborate or formal, but basically if you know the funding opportunity announcement, you can include that. But you should include an abstract, specific aims, study design to get us an idea of what you're proposing. And so we will do a little digging before the call and try to find some information for you to help you as you submit your application. All right. So let's talk just for a moment about finding a funding opportunity here at the NIH. So I'll start with a true-or-false question. So true or false, NIH funding opportunity announcements are only open to US-based or domestic institutions. Now, I can tell you that whenever I travel internationally, and I speak with investigators, and I make presentations similar to this, most investigators internationally think that this is true: that they cannot apply to the NIH directly. But as many of you are probably aware, this is absolutely false. So there are a number of funding-opportunity announcements that are also open to international investigators. And as was mentioned in previous presentations, there are at least two ways for a foreign organization to get funding from the NIH, and the first is through a direct foreign award, and the second is through a domestic award with a foreign component. Now, there are some really key differences between these two that I want to point out. The first is that, as a direct award, you will receive the full allowable budget. That means the total budget you're asking for will go to your organization to complete the research. Whereas with a foreign component or a collaborator, you're only going to receive a portion of the budget that's reflective of the work that you're going to be doing on the particular project. Now, there is a trade-off. So with the direct award, you're also going to be subject to additional review criteria, and I'll talk about those in just a moment. And it also requires a special approval by the advisory council of the institute that's issuing the award. So I usually advise to let the science dictate this. And if you are in doubt, please reach out to a program staff and they kind of can walk you through the differences between these and help you decide what might be most appropriate for your particular project. All right. So the standard review criteria, which is going to apply whether it's a domestic award or a foreign award, reviewers are going to be asked to comment on the significance, which is what I mentioned earlier. What's the impact of the study that you're proposing? How significant is it for that particular field of science? They'll be asked to comment on the investigators. So what is your track record? What do your publications look like? Things like that. They'll ask to comment on the innovation, so how innovative is your approach, the techniques that you're using? And then with the approach, is it scientifically feasible? Do you have preliminary data to back up what you're claiming? And then they'll comment on the environment. So what does the research environment look like where you're proposing this particular project? Now, if it's a direct foreign award, in addition to those, reviewers are basically be asked, why does this need to be done in a foreign country, by a foreign organization rather than here in the US? So is there comparable work already being done here in the US in this scientific area? So a way of addressing that, when you're writing your applications, to really point out if there are special opportunities via unusual talents or resources or maybe access to some of those patient populations that I mentioned earlier. Or maybe there are different environmental conditions that are there. And then finally, be sure to address how the work you're proposing is of relevance to the mission of the particular institute that is going to be funding the award. All right. So what about these research-funding opportunities when you're trying to decide which program might be best for you? And I want you to think about at least three different areas, and the first is matching where you are in your career. So clearly, the types of programs that might be appropriate for a trainee are going to be very different from those of a more established faculty member or a PI. Secondly is the type of research you're proposing. So is this a smaller, basic, pilot-feasibility-sort of study? Or is this a much larger project, maybe a clinical trial of some interventional development that you're proposing? And then finally, the funds that you need. So again, is this going to be a very small project for just a couple of years? Or is this going to be a much larger project that will require a much larger budget? So thinking about these three things will help you sort of guide in the direction of which grant program might be the best one for you. So fortunately, the NIH has several different activity codes, and I did not list them all here but just a few based on my portfolio, the ones that are kind of the most common that we get asked about. And the first is the research project grant or the R01. Now, this is the most commonly used grant program by the NIH. It is generally awarded for 3 to 5 years. These are largely hypothesis- driven types of applications where you need robust preliminary data and generally for 3 to 5 years and under $500,000 US per year. But we also have these smaller grant programs like the R21. So these are for newer exploratory type programs, and you don't need preliminary data for this particular type of activity. We also have the R03. This is also a small grant mechanism, even less money than the R21. And so I often see investigators using this for small, self-contained projects, feasibility studies or even to collect preliminary data for a larger study that they are planning. And then finally, the cooperative agreements. These are very similar to the R01, except that there's much more program involvement in this particular activity. All right. So how do you go about finding these funding opportunity announcements? So this was already spoken about earlier, but if you've not checked out the NIH Guide, I really encourage you to check this out because this is published weekly, and you'll get a list of all the grants and some contracts opportunities that are available from the NIH. You can set up for e-mail announcements. You can follow their Twitter feed, and that way you can stay up to date on the latest funding opportunities from the NIH. These will be published simultaneously on the NIH Guide and also at grants.gov for grants from the NIH. And I want to reiterate that all the applications have to be in response to a funding opportunity announcement. So sometimes, the NIH will have a targeted request for applications. So program staff like myself, we've identified an underrepresented area where we want to target applications. But there are also times when you have an idea that there's no target announcement for that still requires a funding opportunity announcement, but it would be in response to the parent announcement. And so included in your slide set, there's a link here for all of the parent announcements. For example, there's a parent announcement for that R01, for the R21 and so on. So let's take a look at grants.nih.gov. Now, if you've not looked at this site, or you don't look at it regularly, I encourage you to check it out because you can find out information about grants, the process itself, how to apply, all the policy things that had been presented earlier today and information that's relevant for us is foreign applicants link that you see here on screen. So this is important, not only for direct foreign awards, but if you're a domestic institution looking for a collaborator, this is also useful information for you in guiding that foreign component of your application. So next is finding grant funding, which is of course, of relevance to everyone listening. And so you can find this from that NIH Guide that I mentioned earlier. When you do that, you will get a full list of all of the funding opportunity announcements available from the NIH. But fortunately, you can limit those by your area of interest. So let's say I'm a researcher and I'm interested in COVID-19. I might want to search for SARS-CoV-2 or COVID-19, for example. I'll click search. And by doing that, I will be given a hit list of available opportunities that are available right now. So you'll see the hit list, the title. You'll notice that the FOA number is here. some of these are requests for applications. some of them are program announcements. You'll see the institute that's issuing it. You'll see the release date, the expiration date and then one of those activity codes that I mentioned. Now, just because you see them here does not necessarily mean that it is right for your science or that you're eligible to apply. But what you can do is click on one of the links, hyperlinks for these, and you will find more information in the funding opportunity announcement, or FOA, itself. Example here is a request for application. That's one of those targeted announcements I mentioned earlier. But you'll see things like the key dates, how you can apply, the instructions for applying, the objectives of this particular program and contact information, as I mentioned earlier. So if you want more information, you'll know who you should contact here at the NIH. A couple of other areas that you should definitely check out are the eligibility information. So as I mentioned, just because they're on the screen as the hit list doesn't mean you'll be eligible to apply. So check out the section on eligibility, and you'll see in this example, foreign institutions are eligible to apply, and foreign components are eligible. So either would work for this particular example. But that may not always be the case. And then secondly, you'll see the review information. So this is relevant for you as you are filling out your application because these are the things that reviewers are going to be asked to address. So you want to make sure that you put them in your application. The other thing to remember is that there are 27 institutes and centers. They all have their own mission, their own budgets. So I would encourage you to find an institute that most closely aligns with your particular research and then look at their websites regularly, read their strategic plan, look at the priorities of that institute. If you're able, participate in workshops that that institute may have. So individual institutes will have workshops just like the one that we're participating in today, and you will be able to interact with staff of that particular institute as well. And then of course, you'll have to respond to an FOA, and so on the institute's website, you'll also be able to search for their funding opportunities. So let's take a look at an example of that. This is NIAID, where I work, and a lot of the institutes, their websites will be a little different, but they'll contain some of the same types of information, and so you'll be able to see the types of research they're conducting, what their mission is, if they have featured areas of research, like for NIAID, you can notice that antimicrobial resistance is highlighted, HIV and also coronavirus, and they'll list their funding opportunities. And so you can search directly there. Also want to mention that when you're searching for these, you can certainly enter scientific terms in the search, but you can also try something like global or international in addition to those scientific terms. And so by doing that, and I did this as an example with NIAID, you'll get opportunities such as this one, which is the International Research in Infectious Diseases, or IRID, and I happen to be the contact person for this one, so I'm familiar with it. And I wanted to point it out because this one has a really broad scope. Basically any sort of infectious disease research that you can imagine, and it's only open to international applicants. So this is an example where domestic institutions are not eligible to apply. So it's really important to look at that eligibility portion of the funding opportunity announcement. All right. So what about if you are a US domestic institution, and you want to establish a foreign collaboration? How do you go about doing that? So this was commented on earlier, this idea about a foreign component. Now, there is an NIH definition, as we mentioned earlier, and that's the performance of any segment or elements of the project outside of the US. This is whether or not money is being sent there, and so some of the activities included are pretty obvious. So if there are going to be human subjects or animal subjects at the site, if they're going to be really directly involved in the research, maybe they are doing one of the specific aims, those are kind of obvious things. But the activities could also include collaborations that result in coauthorship. If you're using their facilities or their instrumentation at the site, then any of those may be considered a foreign component by NIH definition. Importantly, just traveling to a foreign site to consult with a foreign investigator is not necessarily considered a foreign component.

All right. So when you're thinking about establishing a foreign collaborator, I would encourage you to think about the type of role that this person is going to play. And so what I mean by that is: If they share your area of expertise, and they're really involved in the development of the application, or maybe they are executing a particular aim, as I mentioned earlier, you may consider them as a coinvestigator. So they're going to be a PI, sort of equal standing with you. If they have a complementary area of scientific expertise, but they're still having an active role in the research, you might consider them a collaborator. And then finally if they're providing professional advice or maybe they're performing a service for a particular fee, then you might consider them as a consultant. So in each case, I usually advise the ... Whoops, go back one ... I usually advise to let the science dictate this. So if you're in question, please reach out to the program officer, and we'll try to guide you through that. All right. So how do you find a foreign investigator or foreign collaborator? One of the best ways I've found is through networking like: international meetings, workshops, conferences. Things like that. This is useful because you'll get to see them present their science. They'll get to see you present yours at these meetings. It'll allow you opportunity to exchange ideas to set up these sorts of collaborations. Now I realize this is not always feasible. So maybe you're new to a field, or you have not had the opportunity to present your science in this type of venue. Fortunately, there are also several tools you can use and things like the NIH RePORTER that I mentioned earlier. You can also use PubMed, and I'm sure that any of the scientists listening to this particular webinar have used PubMed before. So you can search for publications and find collaborators that way. But this third tool is one that you may not be aware of that I think is also really useful, and it's called World RePORT, and this will help to identify collaborations between domestic and foreign institutions, and these are collaborations that are not always obvious by just looking at RePORTER. So by going to this site, let's say that I'm a researcher interested in Chagas disease, and I'm located here in the US, and I want to establish a collaboration with a colleague in South America, so maybe I want to take advantage of getting access to certain patient populations or to parasites that might be there. So what I can do is type Chagas as a key word. I can limit it by South America as the continent. I can limit it by NIH as the funding organization. I can also even limit it by a particular country. If I only wanted to find a collaborator in Brazil, I could do that. When you do that, you will be given a hit list again of various projects. And you'll see ones that are direct awards, ones that are collaborations. And then you can find hyperlinks over on this side or buttons that you can click, and when you do that, you'll be taken to more specific information, so you'll be able to see the full abstract. You'll be able to see the site of the award and who the collaborators are. So on the map, you'll notice these dark black circles. Those are where the direct awards are, here in the US. And then these lighter circles and the lines represent where the collaborations are. So maybe you already know these researchers here in the US, and so you can contact them. You can try to establish the collaborations that way.

All right. So in the last couple of slides, I want to talk about managing the foreign collaboration, and there are a few things to consider, and these have been mentioned earlier as well. So the institution in a foreign organization or foreign county, there may be language differences that you need to navigate. They may be in a different time zone. They may have different access to the Internet. Their sponsored program staff may be set up differently than you, and they may not have the same appreciation for NIH funding requirements. Secondly is budgetary considerations. So when you're writing your budget, keep in mind that the salary norms at a foreign institution may be vastly different than they are at your institution in the US. It may be difficult to obtain research supplies there. I know of situations where it could take 3 months, 6 months or more to get certain supplies to a foreign institution. And then currency exchange rates, so your award is going to be issued in US dollars, so you need to make sure that you keep that in mind. So I would just encourage you to plan early, stay involved for the full process before the application is submitted all the way through and then be patient. These foreign collaborations are truly scientifically rewarding, but they do take effort on your part to make sure that they are successful. So I would like to leave you with a few take-home messages, and the first is, I would encourage you to familiarize yourself with the missions of the individual NIH institutes and centers. Remember, they all have their own priorities, their own budget and their own grant programs. Learn where to look for funding opportunities. So I've given you a few options here, that NIH guide going to the individual institute's websites, and then encourage you to reach out to program staff. Please don't hesitate to reach out to program staff. I know new investigators especially are a bit nervous about doing that, but it's one of the most rewarding parts of our job, so please feel free to reach out. I've given you a bit of information about identifying collaborators, and I would leave you with be persistent going back to the very beginning of the talk when I listed the grants process. So at the review meetings, around half of the applications are triaged. That means they're not discussed at the meeting and even fewer of those actually receive funding, and again, I say that not to discourage you but to encourage you to plan early and to be persistent. Take advantage of the resources that you're being given today. These links are included in your slide set as well. I'm not going to go through them all. Just to state the individual institutes, several of them have their own sites for global health programs or international research. So I'd encourage you to reach out to those folks as well, see what's offered there, and that may be able to help you as well. So with that, I'd be happy to answer any questions along with my colleague, Emily Linde.

Kasima Garst: Thank you so much, Glen, for that wonderful presentation. Before we formally kick off the Q and A portion, I want to address a question that we got a couple of times in the Q and A regarding searching for funding opportunities within the NIH Guide for Grants and Contracts for opportunities that either are specifically for direct foreign applicants or that allow foreign components. We currently do not have that specific functionality within the NIH Guide. However, we will evaluate how we can continue to improve the search functionalities there and seek that enhancement for the future. In the meantime, as Glen was saying, the Fogarty International Center listed there on that resource slide does have a curated web page that has opportunities that are for international and global health. I will share that in the Q and A. But thank you all for that suggestion. So let's go ahead ...

Glen McGugan: That's a great suggestion.

Kasima Garst: Thanks, Glen. So let's go ahead and get started. Let's see. The first question, and we did have a few sort of specific scenarios, however, in general, going back to about getting started, who should the prospective applicants reach out to to sort of really talk through the specifics related to the ideas that they're having and to determine if they really meet that eligibility? I know you talked about this a little bit on that reaching out slide but thought it might be helpful to reiterate.

Glen McGugan: Absolutely, thank you for that question. So I would say the first point, or the first stop, would be looking at the funding opportunity announcement. So there's going to be a contact person that's listed there. So sometimes funding opportunities go out, that I don't even know about yet, and an applicant will contact me, and I might contact the person who's listed in the FOA myself. Other than that, if you just want to bounce the ideas off, so you have a particular scientific idea in a particular area, use that Matchmaker tool and find a program staff to reach out to, and we can talk you through that because we have experience with looking at these types of applications, how you can design them to be most competitive, things like that. So, yeah, I would say the contact information in the FOA and the program staff.

Kasima Garst: Wonderful, thank you. The next few questions here, we have some more around that additional review process. Can you talk about that a little bit more, and is that foreign justification reviewed at the meeting?

Glen McGugan: Yes, so at the meeting, the way these applications are handled ... And again, this is going to be handled by the scientific review officer. Program staff, such as myself, we're there, but we don't comment. We don't control the review process. So you could also talk to one of the review staff as well. But basically, in the review, the reviewers will first be asked to address those main topics that I mentioned at the beginning, so the overall impact, the significance, the investigators, things like that. And then after, since it's a fully foreign award, they will be further asked to address the appropriateness of having this research done outside of the US. And so as an applicant, you want to make sure that you emphasize, that you have access to special patient populations. So I can tell you in my experience, since I work in parasitic diseases, most of these are not endemic here in the US, to it's much easier for you to make the case to say, "Well, hey, this is a malaria population. We don't have these malaria patients in the US. And so we're going to get access to this particular population," things like that, but it is addressed in the review meeting just usually as a separate review item after the main review has been conducted. Does that answer the question?

Emily Linde: Glen, I would like to add one piece to that. I think the other piece that they're thinking about is when it goes to the IC's National Advisory Board or ...

Glen McGugan: Got you.

Emily Linde: ... National Advisory Council, and for all ICs, for any direct award, those applications are specifically brought to the attention of that board. That board has to review and approve that as a special action in order for the IC to be able to consider it for funding.

Glen McGugan: That's exactly right. Yeah, that's an important point. So when it goes to the advisory committee meeting ... So all applications have to go to the advisory meeting, but some receive en block approval, but these have to be presented, as Emily said, as a special issue, so they're brought up separately at the advisory meeting.

Kasima Garst: Thank you both for that. Continuing on the questions about the additional review, how would a multiple principal investigator, or multiple PI, proposal with the lead PI or institution being in the US and the other PI maybe being based at a foreign institution be treated?

Glen McGugan: So I can speak to the scientifically how it would be treated. Maybe Emily could address more of the compliance and budgetary issues. I don't know if you want to start, Emily.

Emily Linde: Sure, I can. So what we're looking at there is whether or not the applicant organization is a domestic organization or a foreign organization, right? And so if it's a multiple PI application and the contact PI is with a US organization, that US organization will be the submitting institution, in which case it would be brought for a regular review. If you had a multiple PI application and the contact PI was at a foreign institution, then we would consider it a direct foreign award.

Glen McGugan: Yeah, and scientifically speaking, if you have a question, you can reach out to the program staff, and we'll help you walk through that, what are the pros and cons and really how is the science set up and does it make sense to actually have a multi-PI application. It may not make sense. So we can help you ... help walk you through that as well.

Kasima Garst: Great, thank you both. The next question we have, if human subjects research happens at the foreign subrecipient site, what is the responsibility of the prime US organization? Is the IRB of the prime involved at all?

Glen McGugan: Yeah, that's a great question. And maybe Emily wants to comment on this as well in terms of compliance and policy. But ultimately, the institution that serves as the prime, they're going to be responsible for making sure that the subcomponent is complying with federal rules and regulations. So there are some times IRB approvals at foreign sites. But ultimately, it's going to have to fall to the institution that's receiving the direct award to make sure that you're in compliance with federal regulations.

Emily Linde: And that's exactly right. I wouldn't add anything to that. The prime recipient is ultimately responsible in that case.

Kasima Garst: Great, thank you. The next question we have, this goes back to what you were referring to about foreign consultants and that definition of a foreign component. Someone asked, is a foreign consultant considered a foreign component? You mentioned that foreign travel for consultation is not a foreign component. Can you please elaborate?

Glen McGugan: Sure, so this is kind of confusing, and I know earlier there was discussion about the distinction, maybe ICs treat it differently. And I can speak for NIAID, where I work. There's some times in the application where you have an activity that's ongoing and a foreign collaborator in the organization that scientifically doesn't really seem like a foreign component, but we also have to alert the State Department, right, that there is activity ongoing in a foreign entity, and so we use that to guide us as well. So sometimes we want to track this just so we know, hey, there's activity ongoing in a foreign institution that's the result of federal NIH funding for this particular project. So we can walk you through that if you have a question about how you want to set this up. Is this actually a foreign component? Is it not? Contact a program staff, and we'll try to work you through that. And the institutes, like NIAID, we also have an Office of Global Research, OGR, that also walks us through these, and so it may be possible to reach out to those staff as well. I don't know if Emily wants to comment on that.

Emily Linde: Well, I think we're unique. I think we're one of the few ICs that actually have an additional office because we do have so much global involvement because in the nature of infectious diseases research that we support. I would say, though, depending ... just because it's a consultant doesn't mean that it is or is not a foreign component. For the most part, it's not going to be a foreign component. But I think Michelle covered this fairly well earlier in the sense that if there are humans or animals involved, even if it's a consultant, then we would consider it a foreign component. We're going to look at the level of involvement. Are you expected to have a coauthorship? Have you called them a consultant, but their scientific involvement is really a little bit more in depth than what we would see for a normal consultant? So just because it says consultant doesn't mean that we're not going to be looking. We're going to be looking very much at the scientific structure of that and what's appropriate to go forward from that point.

Glen McGugan: So if I can, I'll give you an example. Maybe this will help. So let's say that you are a domestic institution. You've set up a foreign component and there is a foreign investigator who is an expert on a particular technique. And you propose to do that technique in your application. You know how to do the technique. You have the materials in your US lab, but you get a letter from them saying, if I run into trouble, then this person is going to offer advice on how to do that. In general, that would not be a foreign component because they're not actively involved in the research. They're just saying, "Hey, if you run into trouble, I'm happy to share my expertise." This could be by a phone call, by e-mail. But on the other hand, if they are going to perform this particular technique for you for the application, then that most likely is a foreign component, even if they're not requesting a budget in the application.

Kasima Garst: Thank you both so much, and thank you for everyone who was able to join us on this incredibly informative discussion. The PowerPoint and related resources have been posted to the International Collaborations Precon page on both the NIH Grants website and the NIH Grants Conference Center, once you've logged in. And the link was provided in the chat as well. Thank you, everyone, for joining us for this 45-minute presentation with some case studies ... this presentation focused on foreign international ... foreign interference. This topic is of utmost importance as we strive to protect the biomedical research, innovation and research integrity. We invite you to get involved in our case studies and ask your questions be added in the Q and A box in Zoom if you are joining us for the live event. My name is Kasima Garst. I'm a systems policy analyst in the NIH Office of Policy for Extramural Research Administration, or OPERA, and I will be your moderator for this presentation. I'd like to introduce you now to our presenter, Miss Ki-cha Flash-Zapata, the Deputy Director of the Division of Grants Compliance and Oversight, located within the NIH Office of Policy for Extramural Research Administration. Ki-cha, I'm going to turn it over to you. Ki-cha, I think your audio is not coming through.

Ki-cha: Thank you, Kasima. Good afternoon, everyone, and welcome. This afternoon I will be providing a brief overview on foreign interference. NIH is the largest public funder of biomedical research in the world in that it has invested approximately $32 billion annually towards research. Because of this big responsibility, NIH has developed numerous policies and procedures to ensure scientific integrity and to facilitate the fulfillment of its mission within and throughout the intramural and extramural programs. NIH's core values include promoting the following principles, but I will only highlight a few, transparency, honesty, collaboration, integrity, fair, merit-based competition. These four principles and values align with the White House Office of Science and Technology Policy and the NSPM-33 implementation guidance. At the heart of fulfilling the NIH mission is ensuring and safeguarding the integrity of science and science-based policy making. Scientific collaborations are encouraged, both domestically and internationally, because they are important for scientific advances critical to solving the most pressing and perplexing health challenges. They are an essential part of innovation and is vital to our global competitiveness. The NIH-funded biomedical enterprise depends on a competitive system which is fair, transparent and trustworthy. Some foreign governments have tried to take unfair advantage of or exploit NIH's long tradition of trust, fairness and excellence. NIH has taken steps to address inappropriate interference by foreign governments, institutions and researchers over federally funded research and technology. Since 2016, NIH has worked on undue foreign interference in NIH-funded research resulting from discoveries of noncompliance with other support, invention reporting and financial conflict of interest requirements. As mentioned before, NIH core values and principles align with the NSPM-33, National Security Presidential Memorandum on Research Security and Integrity. The guidance provides a harmonized approach for federal departments and agencies across research platform to strengthen disclosure requirements within the federal government. The goal is to strengthen and support the research programs against foreign interference. As mentioned before, NSPM-33, maintains and promotes core values which aligns with the NIH core principles and core values as well. And here we have repeated openness, transparency, honesty and the same as mentioned before. The NIH has implemented these provisions in a nondiscriminatory manner and NSPM-33 is also broadened to include international students, scholars and collaborations. This slide reveals the core values and principles that is very similar to NIH's core values and principles as previously mentioned. And here you see openness, transparency and the like. So why is NIH focused on preventing foreign interference? Integrity, foreign interference puts NIH core principles and values at risk. And these are the core principles, as a reminder. For overlap, foreign interference increases the risk of budgetary commitment and/or scientific overlap due to nondisclosure. For innovation, foreign interference could lead to intellectual property theft, which weakens our national innovation base. For compliance, failure to submit complete and accurate other support information and comply with the FCOI and invention and patent requirements represents a violation of the terms and conditions of NIH awards, including federal regulations. In compliance, these are typical noncompliance areas, the FCOI requirements and the Bayh-Dole requirements for IP have not changed. For the peer review process, foreign interference threatens the objectivity of the peer review process to identify the most promising biomedical and behavioral research. Okay, let's briefly review some of the NIH requirements for disclosure. Recipients are expected to provide full transparency in NIH applications and throughout the life of the NIH grant. The NIH Grant Policy Statement, specifically section 2.5.1 provides details on the other support expectations. Also reminder, recipients are required to fully disclose all other support information for individuals designated as senior key personnel in grant applications or progress report. This notice, Notice NOT-OD-21-073, also provides details on other support for applicants and recipients regarding full transparency and disclosure of all research activities. And then we have the other support page, which also provides more details on the requirements and includes frequently asked question. So how does NIH identify foreign interference? Some are anonymously disclosed through self-disclosure by the recipient, or NIH staff may review and refer the details to our team. They may review and analyze the other support or FCOI information or Biosketch, just to name a few. There may be law enforcement referral, or we may receive referral from other federal agents and OPDivs. Sorry. Essentially everyone shares in the responsibility of promoting scientific integrity within and throughout the research enterprise and protecting the federal interest. What have we seen thus far? The failure to make complete disclosures, such as a failure to include foreign employment contracts, consulting agreement, talent awards, foreign research support, foreign research space. Also we've seen undisclosed significant financial interest by an investigator. Therefore, there was no institutional FCOI review. For example, we have seen an investigator with equity interest in foreign companies who received remuneration from foreign institutions that were not disclosed to the university until way after the fact. Only after the recipient had been made aware of this noncompliance item by NIH or other agencies were they able to take action, egregious violations of peer confident ... peer review confidentiality rules, such as the sharing of confidential applications with foreign entities.

This table shows a brief overview of the outcome of the compliance review on foreign interference cases. Most reviews are still open, approximately 65.6 percent. However, we have determined from that, that for 80 percent of the cases, there were at least one serious compliance violation. So we have here undisclosed grant support, undisclosed talent awards and equity, all that here. Also, less than 10 percent of the cases were found to have no violation. That is no undisclosed foreign affiliation and no serious violation as you see here. And over half of the scientists were removed from NIH grants via corrective actions, either through institutional separation, such as termination or resignation or other internal institutional actions. So the following provides a brief high-level overview of the allegation review process. Basically, when we receive the allegations, we first conduct an initial review or assessment of the information. Then we contact the institution and ask for more information. Depending on the details we receive and our analysis, we may remove the individual from peer review service. Depending on the seriousness of the noncompliance items, NIH may refer the case to another agency for their review and oversight responsibility. And we work with the institution to then provide guidance on administrative actions as needed, working to bring the recipient back into compliance with NIH policies and federal regulation. So this slide pretty much covers what was mentioned previously regarding our assessment and process of these cases. So we can move on.

Okay, now it's time to review some case studies. We will be collecting the answer by polling, I think, and then we'll discuss the answers thereafter. So for the first case, the first ... Let's see. Person A, a professor at 123 Medical University which is a domestic entity failed to disclose the following to the university, various foreign affiliations, positions, foreign funding via grants, contracts, honors and awards from 2012 to 2020, outside FCOIs which included a multi-million dollar investment in another company where Person A had approximately 57 percent equity and was a founder, president and signing official. Person A marked no on the university's internal annual significant financial interest disclosure form, which was a false statement. Company received patents and sold products derived from the NIH-funded research. On NIH-funded grants, the university declares that there are no FCOI to disclose or manage. The university became aware of this situation because NIH inquired about the company and Person A's investments. Okay, so the first question there on the screen, what is 123 Medical University required to do once they were alerted to the facts of this case? A, keep the information, not review or investigate the details further and thank NIH for the information? B, tell Person A not to do it again, chalk it up to lessons learned and move on? C, investigate and promptly notify and report the information to NIH? D, all of the above? Let's see what the responses here are. Oh, wonderful! Ninety-four percent said C. Let's see. Yes! Correct. The answer is C. The university should have investigated and reported the details to NIH. As noted in NIH GPS Section 2.5.1., recipients are expected to establish and maintain effective internal controls, such as policies and procedures, to ensure that individuals designated in applications as senior and key personnel fully disclose all Other Support information as soon as it becomes known. If the recipient discovers that a PI or researcher failed to disclose the Other Support information, they should submit as soon as they find out the information. The recipient must submit updated Other Support to the Grants Management Specialist named in the NoA as soon as it becomes known, and I just want to highlight "as soon as it becomes known." Additionally, the NIH GPS Section 4.1.10 Financial Conflict of Interest states that NIH requires recipient institutions to comply with the requirements of the regulation noted here, 42 CFR Part 50, and essentially the overarching goal for that is so that reporting ... The reporting is to promote and encourage transparency in order to avoid distorting NIH funding decisions. So I won't go into much details, but essentially the recipient institutions ... comply with the requirements, and there are some important requirements there.

Okay, so let's go into Case Study number 2, question number 2. What information should Person A have shared with 123 Medical University? Person A should not have shared any information? Person A should have abided by 123 Medical University's policies and be honest/transparent by disclosing everything to the university, including all foreign affiliations, research activities, investment and roles in other companies? Person A should have denied everything? D, all of the above? All right. Everybody should know at this point. Correct, 98 percent got the right answer. The answer is B. Person A should have abided by 123 University's policy and be honest/transparent by disclosing everything to the university, including all foreign affiliations, research activities and investments and their roles in other companies. According to NIH GPS Section 2.5.1, which we just discussed, reporting of other support is required for all individuals designated in the application. Also, other support includes all resource made available to a researcher in support of and/or related to all of their research endeavors, and it goes into more details. This is just a high level of what is seen there. Also, in NIH GPS Section 4.1.10, Person A should have abided by the University's FCOI policies and reported the investments and equity in the foreign company, so that the university is able to comply with the FCOI reporting requirements.

All right. So let's look at the outcome of this case. Based on NIH's findings and guidance, the university investigated the issues, validated the FCOIs, conducted a retrospective FCOI review and reported the outcome to NIH. NIH worked with the institution to develop the corrective plan, and the corrective actions or plans that were implemented on Person A and across the institution included refunding NIH-funded grants because of the failure to meet its own FCOI policies; prohibiting Person A from participating in NIH-funded research activities for 1 year, 1 fiscal year; replacing Person A as PI and Senior/Key Personnel on NIH-funded grants; developing a robust plan in place for oversight of Person A's research activities; providing the FCOI and disclosure trainings to Person A; and assessing its own FCOI program and policies in order to improve its ability to identify and develop appropriate management plans for FCOIs stemming from faculty start-up companies and providing the outcome of the report to NIH. So you see all of that based on what happened, but then NIH did work with the recipient to bring them all back into compliance.

All right. Let's move on to Case Study number 2. Person D did not disclose the following to 123 Medical University: foreign affiliations, foreign honor/awards, foreign funding. They received multiple foreign grants where Person D was listed as PI and devoted significant effort to these foreign-funded grants, and this, in one particular, there was a full-time contract at a foreign-funded university where Person D was devoting 12 person-months in effort to the foreign-funded grants. Person D also had significant involvement as PD/PI and Senior/Key Personnel in many NIH-funded grants. The university was not aware of Person D's foreign affiliations and foreign-funded grants and therefore could not report complete and accurate Other Support information as required in the Just-in-Time via eRA or in the RPPRs. So what ... For Question 1, you have it on the screen. What is 123 Medical University required to do once they were alerted to the facts of this case? Tell personnel ... Tell Person D not to do it again, chalk it up to lessons learned and move on? Investigate and promptly notify and report the information to NIH? Ignore NIH and continue with business as usual? And D, all of the above? Let's see what the answer is. Exactly, 100 percent got it right! All of the above, correct. Sorry, not all of the above. My apologies. Answer is ... The answer is B. The university should have investigated and reported all the details to NIH, and again in Section 2.5.1 of the Grants Policy Statement, the applicants are responsible for promptly notifying NIH of any substantial changes as ... changes to their Just-in-Time information and the Other Support in RPPR as well. And we also have the description on any kind of Other Support changes that could lead to budgetary overlap, scientific overlap or commitment of greater than 12 person-months for the PD/PIs or any Senior/Key Personnel. Should be ... They should notify NIH. So the reason why I have the second one there is that as soon as the information becomes known, the recipient is required to provide us with updated Other Support information.

Okay. Question number 2, what information should Person D have shared with 123 University? Person D should have abided by 123 University's policies and be honest/transparent by disclosing everything to the university, including all foreign affiliations, research activities, grants, et cetera? Person D should not have shared any information with 123 University? Person D should deny everything, "what they don't know won't hurt them"? And then D, all of the above? All right. The answer is A, 100 percent. All right. Person D should have abided by the university's policy and be honest and transparent by disclosing everything to the university, including all foreign affiliations, research activities, investments and roles in other companies. As a reminder, NIH GPS Section 2.5.1 says reporting of other support is required for all individuals designated in the application as Senior/Key Personnel and also those devoting measurable effort, and we've reviewed the second bullet before as well so ... But it is required, and as soon as you know the information, report it.

All right. Let's look at the outcome. Based on NIH's findings and guidance, NIH reported the foreign talents contract to 123 Medical University. The university investigated the issues and reported the details to NIH. NIH reviewed and analyzed the details which included commitment and budgetary overlap for Person D but found no evidence of scientific overlap. NIH worked with the 123 Medical University on the corrective action plan which included prohibiting Person D from participating as PI or Senior/Key Personnel for a 1-year period, replacing Person D as PI or Senior/Key Personnel on NIH-funded grants, requiring a bilateral termination of an investigator-initiated NIH-funded grant where Person D was a PI, refunding Person D's salary, fringe and associated F&A costs for all fiscal years where commitment overlap was identified and developing a monitoring plan for oversight of Person D's research activities which included FCOI disclosure trainings.

Okay, a few reminders: Know and abide by the Other Support, FCOI and IP policy requirements as well as Foreign Components. I have listed and explained a few ... in a few details what each of these are, but if you were to take the time and look at the Grants Policy Statement and some of these references, it will provide more information to you. Also, when in doubt, ask early and often. This is greatly encouraged, and the hope is that you will continue to contact your program and/or grants management staff as often as you need, just in case you're not sure about things. Just reach out to them, and they will provide as much answers and details as needed. Remember that transparency and honesty is key. Finally, everyone has a part to play. This is something that we need to remember. Everyone has a part to play. Together we can protect the NIH research enterprise and embrace research collaborations abroad while maintaining NIH integrity and values. I have provided some references here for you to go back and review if you have any questions, and now I thank you all for listening and being a part of this presentation. Do you have any questions?

Kasima Garst: Thank you so much, Ki-Cha. So we're going to go ahead and get started with some of the questions that we've received in Q&A feature. A reminder to those in the live presentation to continue to send your questions through the Q&A feature. To start off, can you please speak to ... We have a few questions related to the disclosure requirements. If a ... Sorry, my screen just jumped on me. Oh, no, what happened? Okay. Apologies, my screen just jumped. Can you please speak to what if a individual is not appointed or employed with a foreign entity but have a sponsored research project such as a grant from a foreign entity? Do you need to report that to NIH?

Ki-Cha Flash-Zapata: So is the individual a key person? If the person is not key or if the person is not designated as key or Senior/Key Personnel or PI, then they should not have to be concerned with that. I can't remember what the full context of the question is. Kristin, you could help me, if you feel like it.

Kristin Ta: Absolutely. So Other Support is one that we do get a lot of questions on. So if an individual does have a grant from a foreign organization, that is something that they would need to include on their Other Support disclosures, even if they do not have a formal appointment with that organization. Remember, Other Support includes all resources that are available to an individual in support of their research endeavor, so that would include any grants that they have from an outside organization.

Kasima Garst: Thank you so much, Kristin. And I know Kristin will be hopping off for another session, but I would also like to introduce Michelle Bulls, the Director of the NIH Office of Policy for Extramural Research Administration, who will also assist with some of our Q&A. The next question that we have, if a foreign component reimburses the U.S. institution for the U.S. PI to travel internationally, present at a conference and hotel stays, do you need to screen the banks and institutions where the dollars come from?

Michelle Bulls: So, Kristin, did you want to take that? I saw you pop up.

Kristin Ta: No, you can go ahead.

Michelle Bulls: Okay, so when you say "screen the banks," what does that mean? Is that what the question says, Ki-Cha ... Kasima?

Kasima Garst: That is what the question says. I have a feeling that it is related to just the level of oversight for the U.S. PI and with regards to the banking institutions. If the individual would like to elaborate ...

Michelle Bulls: Yeah, I think that would be helpful because that sounds like a ... I can answer the first part of the question, but I'm not sure that it's going to ricochet it around to the right end.

Kasima Garst: If you would like to write it again in the Q&A, feel free to do so. In the meantime, I'm going to go ahead and skip to the next question. Excuse me. The updated guidance for Other Support documents asks us to clearly distinguish between domestic and foreign support. How should we advise foreign Key Personnel on these projects to provide this information?

Michelle Bulls: The requirements for the foreign or the subs is just the same as it is for domestic. If they identify the resources, if it's in-kind, they fill out the same disclosure requirements of the support, and if it's in-kind, they include it there, and they need to outline the effort that they ... or the person-months that they are ... the level of effort that they are giving to the sub. I don't see that there's any difference in terms of how they are reporting.

Kasima Garst: Great, thank you. All right. Let's see. This next one ... And maybe, Michelle, you can speak to this related to some of our fed-wide efforts related to the biosketch and other support. Has NIH considered updating the biosketch and Other Support forms to have a stand-alone section on each that clearly asks if there are any foreign positions, involvement, collaborations or partnerships?

Michelle Bulls: So ...

Kasima Garst: Yeah, go ahead.

Michelle Bulls: It's very interesting because we are working on a common form through the NSPM-33 efforts, and one of the things that we are trying to do is make it very clear for each investigator what they ... the level of effort, the amount of support, in-kind contribution and all those kinds of things specific to the investigators and not wait until the end of the form like we have. The challenge then there becomes ... is we are ... We received over hundreds. I'm not even going to say how many hundreds of comments regarding the common form, and it looks like we might be in the situation where we should be thinking about doing that. So more to come on that, we are still in the throes of looking at the common forms, looking at the data elements and looking at what our community is asking for. We did a ... what we thought a yeoman's job of trying to pull together common forms that would collect and harmonize the data element requests, but we did hear from the community, and the community, there's still some level of confusion that we need to address. So we will see how that goes, and we might end up with a similar ... a new requirement that outlines the foreign support as well.

Kasima Garst: Thank you so much, Michelle. Ki-Cha, I have a question for you about Case Study number 1. What key factors made it so that Case 1 had to return all NIH funds, where Case 2 only had to return the salary and fringe ... or the FNA?

Ki-cha Flash-Zapata: So Case 1 had to do with significant financial conflict of interest. The individual could not ... did not report and was not honest, had all this equity interest and everything and did not report it to their institution whereas ... so that was ... and the institution also did not comply with their own university policy on FCOI where Case 2, however, there was a problem with overlap, overcommitment, and so when we ... if you looked at it carefully, you would see that the individual was ... had, I think ... was committed 12 person-months to a foreign brand and then also had a lot of NIH grants. So when we did the calculations, we went back and asked for the overcommitted amount. So that's the difference between the both of them primarily.

Kasima Garst: Thank you so much, Ki-Cha. Okay, next question here, let's see. If foreign collaborations and activities are disclosed for prior approval from the NIH, but some of the activities occurred already ... or, excuse me, some of the activities have occurred already, will charges incur before the approval be allowable?

Michelle Bulls: Well, that depends, right, because what we would need to understand is where the overlap, whether there was budgetary, scientific or commitment overlap, and what would have to happen is for NIH to do an assessment, conduct an assessment of where the overlap is or was and whether or not the prior approval charges were allowable. Typically, I'm going to say this because I've said this before with ... as we were talking in our earlier presentation. It is very dicey to begin charging a grant where prior approval is required, and you don't obtain it prior to doing so. NIH is not obligated, just like any other federal agency is not obligated, to allow for funds where the compliance requirement is that you obtain prior approval. Now I will say that if there is a scenario where the prior approval was delayed or there is a hiccup, I strongly believe that we have to work with our recipients to make sure that we provide as much understanding and help them come into compliance, but it is not always going to be the case where an IC will allow for that if the recipient is late, and maybe the recipient even has a reputation of being late, and that's just something that we would have to consider.

Kasima Garst: Thank you, Michelle. The next question we have again relating to the timing on those disclosures. Are Senior/Key Personnel required to first disclose foreign support or conflicts of interest at the Just-in-Time stage, or is full disclosure required at the application submission stage?

Michelle Bulls: So that's a tricky one too because if it's not at the application submission stage, it should be reported, right, but typically for Other Support ... well, at the biosketch, right, that's always submitted, but with Other Support, Other Support is collected at Just-in-Time, and that's the agency's way of giving our applicants an opportunity ... or recipients, at that point, when they're under Just-in-Time because they have a good chance of being funded, to update Other Support because it's been almost a year, 9 months at least, where they submitted the original application. If known, they should disclose it at the time of Just-in-Time, at the time of Just-in-Time, but then if it's known after award, but it's prior to the RPPR, they should notify us within 30 days of learning of the information, and that ... We really did update that in our FAQ as well as in the Grants Policy Statement to make that requirements very clear. So I hope that's helpful.

Kasima Garst: Thank you so much, Michelle. Ki-Cha, what are some of the circumstances based on which temporary or permanent debarment may be recommended? Oh, Ki-Cha, I think we're ... you're on mute.

Ki-cha Flash-Zapata: Sorry. It depends on the egregiousness of the case. We have to look at the ... all the details that's provided and see how things lie before we can move forward. So ...

Michelle Bulls: Yeah.

Ki-cha Flash-Zapata: ... if ... Go ahead, Michelle.

Michelle Bulls: No, I was agreeing with you.

Ki-cha Flash-Zapata: Yeah, so if it's something that's minor, we still work with the institution to get into compliance, but if it's something that's really major ... And again, it's kind of hard without having those details to kind of say what it could be, but it depends on the details that we have in front us, and Michelle and Kristin can jump in on that as well, if they have more to say.

Michelle Bulls: Yeah, I will say that it is very difficult for NIH to have to move into a suspension and debarment arena using the suspension and debarment regulations, and that's hard because you are identifying specific issues within the cases, but what we stick to closely are the factual debarment regulations, and we use those to make our determination as to whether or not it is a scenario where we believe the individual should be suspended or debarred. The other thing is that there are some institutions that take their own action and might determine that they would suspend activity of a research investigator for a period of time such that they bring them into compliance and correction and correct actions, and so NIH does ... As we've grown and learned more and seen more cases in this foreign interference space and harassment space, we've begun to work with the institutions to determine whether or not the actions that the institution has taken is sufficient or whether we, like Ki-Cha said, whether it's so egregious that no matter what action the institution has taken, NIH has a responsibility and an obligation steeped out of the regulations to suspend or debar an individual.

Kasima Garst: Thank you, Michelle. The next question we have is related to establishing those subaward requirements. What U.S. Prime recipients or ... should look into foreign subrecipient audit findings when trying to establish those collaboration agreements? So I guess the question is, should those things be looked into and considered as those agreements are being established?

Michelle Bulls: Yes, and so we only make awards to what we call eligible institutions, and if there are audit findings that would prevent an entity from being an eligible institution or if there are ... If there's a high risk in entering into that relationship, NIH would take that under advisement, and some decisions would ... may be made. If it's something that is past and the corrective actions have occurred and the Prime believes that there is a need, primary recipient believes that there is a need to document that, then I think that that's important and place that in the written agreement, making certainly that the ... all of the requirements of the written agreement are clear and ... But I don't believe that if there's an audit finding and there's a challenge or a risk to NIH that a primary recipient should be thinking about entering in if the sub is not in good audit standing.

Kasima Garst: Thank you so much. So in wrapping up, I think we have time for one more question, and I believe this one we can make it a little bit more general in the sense that when there are some countries that have concerns with the data that is collected or used under an NIH grant, that may be subject to the Patriot Act or other regulations. How does NIH either work to assuage some of these concerns, or can you talk a little bit about how some of the foreign legal aspects come into play?

Michelle Bulls: Is that for me or Ki-Cha, Kristin? I don't want to be the only one talking.

Kristin Ta: Sorry, I missed the tail end of the question. Could you just repeat it for me quickly, Kasima?

Kasima Garst: Yes, just how sort of the U.S. laws and regulations versus the foreign laws and regulations and how those are handled.

Kristin Ta: Sure. So I think this is a situation where you really need to look at both your Notice of Award and the Grants Policy Statement because it really breaks out specifically which U.S. public policy requirements and other requirements apply to all recipients and where there are specific differences for foreign recipients or for foreign subrecipients. So as we talked about a little bit in the earlier presentation, most of our NIH requirements apply to all, but there are some distinctions for foreign recipients, especially in countries where the laws may differ from the United States. For example, in Europe there are some different data protection requirements, and that is going to impact how you set up your agreements with an organization in one of those countries, so it's really important to look at those key requirements, and we do lay that out in the policies.

Kasima Garst: Thank you so much, Kristin, and thank you to all of our NIH experts and to all the attendees for joining us for this important discussion on foreign interference. The PowerPoint and the related resources with the updated case studies will be posted on the International Collaborations PreCon page on both the NIH grants website and the NIH grants conference center once you log in.

Kasima Garst: Hello, everyone. The NIH is pleased to have brought you a number of presentations related to international collaborations today. To wrap up our day, we are honored to present leadership from universities across the United States to share their perspective on developing successful programs to support international collaboration. I'd like to introduce you to our moderator for the next 50 minutes, Pamela Webb, the Associate Vice President for Research of the University of Minnesota. Pam, I'm going to turn it over to you.

Pamela Webb: Here, we are just so pleased to be here with you today. It was very nice of NIH to invite us to join in this extremely important event. As Kasima said, we're flipping the tables now. We're talking about things from the institutional perspective and how we go about dealing with international collaborations. We noticed in the poll that there was a lot of interest in policy and procedure around this area, and we're going to focus a lot on that today. The other thing I wanted to share with you, though, is that we really want to also focus on a theme of communication. You'll hear that from us a lot today, and that's because it seems so basic, but it's just so pivotal overall and powerful in terms of success. Before we get into our topics, though, I want to take the opportunity to introduce the panel to you. So I'm going to ask each person to just say hello and your role at your institution as I announce you, Geeta?

Geeta Swamy: Good afternoon, everyone. I'm Geeta Swamy. I am the Associate Vice President for Research and Scientific Integrity at Duke University. I'm also a faculty member and as researcher as an OB-GYN, so I have that viewpoint as well. Thanks, Pam.

Pamela Webb: Thank you, Missy? I think you may need to unmute.

Elizabeth Peloso: Sorry.

Pamela Webb: [Indistinct]

Elizabeth Peloso: Lost my cursor, of course.

Pamela Webb: How you doing?

Elizabeth Peloso: Of course, I'm Missy Peloso. I'm Associate Vice President and Associate Vice Provost for Research Services at the University of Pennsylvania. My office manages both grant post-award as well as compliance issues for all federally sponsored research at Penn, and we have a pretty significant NIH portfolio, so I'm really happy to spend some time with you today and talk about our experience.

Pamela Webb: Thank you, Kim?

Kim Moreland: Hello, everyone. I'm Kim Moreland. I'm from the University of Wisconsin at Madison, and I'm the head of an office that does pre- and post-award activities combined, also does financial compliance regarding sponsored programs and works with the federal government on a great indirect cost rate.

Pamela Webb: Thanks, Kim. All right. So when we were talking as a group today, we decided in addition to that overarching theme about communication that there were a series of topical areas that are things that we think are pivotal to success in terms of creating a program for international collaborations. So we're going to talk about the things that you see here on the screen, that creating that partnership, being able to aggressively and appropriately manage issues both at the time of the award and then as they arrive throughout the life of the award. And then we have a series of special circumstances that we want to talk with you about. We'll try to put in a few vignettes from our own institution as we go through here, but we'd also like to invite any of you that either have comments or questions to please go ahead and put them in Q and A. We have reserved some time at the end for questions, and we will try very hard to get to as many of those as we possibly can, but we want to get right into the topic, so I'm going to start by asking Kim if you would start with talking about how to establish that strong partnership at time of proposal.

Kim Moreland: Thank you, Pamela, and I hope that the other panelists will feel free to interrupt me when I get something wrong because that could certainly happen. When I started in research administration, okay, it was a long time ago, but things were a little different then, and at that point in time if you had to submit a proposal, people brought in boxes of paper, big boxes because in many cases a proposal, again, without page limits would run 500 pages, and then my office would FedEx those out of here, and we memorized what locations ... This was in Lawrence, Kansas ... Had the latest pickup times, so we knew that we could get those submitted to some FedEx location. If it was a really important proposal for a large amount of money, and we missed that deadline, then we'd been known to get on a plane and fly those proposals into Washington. Now my point of all of this is that time times have changed, and it becomes so much more important to read the guidelines even if they're long. I didn't put and boring on here. Even if they are tedious, and you really do have to concentrate on them. It's also important to understand what your campus support systems can provide and not. I'm not aware of anybody who flies proposals into Washington, DC, any longer. That means you've got to hit the deadlines. You have got to hit the pieces of a proposal in the way that is now mandated by federal guidelines, so I urge you stay close to the guidelines for your proposal and to the NIH Grants Policy Statement, which is so helpful. Pamela mentioned communications, and I just want to note that right here because as you are starting to develop proposal, or if you ... I know many of you were administrators, so you're supporting other people who are submitting proposals. It is so important to establish the right lines of communications with your counterparts at a different institution so that if you're hitting a glitch, if you've got one PI who is simply not going to make the deadline you established for them but might be able to squeak in under the NIH deadline, you know that if you have the ability to manage that or not. And I want to suggest also really here. I want to mention something that might be really helpful for you to look at when you're putting those collaborations together, and that is to take a look at the Federal Demonstration Partnership website. I'm sorry. I don't have the link right here because they have established a model template for working with foreign institutions. It's a commonly accepted template among US institutions. It hits all of those important compliance and regulatory items. It might save you a lot of time while still allowing you as necessary to add specific terms and conditions. There's also the importance of understanding what the process is to get an endorsement, a signature on any proposal. Every university does it differently whether you're in the US or whether you are outside this country, and so you need to understand that, and typically it is the same process whether you are the prime submitter or whether you are a subrecipient. In the case of Wisconsin, we'd want a review by the department chair. We need a sign-off at the dean's level. It has to come through my office on its way out the door. All of that can take time. There are systems I'm sure you have that you need to be aware of so you can meet those deadlines so understand the process, and then I just want to comment. There was such an excellent presentation. I didn't get to hear all of it but on subawards, it really sort of dived down into the details. What I want to though for just a minute is the prime institution's responsibility for the subrecipients because you heard it said this morning. Ultimately NIH is going to talk to the prime recipient. That's we hold the responsibility for the actions of our subrecipients. That's financial liability in some cases as well as legal liability, goes back to why those lines of communication are so important. All of us are required if we are the prime recipient to do a risk assessment on potential subrecipients. And when we started with this requirement, which was a mandate from 2 CFR 200 uniform guidance. One of the things we did was we've all created these checklists for our own offices so we could look at a standard set of items and say, yes, this institution, the University of Minnesota meets that requirement, so we can go forward. So this is a process that applies whether it is a US or a foreign recipient institution, and, again, if you go back to the FDP template, and thank you, Courtney, for posting that link on there and also to Joanna, who posted the main FDP link. There is indeed a risk assessment tool that was created. When the FDP creates it, it means that there was some level of participation from the member federal agencies as well as from the body of FDP institutions, and so it asked you. It tells you, I'm sorry, the questions that you are responsible to check with your subrecipient. Many of those can be ascertained by looking at a single audit report if there is a single audit. If there's not a single audit, you might ask if there is a financial statement, or if a financial audit has been created by some other entity even if it is not consistent with a single audit, so there are a lot of ways to get information but remember that we as the primes are responsible for taking charge of that. Does anyone want to add anything? I want to be aware of the time constraints here, yes, Missy.

Elizabeth Peloso: Yeah, so, Pam, that was great, but I think one of the things that we really think about a lot is not only the risk assessment required under the uniform guidance but also institutionally are there other risks associated with doing business with this foreign entity that we may not know that might give us pauses to whether we would want to continue? So one of the things that we do at my institution is, we do export control checks. We check and make sure that neither the institution or the investigators that we're considering working with are restricted parties that would be very difficult to work with in those circumstances and other institutional risks, so is it an area of research in a country, in a place where we're confident that there's not undue risk to Penn institutionally in conducting that activity?

Kim Moreland: Thank you, Missy. I didn't delve into the items on that assessment form but just in the interest of time, but those I think actually appear on there in some form as do issues. Does the subrecipient have adequate accounting systems? Are they a new organization? So they might not have practices in place. Are they debarred or suspended? Of course that's where we start. All of those items sort of add up and become the basis for scrutinizing any subrecipient.

Elizabeth Peloso: [Indistinct]

Geeta Swamy: I might and done thing. That started really quickly, so I agree with everything that's been said, and I think we all do all those things in, yeah, ever so slightly varied ways, so I think, but they are commonalities. One thing I think that's important, Kim, that you mentioned was read the guidelines even if they're long and understand what's available to you. One thing I will note is that as a research investigator perspective, what we are taught and learn through our mentored career development and all of the other efforts about grant-writing is how to find requests for proposals, how to find topics that the institutes are interested in and looking for to fund because they're priority issues for the NIH strategic and also things about how to write your grant like looking at the SF-424. Research investigators really know almost nothing. I will just say about the NIH Grant Policy statement: That is something that I think all of us as, from the administrative perspective pour over and look at and refer to on numerous occasions as well as those NOTs or notices or notices or other things, and so I think it is also important to consider that as a, almost a campus service. How do we make sure that our investigators and grant managers are aware of those things as they're coming, the updates that come forward and so forth? So I just put that out there to say the communication also is about who's communicating to who and what we're bringing forward as important communication as well.

Pamela Webb: Thank you.

Kim Moreland: [Indistinct]

Pamela Webb: That adds a lot. I think in the interest of time we'll move on, but I know we may get some questions in this area as well given how important it is. Missy, do you want to talk a little bit about the next topic, grappling with potential issues that may arise especially at time of award?

Elizabeth Peloso: Absolutely, so there's lots of things that can make international collaborations a little bit more challenging at the time of the award and as we move forward once we know that there's going to be an award in place. One of those is conflict of interest. I think Michelle mentioned this morning that you have to make a determination as to whether or not a subrecipient was going to come under the prime's policies or its own policies for conflict of interest. That can be really challenging depending on what country you're working in and what infrastructure they're having in place, and the important thing is that NIH public health service has a very specific conflict-of-interest policy that we have to follow as a recipient of the NIH funds, and other countries have very sophisticated conflict-of-interest policies of their own, and so we really need to communicate well around that and making sure that everyone understands that it's not a judgement of another country's policy or another institution's policy if it's not exactly the same as the PHS policy but that we do need to make sure that it complies. There is a service, well, may refer back again to the Federal Demonstration Partnership. It's such a great organization and tool for us all to use. The Federal Demonstration Partnership does have a model conflict-of-interest policy out there that institutions can adopt if they don't have one that's compliant for purposes of a subaward or for a foreign recipient. One thing at Penn, we try not to serve as a reviewing body for conflict of interest for our subrecipients. There's some local context, and if we do have to do that, we generally assume the conflicts are not manageable, which can sometimes disadvantage the foreign partner in some ways. There can be issues related to IT. There's federal regulations in the US against using federal rewards for certain telecommunications equipment and companies, and those companies may be common providers of telecommunications in foreign countries, so we need to be mindful making sure that it's not only the grant's policy statement but that other federal rules are not being violated as we set up the agreement that's going to be in there. Translation issues, generally US institutions would want US to be the governing language for their agreements, but we do understand that there could be issues around translation. Who is doing those translations? Is it the investigator? Is there a legal service? How is it being done? What level of diligence is going to be required around that? And that may be part of the risk assessment. It may be that if it's a low-risk thing, we'll take a Google Docs translation, but if it's higher-risk, we want a legal translation, make sure we understand what everybody is signing, and that's part of the communication piece and making sure that everybody is understanding the same language around that. Scope and budget can change due to funding restrictions. We are currently under continuing resolution, so many of us have seen NIH awards come in at a lower level than what we had asked for, and so there needs to be a really big communication at the time of the award with the subrecipient about how rebudgeting is going to occur and how the partnership can move forward and if the work can actually still be completed with less funds. Negotiation of terms and conditions, thinking about local context and local laws as well as the grants policy statement and US requirements and then, again, there's a little bit around risk mitigation and risk management, so how is this subaward going to be managed? I think there was some discussion this morning around currency in particular and kind of how to manage if your award is in US dollars, and you're working in a foreign location. How does that work? One of the things that we not uncommonly do at Penn is that we would make a fixed price subaward if it were permissible and appropriate to do so, and that alleviates some of that currency risk both for Penn and for the subrecipient on there because it would be a dollar value transaction. And always if we're dealing with foreign currencies at Penn, if we were for some reason the subrecipient not the prime, and there was foreign currency come in, we would do a currency conversion on the day the dollar came in or the day the award was made and manage very carefully around that, probably invoice more frequently if we're dealing with foreign currency and US dollars. Does ... That was a lot to talk through very quickly. Does anybody have comments and corrections to make for me?

Pamela Webb: Well, no corrections, Missy, but I would just maybe add one thing to the scope and budget discussion. I think you covered it well, but I think when we have international partners we just have to be extra careful about particularly budget changes because what a US large institution researcher might consider to be, oh, I'll just fit that in. I can manage my resources. That isn't always possible for our international partners or really some any partner. It holds true for everyone, but I think in my experience, it's been particularly true where those conversations about do we need to adjust the scope? This is how much money we can make available given the budget reduction the whole project has taken on, for example, becomes even more important with our international collaborators. Do others have input?

Geeta Swamy: I think Missy mentioned one thing about the COI disclosures, and I do think it's important to know what the other institution's COI policies might be and how they manage those. I agree with you, Missy. It's on the onus of that subawarding institution or the recipient, that subrecipient do that, but I also think if we presume, right, that they're going to do it, right, how do we know that we're looking at that? So it's, again, I think part of that sort of screening and awareness of what the subsites have in place.

Pamela Webb: Great. Any other thoughts on this topic before we move on? Okay. Well, we've got it all set up. It's all perfect. Right? The proposal is great. The award is great, but then the work is actually starting to happen, and so we all know that things can happen there as well. Kim, can you start us on talking about some of the challenges we see in this area?

Kim Moreland: I'm happy to open this topic, and I'm going to open it with one we just mentioned which is determining if there are systems that manage expenditures and progress. Progress is of course very different for managing the financial oversight of this, two equally important items often managed by different parts of the university, and so when I talk about systems, I want to tie this back into the very last bullet, which is considering the possibility of an audit because just as I mentioned on the risk assessment tool, there is a question about, is there a sufficient accounting system? And is the organization a new entity? That all goes to a level of risk, but it also goes to a level of performance, and so I will mention an example in which we're prepared to subcontract to a recipient in the US. This is not a foreign institution, and they did not have a single audit. They did not have a financial audit of any kind, and so we asked for their financial statement, which was not helpful, and when we required them to have at least a cursory audit before we engaged with them, the audit came back with nothing but findings. This was an entity that literally did shoebox accounting. That is not acceptable, and it certainly influenced our choice not to continue to do business with this organization because again, a subrecipient failure on the basics of managing federal funds leads right back to the prime recipient, so those systems need to be in place, and they need to be systems that are reliable, that have been in continuous operation for some period of time and hopefully those that have been audited in some way. In terms of progress, I want to hit this because again, with the changes in the uniform guidance, there has been significant change on the part of all federal agencies including NIH because it's a requirement now regarding progress reports, so administratively those of you on this call may well be responsible for financial reporting, and you're aware of the very tight timelines to get those financial reports submitted and of the consequences if we don't. A far more difficult issue for us to manage centrally in an office of research administration is progress reports submitted by our faculty, which are of course required. We have not a lot of leverage to encourage someone to submit that financial report. We send them very polite e-mails. We repeat those e-mails. Then we start contacting a department chair and a dean. Eventually we bring in a vice chancellor, but there are times it is very difficult to get somebody to write a financial report even though they have expended the funds. So I think that what it requires is considerable more diligence on our part as administrators as well as considerable more education on the campus about the very significant consequences that it can befall not just the investigator but those people who work with him or her and who work in that institution. So just a little scare tactic there, and that ties right into ... Well, it goes right into I think, Pamela, I think you were going to talk about the cash flow issue. You want to jump in on that?

Pamela Webb: Sure, I think that one of the things that when we're dealing with any subrecipients that we need to make sure is we are able to engage some of our partners whether they be community-based organizations or small institutions or just institutions or entities that may not be as used to doing large-scale research that we'd better be thinking about cash flow and talking with them about cash flow and making sure that they have enough funding to be able to do the work that they want to do, and we're in the position to help make that happen for them. Now obviously we need to manage this actively if we're going to do something other than simply getting an invoice at the end of the month and paying that invoice. I think we can all do that or quarterly, however you're set up, but some entities can participate in research activities only if they have the cash up-front. And so we have to think through the possibility that, that could be the case, be able to have good conversations with them whether they're dealing with cost reimbursement or fixed price and set up some kind of a schedule that if in fact that is an issue for that entity, that make sure that they have enough cash to operate, but we're still being good stewards of federal funding. So one of the things my institution does is, we will when the need arises advance 3 months of funding, and then at the end of the first month assuming it's cost reimbursement, we're going to ask for that invoice for the first month of expenditures, and then we're going to either give them some extra money, or we don't need to give them more money if they didn't spend the amount we had forecasted for the first month. But the idea would be that we're reviewing that every month based on actuals but giving them a starter set of funding to allow them to begin work when they need to do that. The three months allows for periods of time to invoices received, reviewed, approved and paid, and so the entity always has at least 1 full month of cash in their hands based on what we expected their needs to be in order to be able to perform the work. What we've found is, this has really helped us engage partners that might not otherwise have been able to participate in the research, and while we certainly don't need to do that in every instance or in every international collaboration, that ability to think that through and create a plan that works for that particular science may very well enable the success or foster success for our partner organization as well as, of course, for ourselves. So I would encourage that possibility and happy to answer more questions about that and so thanks, Kim.

Kim Moreland: Sure, I wanted to just mention one more item that's on here, and you'll see that it says, "Manage any significant or unexpected issues that arise." Now, Geeta and Missy have really interesting information coming up, so I don't want to step into that area, but I think this goes to, the bullet goes to the need to be prepared and again, to keep those linkages across not only researchers but research administrators who are supporting this. So I want to give you a little quick example of an unexpected issue that arose that nearly derailed our project. We were doing some clinical research in Ethiopia, and we had employed a consultant who would help with both language and sensitivity issues with a largely female population, and so as a result she would work for us maybe four times a year but about 6 weeks at a time. It was certainly targeted expertise on a particular area we needed, and we sent through, the department sent through in my office, endorsed a consulting arrangement for this individual, and our purchasing department sent it right back to us. And they said, "No, no, we can't do consulting. There are problems." Now, we are a state institution, and that may be part of it right there, but they sent it back and said, "No, she has to be an employee of the University of Wisconsin in Madison." And, well, you can just try to imagine the problems that that arises as you're beginning to start a really important project. And we spent a month arguing inside the university about the appropriate mechanism to use in order to be able to access the services of this really key consultant. I never without have guessed it. It seemed like an obvious solution to me again based on federal regulation, not based on my local institutional norms. With that, I think we want to go, "I gave you the headline that you have really interesting stuff," so I think we want to go to Missy and Geeta.

Pamela Webb: We do.

Geeta Swamy: So do you want me to start, Missy, or would you like to start?

Elizabeth Peloso: Oh, you go right ahead.

Geeta Swamy: Okay, well, I think we're calling this special circumstances, but I'm sure there are lots of other bullet points that could come up just as Kim gave an example there. There's been lots of discussion over the last few years about the concept and the issues of foreign interference, and I think you heard through presentations earlier today. It's clear that we need to be open, transparent, communicate, right, disclose when in doubt, ask or disclose, but there will come issues that either by misstep, meaning lack of awareness or misunderstanding of how to interpret the requirements, and certainly we hope that this wouldn't be the case, but there always is the risk of there being someone who's just not completely forthcoming. So I think in the best way that I can say, this is where, as institutions in the US, as prime institutions, that we should be thinking of our partners at NIH as exactly that, partners, and how we can work together to address the issue. I think that we often have the perspective that the institutions messed up. Michelle or Ki-Cha or others are going to be looking at, why did this happen? Why didn't you all catch this? At the end of the day, we're all human beings, and we need to figure out how to actually talk about it and get to the bottom of what it is and then work to resolve it. Sometimes that can be done very successfully, sometimes not the case. One of the questions I saw earlier in the chat that was posed for us is, how are we going about obtaining information about outside interests, outside activity, foreign interests? And I can speak to what we do for that at Duke because it then feeds into how we might handle those kind of issues when we identify them afterwards, but we have an annual disclosure process. I suspect most institutions do. This gets back to how we've often, how many of us have managed under the PHS regulations for financial conflict of interest, and we've essentially expanded that activity to obtain information specific to foreign entities, foreign interests, foreign consulting. That doesn't necessarily mean anything different is going to happen. We still look at it to see if it has to do with the research itself. If it's consulting, if it's a position or appointment how that would then be disclosed on biosketch information, other support information in that sort of issue. But I think at the end of the day, really how we look to handling those issues are to gather everyone in our institution who might need to be involved or, excuse me, who might need to be involved from the perspective of awareness about how we're managing a subrecipient, what our screening process, as Kim mentioned, and what information we've obtained from them. How do we gather the information might be an issue? And who at the subrecipient institution should we be discussing that with as well? And I will say that over the years as these things have been ... We've seen more light shed on this. I think we've gotten more aware and more keen about trying to address those things up front rather than having them occur after the fact. So, Missy, I'm sure you probably have something to add to that as well. Oh, you're muted.

Elizabeth Peloso: One of the things that we've done at Penn to help support that process and make sure all the stakeholders are aware is, we've developed tools for our faculty where we can actually pull all of the information an institution has about them together in one place so that they have all the information in front of them that they need to do accurate other support reporting on that. So I think that's one of the big things is, all of us who wear a compliance hat from time to time know that the real key to getting people to comply is making it easy to comply. People want to do the right thing. We need to make it easier for people to comply than to come up with creative solutions of their own.

Geeta Swamy: Agreed.

Elizabeth Peloso: So I think that that's sort of my main takeaway.

Geeta Swamy: Mm-hmm. We've worked on the same thing. I think it can be ... Looking at systems is always an interesting effort to see if you have systems in place that are vended solutions, or if you have your own systems that you've built over the years. We've done a similar thing over the last year as well, Missy, and we actually, with the other support documentation changes, we actually now have that information available to grant managers as well. So if it was my grant manager, they can see my information so that that way they're also a second sort of check. If I didn't write something, they can say, "Hey, Dr. Swamy, did you see this? I saw this on your listing. Has that changed? Is that not relevant?" So not, again, as a gotcha but more as a, "Hey, let's make sure we're getting all the right information."

Elizabeth Peloso: Yeah, absolutely, that's a big one, making sure that we delegate different people with different responsibilities across the institution can also see that information and make sure that when we're an AOR certifying to the NIH information that it's correct to the best that we know. That's absolutely huge as well as the pieces about making sure the information is clear and transparent and that their requirements are clear and transparent, so looking at the training that we do and making sure that the information is really clear, making sure that we have on-the-ground resources available to answer questions all the time about, oh, I'm not sure. Is this a consulting thing that needs to be disclosed? So we're really trying to provide a lot of hand-holding and support for our people.

Geeta Swamy: Absolutely.

Elizabeth Peloso: One thing I wanted to make sure we touched on a little bit, Geeta, and I know this is probably more your wheelhouse than mine is, dealing with the complexity of different regulatory environments in different countries, particularly for the areas of IRB and IACUC, kind of the regulatory and ethical-compliance pieces.

Geeta Swamy: Yeah, absolutely. It's really important. It already has been important, but I think what Kim was talking about earlier about progress and documenting that as we go into the new NIH requirements about data-sharing and data requirements and that also being included as part of progress reporting in RPPRs is going to be even more important to make sure we know how the acquisition of data has been approved by IRBs, the storage of data or transfer of data, whether there needs to be separate agreements for that, or if that's been incorporated into the subaward agreement and that sort of thing as well. From the IRB perspective, we, generally speaking for NIH policy, right? If there's human-subjects research activity, as the prime we would have an IRB review and approval at our site, but let's assume this is not a multisite clinical trial where we're looking at a single IRB at the moment. Although, I would maybe use that as an example, too. When Duke, say, for example, is the prime awardee, and we are serving as the single IRB, we will do that for domestic sites only because we feel that we do not have enough expertise in the in-country laws regarding, say, even the definition of a minor, allowability for consent or other requirements, disclosure of information. Right? There are specific state requirements of disclosure, say, on certain reportable diseases. How do those things come up in other countries? Now, if there are questions,we sometimes have our associate counsel at Duke who is involved in foreign activities as well to help provide some context, not an approval but to maybe consider where the risk level is and whether it is something that requires outside interpretation or outside expectation as well. But we really work hard to make sure that we have awareness of all of the activities happening in the foreign country or with the foreign institution so that we can make sure we have those regulatory issues covered. I think they are different for every type of study or every type of work, so it becomes, I think, very important to say at the time of a study start or a project kickoff to say if there's foreign activities ongoing. Let's make sure that we're all on the same page to do that.

Elizabeth Peloso: Yeah, and then I think the last thing I really wanted to make sure that we touched on a little bit was technology-specific issues, making sure that we're protecting research data that taxpayers are paying for and making sure that the taxpayers and our institutions have the benefit of that data, making sure that we're protecting our intellectual property and all of that. So it's a complicated issue. I think when we look at what's going on in the foreign-interference sphere, there's not a lot of documentation that there's actually been IP leakage out of academic institutions intentionally beyond the normal tension between open sharing of science and as opposed to misappropriation of confidential information.

Geeta Swamy: Right.

Elizabeth Peloso: But I think that's one thing particularly when it comes to patient data that may be shared internationally or identifiable human-subjects data that we're trying to be very, very careful to make sure that we know who our partners are and what they're doing with that data, and then the use of the data is very limited to what they need it to be for.

Geeta Swamy: Absolutely. I think there also, as you all know, there are laws in the opposite direction, right, as far as privacy and security. GDPR for European countries, the People Acts in East Asia and so forth, so there are those things where I also have concerns about our investigators not being aware of some of those things as well going in the other direction. I'm assuming that they're following everything they would normally follow here at their own institution and for our own policy and per NIH policies and not thinking the other direction on how those might, how that might play in as well.

Elizabeth Peloso: Right, and I would not be in my own happy spot if I didn't at least get to mention export controls once. So I do just want to point out that in international collaborations, particularly if the equipment is moving back and forth between countries as well as technology, we need to be mindful because even if it's okay to share it within the US with a foreign person, when we're actually physically exporting things, it's a different can of worms, and we just need to be mindful to protect the researchers on both sides of the equation

Geeta Swamy: Right. We've had, for example, some studies where we had investigational products from investigational device where a Duke investigator through institutional support held an in IND or an IDE, and that becomes even very, very different from an export-control perspective because it's different country-by-country. There isn't some general law across all other countries on how to manage that, how to log that. Many of our hospitals or health systems probably have a clinical-engineering services that comes through and makes sure that things are working, so forth. How do you ensure that in another country not knowing what their procedures are? So it's often where really exciting work is being proposed to be conducted, but also where there's a lot of things to make sure are correctly managed.

Elizabeth Peloso: Sure, and I think some of us at bigger institutions like Duke and Penn and Minnesota and Wisconsin that have large infrastructures are well-equipped to help our faculty with that. As an example, Penn has an Office of Global Support Services, so we have people who just help with all of that business, things from international-employment law to kind of shipping and getting labs set up and everything else in between and can really help us with the compliance things. And so it's great. It's great to have institutions that have that resource, and I'm sure we are always willing to partner with our colleagues if they have questions, if they don't have those services and that we can answer from if we have.

Geeta Swamy: Absolutely.

Pamela Webb: Missy, hearing you describe it makes me ... I think we have a reasonable level of support, but I think I want to send some of my questions for investigators to Penn to get help.

Kim Moreland: Me, too, me, too, yes.

Pamela Webb: It sounds great, so ...

Elizabeth Peloso: You may just decide to keep them, not just answer their questions.

Pamela Webb: Oh, no, no, no. No. Can't do that, right? Does anyone want to add anything else before we move into the Q and A? Okay. We have some good questions I can see in the Q and A section, so I'll go ahead and start. We have about 5 minutes, so we should be able to get through a few of them. We had a question from Jackie about how a subrecipient can hold a prime accountable if it takes the prime months to provide the subaward either initially or for the continuation year, and what do you do since that definitely impacts financials and impacts project progress downstream? Anybody care to answer that?

Kim Moreland: I'm just wondering if the prime is Wisconsin. It could be.

Pamela Webb: All right. Yeah. All right.

Kim Moreland: So what I would say is this, is that ... This is a whole other topic, but the process of recruiting staff right now is very difficult, and so I have a subaward team that should have three people on it. We've been down to one. I eventually added a second last week, so it is ... We are behind, but what we notice is that the subawards coming into us are also very light, and I don't know ... Obviously, I would urge everyone possible to use the FDP template because that's the simplest thing to issue and the simplest to review and accept, but I don't know that there is a quick fix to this. You can, of course, send those incredibly irritating e-mails that say, "But, Kim, you told me you all would get to this." And eventually, I will push your project to the top. It is a fairly common problem right now with timing on anything to do with subawards, even in terms of getting payments for invoices we're issuing.

Geeta Swamy: Right. We're terribly behind on that and short-staffed, terribly short-staffed, on our post-award financial management central team at the university where those invoices are paid, and it's a struggle, and they are not happy with themselves being behind, but there's not a whole lot they can really do either.

Elizabeth Peloso: So, Kim, I think, though, not blaming staff, not to put this on staffing issues because I suspect that this could have sometimes been a problem even in the before times when we were fully staffed. I think it comes back to the first thing that Pamela opened up with which is communication. So as a subrecipient, how are you communicating with the prime awardee. Is there's some other reason that may be holding this up? So for instance, one of the things that we discussed was a reduced budget because of NIH funding levels. You can have a reduced budget. There's probably at somewhere some difficult conversations being had about what part of the projects can move forward now, what needs to be put off. And PIs are generally aware of that even if their research- administration offices are not, so I think it's important to have discussions with your investigators if you're an administrator at a subrecipient institution to understand what they're hearing around that. And it's also important to just get on the phone and say, "Hey, how does subawardees work at your institution?" Because some places may, as soon as the notice of award is received by the prime, start setting up subs. Penn is a very decentralized place, so we don't do that. We wait for the PI and department to say, "Yes, we're moving forward with the subrecipient," and so kind of understanding where it can get stuck is also through that communication is also a pretty useful thing to do.

Geeta Swamy: As an investigator, one of the ways that I've tried to deal with it is to also think about the timing, so when I've designed a study or a project, think about whether you're going to want and/or need the subs from day one. Right? Or is it part of your planning to say that maybe there's a small component that you ramp up so that really there's not a strong dependency, right, from the very beginning for them to have those dollars. Now, I'm not saying you can do that all the time. You should just make it that way. But sometimes I think we put grants together, and we just automatically do the budget from day one through day 365. Right? For the period of performance, and so sometimes thinking that through could also be helpful. Yeah.

Pamela Webb: That's helpful. We only have about 1 more minute, so I'm going to do a really fast question and see if you all have the same answer to it or different. The question is, can you have a cost-reimbursement prime award and make a fixed-price sub?

Elizabeth Peloso: It's a trick question?

Pamela Webb: No.

Elizabeth Peloso: Oh, okay.

Pamela Webb: It's good. It's an honest question. I think it gets a straightforward ...

Elizabeth Peloso: Well, yes, and that's one of the ways you can mitigate risk in foreign subs is to fix fix the price instead of them ...

Pamela Webb: Yep.

Kim Moreland: Yeah. I started to say that earlier, too. It's another way in addition to advance payments of the sort you were talking about, Pamela.

Pamela Webb: Yeah, yeah.

Kim Moreland: A fixed-price award gives a lot more flexibility to the subrecipient.

Pamela Webb: Yes. Yes, and the nice thing as prime, we have the ... We're serving as the pass-through entity, right? So if that's the role we're in, we get to determine the form and format of the agreement that our subrecipient is going to get, and that's totally allowed under policy for all the reasons that you have just already stated, so ...

Elizabeth Peloso: Yeah, and it helps, to get back to the earlier questions of mitigating currently risk, if it's fixed pricing, they get that money on that day, and they know what that is.

Pamela Webb: Yeah.

Geeta Swamy: There was a question in that earlier, too, from, I think, say, community organizations or participants because that is fairly similar in structure and I think resources, and we've used a similar model, and that's actually worked quite well.

Pamela Webb: And I ...

Geeta Swamy: A big surprise.

Pamela Webb: Yeah. I agree with them, and I've also done cases where even if they're reimbursing, if we're paying on cost-reimbursement invoices, moving up how quickly we pay that invoice so that they can get payments more rapidly just so that if they told us that that's an issue for them. Okay, with that, I think we're out of time for that, and I'll turn it back to Kasima and Michelle.

Kasima Garst: Thank you so much, Pamela. I am actually just going to reiterate my thanks and turn it over to Michelle for a quick few words while we close up, and then I'll have some final logistics at the end.

Michelle Bulls: So I really want to thank our panelists today. You guys jumped right in. I reached out saying, "Can you help us? Can you help us?" And this is the team, and, Pamela, thank you so much for your leadership. Missy, Kim and Geeta, we really appreciate your perspective. The entire event has been an amazing event, and I just have to give kudos to Cynthia Dwyer. She knows how to put together a great event that provides a lot of detail and information to our recipient community. I am so grateful for all of you guys. It was very informative. I want to thank Kasima as our moderator, what a wonderful job. Thanks to all of my staff, and thank you so, so much to the NIAID staff, Emily and Glen. You guys have answered so many questions and helped us in so many different ways today, and then, of course, Alan and Ki-Cha and Kristin. I want to just let you guys know I truly appreciate you. I am so happy that we had this, and I'm so glad that we were able to partner with our recipient community and give that different perspective, so thank you so much, and, Kasima, I'll turn it back over to you.

Kasima Garst: Thank you so much, Michelle, and, of course, as always, thank you for all of your insights and your participation as well. So with that, thank you to everyone who was able to attend. We are just wishing you all the best as you move forward in building these important partnerships with the NIH and with your collaborating organizations and those from around this world working to make this world a healthier one.