International Organizations and the NIH Grants Process

>> Emily Linde: Hello, everyone. I am Emily Linde. I am the chief grants management officer for the National Institute of Allergy and Infectious Diseases, and I'm glad to have you joining me today electronically. I'm sorry we cannot be in the room together so that I could get a gage of what your experience level is. That's usually how I adjust the presentation as I go through. So without having that, what I'm going to do is assume that people are really at the beginner level for this and work through some information about grants to foreign recipients and also to US recipients with foreign components. So much of what I'm going to cover today is some of it's specific to foreign grantees and foreign components, but some of it's applicable to all NIH grantees. So where there are differences, I will try to point that out. So let's start with some of the most important differences, which is that foreign institutions can function differently than US organizations in many ways. They might be in different time zones. The primary language for the individuals working there might be a language other than English. They might have Internet connectivity issues or less robust access to the Internet. They might not have as many sponsored program staff to help support them through the application and award and close-out process, and they might not have as much information or experience with NIH funding requirements and NIH policies and the frequency with which those things change. So given all of that, it is definitely advisable to plan for delays and differences and to allow time for that dialogue as you're assembling that application. So why does NIH support international research? And we support international research for the same reason that we support research in the US, and that's really to augment the resources of the US and to improve the sciences, the health sciences specifically, and the health of the US population, right? So NIH is funded by US taxpayer dollars, and so that's why we're primarily interested in the health of the US population. So given that, why would we support research internationally? Well, one of the reasons that we do that is that those applications might present special opportunities, for example, different talents in the researcher pool, resources or maybe unique populations that will help us understand a scientific problem better. So that is one of the things that if you were submitting an application from a foreign organization that you would need to address in the application so that we understand exactly what special opportunity you are providing to us in this application. And then every application should also address the specific relevance to the mission of the IC that would be funding the award. So I work at NIAID, so what is in that application that's relevant to the work that NIAID does, which is allergy and infectious diseases. So just a little bit of background about where NIH money goes for international research. So predominantly we issue to domestic organizations, but we do, from time to time, issue direct foreign awards, and you can see the numbers for the last several years have been fairly constant for that in the 500 range. And then we issue awards to domestic organizations with foreign components, and we do up to 8,000 of them, at least we did in FY 2020, which just closed recently. So at NIAID for example, we have a large portfolio with foreign involvement, and that's basically just due to the nature of the type of research we do. So infectious diseases don't know a boundary, and so that's often why we invest in, for example, tuberculosis research or AIDS research or COVID research across the globe. So what is a foreign component? So a foreign component is the performance of any significant scientific element or segment of the project outside of the US, and traditionally we've known that to be any activities that might have involvement of human or animal subjects, extensive foreign travel to other sites for surveying or sampling, for example, and any activity that might impact US foreign policy. Several years ago we expanded the clarification of that definition to include things like collaborations that might result in coauthorship or the use of facilities or instrumentation at a foreign site and also the receipt of financial support or resources from a foreign entity, and I think that it's really good to highlight those clarifications because they have become important in how we define a foreign component, so be sure you're familiar with that as you're submitting applications. Foreign travel for consultation is not considered a foreign component. So the first thing that you're going to do if you are considering submitting an application from a foreign organization or from a US organization that might be proposing a foreign component is to check the eligibility in the funding opportunity announcement, or FOA. So in every funding opportunity announcement, it will list whether or not foreign institutions can apply, and it may be that they can or cannot, and the same is true with foreign components which may or may not be allowed. And if you're submitting an award from a foreign organization, you will always be submitting that with a detailed budget. If you're ever in doubt as to whether or not a foreign component or a foreign award is eligible for the application, contact the program staff listed in the funding opportunity announcement. And this is just a sample of what that language looks like in an FOA. So you see here in this example, foreign institutions are not eligible to apply and components are not eligible. DeRon I'm going to start that over. I'm starting from here. Here's an example of the funding opportunity announcement and what it looks like for eligibility where it will specifically list out whether or not foreign institutions are eligible to apply. So I include that as an example, and you can see that in section three of the FOA. So some general guidelines about eligibility. There are a few programs that generally foreign applicants are not eligible to apply for, and that is the Kirschstein-NRSA institutional research training programs, program projects, center grants, resource grants, small business grants and construction grants. There are some exceptions to this. So some activity codes such as the program project grants, the P01, some ICs may support those to foreign organizations and others may not. So again, this is where the eligibility section of the FOA becomes key. You'll definitely want to review that before submitting an application. So once you've determined your eligibility, you're going to work on developing your research idea, and this is applicable to everyone, not just foreign awards. You're going to want to be sure that what you're proposing is going to have a high impact. It's one of the things that will be reviewed, and it needs to align with the IC's mission, right? So what does that IC do, and what are you proposing to do? Do they match up appropriately? If you're unsure, talk to your NIH program staff about that. They're a very, very good resource that we definitely encourage you to use prior to submission of an application. They can help you figure out if your application is a good fit with their IC or if it's more appropriate with another IC. Be sure that you identify a funding and opportunity announcement. So look for things that are specific to what you're recommending to do. If you can't find an FOA that matches that same level of specificity in the scientific area you're looking at, go and look for a parent announcement because you might be able to submit in response to one of those. And then write a strong proposal, and that means that you would want to be sure that you understand what the review criteria are and that you're addressing those review criteria in your application. And if you're unsure who to contact, here is a sample of what you would see for agency contacts. There are almost always three contacts listed for the agency. One would be the scientific contact. One would be the peer review contact, and that's really for matters that are applicable to the review of the application, and then if you had financial questions or questions of a budgetary nature, you would address those to the grants management contact listed in the FOA. Some things to think about are collaboration. Collaboration may be required in the FOA announcement. It may not be, but definitely think about that. The review group is going to consider who you have proposed that you will be collaborating with in your application. They're going to look at the background and the research record of those investigators, so be sure you're forming a good team for that, and to do that, one of the places that you can go is NIH RePORTER. It's a great tool for finding investigators and what they're investigating, both foreign investigators and US investigators that might be a good connection for you. So we definitely encourage using that tool. So some tips for foreign investigators. Eligible doesn't necessarily mean competitive. Not all NIH applications get funded, so you need to be sure that you're submitting a very strong application that would review well and get a good priority score and then potentially be selected for funding. To do that, definitely talk to your program staff about your idea and where it fits. We discussed that a little bit, and think about your publication record and the publication record of those you're going to collaborate with. Think about previous funding, if you've had previous funding from NIH, the reviewer may consider that as well, and then also you're going to want to justify the use of a foreign site. So what do you have that's a special and unique thing that makes you competitive? Do each FOA is going to always specify the review criteria, so definitely take that into consideration when you are making your application. Here is definitely a slide that people who have never submitted to NIH before need to take note of. There are quite a few registrations for any applicant to make it through the application process to NIH. There's an additional one for foreign grantees, so let's just walk through those for a moment. So you will need to have both a grants.gov and an NIH eRA Commons registration, and that registration must be in place, both of those registrations must be in place, prior to application submission. Before you can even complete those registrations, you would need a Data Universal Number System number, or DUNS number. This will be changing in the future, but for right now the DUNS number is still applicable, and you would need that, actually, before you complete your grants.gov registration or for your SAM registration. That's the system for award management, and that is a registration that has to be renewed annually. In addition to those registrations, our foreign applicants must also have a NATO Commercial and Government Entity registration or an NCAGE number, and the reason that I am emphasizing these registrations is not because it's particularly difficult. Some of them do take a little bit of time to get through, but if you are a foreign organization and you have an application that has been successful and you did a really good job in addressing all those review criteria and you're selected for funding, the next thing that you would need to do is complete and register with the HHS, so that's Health and Human Services Payment Management System. And all of those registrations must match each other. So you can't use a different name, for example, on your SAM registration versus your eRA Commons registration. Most likely everybody has those the same. It's where they come to the registration for the payment that things are a little bit different. So think about what name you want to use and think about what name is currently on your bank accounts because you will have to have this linked to a bank account, and the time to think about is really before you submit your first application. So you will see a request in the applications for an EIN number. So that's an entity identification number. For foreign applicants, if you don't have one of these, you would just put a string of fours in the application for that. If you have previously received funding from NIH and you have a pseudo EIN number, you would use that, and you would definitely want to make sure that your grants management specialist knows what the source of that was that you've had previous NIH funding, and that's when you received that number. In very few instances we have some grantees that receive an EIN from the US Internal Revenue Service. So if you did receive one of those from the IRS you would use that, but definitely work with your grants management specialist to make sure that we get that right before the award goes out. So next, do I absolutely have to contact NIH before applying? Sometimes yes and sometimes no. I would say it's always advisable to do so, especially from a scientific point of view and contacting your program official or the program official listed in the FOA, just to make sure that everything is a good fit. There are times when it's mandatory, so for example if you were submitting an application with a budget that's over $500,000 direct costs, and that's excluding consortium F&A, you would have to do it then. Sometimes it doesn't apply for RFAs. Some ICs ask for it anyway, and then the other times that you would definitely want to consider it is when there's a letter of intent requested, and that's actually really important because one of the things that submitting the letter of intent does is it lets the review committee begin to pull together the reviewers for that and to determine how many applications might be submitted in response to that FOA and how many reviewers they'll need for that review group. So I definitely think a letter of intent, while not always required, is definitely advisable. So some budget considerations for foreign components and for direct foreign awards. Think about what the salary norms are at those foreign sites. They may be very different than they are from domestic organizations. Are there any problems or potential delays when it comes to procurement or availability to supplies? So I've just listed one here, which is something that we come into contact with fairly quickly when we're doing a clinical trial where we would need to get drugs to a specific country to perform that clinical trial. Many countries have limitations on the importation of drugs, and that might take longer than to do it, or you may need to coordinate with other applicants or other grantees to do that. Currency exchange rates. We hear often about fluctuation in currency exchange. NIH can sometimes accommodate for fluctuations in currency exchanges, but that is most likely only going to happen prior to awards. So between the time of submission and the time of award, the exchange rate has changed greatly. You'll want to reach out to NIH before award. And then some other costs that we see frequently are costs for travel, international travel, transportation for short-term visas, for value added tax, and we'll get a little bit into allowable costs and where to look for those for these types of grants later. And then also, do you need to plan for face-to-face meetings? It might not be feasible all of the time, and you might use Skype of some other tool like that to conduct meetings or you may need to go in person or have your collaborators come to the US. So do plan for those face-to-face meetings and consider them when preparing a budget. Facilities and administrative costs for foreign awards. So let's just talk about facilities and administrative costs for everybody for a second. So those are costs that are necessary, and they're incurred by the recipient, but they're incurred for a common purpose. So it's hard to identify them with a specific grant. It might be applicable to more than one grant, or it might be applicable to more things than just a grant. And for foreign awards when NIH provides F&A, we provide 8 percent, and it's always 8 percent, but that 8 percent doesn't actually cover facilities and administrative costs. In this case, it's really just the cost for compliance. So that 8 percent is to help you comply with all the rules and regulations that we have in place that have to do with clinical trials and human subjects and invention reporting or animal welfare, et cetera, et cetera. So I'm not going to spend a lot of time on these next two slides. If we were in person, I would probably try to walk you through it and let you know how I'm calculating the math. So in this case really what I'm going to provide is two slides that show different ways to approach the math for calculating F&A for foreign awards. So as I said, it's 8 percent, but it's 8 percent of the modified total direct costs, which means that it is the total costs, less tuition and any related fees for tuition, equipment or sub-awards in excess of $25,000, and the next couple of slides will show you how to calculate that, but I want to highlight that again because this was a change just a few years ago. Previously it had been 8 percent of the total costs, less equipment, but now it's less equipment, tuition and related fees and sub-awards, the portion of which is over $25,000. So I'll try this just a little bit. So here is, in this example, the direct costs to the foreign prime are $290,000. They're requesting $9,000 for equipment, and they have a sub-award for $30,000. So to get to that number, one method is the subtraction method. So you would take the 290, which is the direct cost, remove the equipment, $9,000, and then remove the portion of the sub-award in excess of $25,000. So in this case it was a $30,000 sub-award. You subtract $25,000 from that and you have the $5,000 differential which is subtracted here. You then multiply that number by 8 percent to get what your F&A is, and then when you add the total direct costs and that F&A number, you get down here to the final total costs for the award. This is the exact same example. It's just showing a different method. It's showing the addition method, so you can use this as a reference, and you can certainly ask me questions about these methods when we get to the question and answer portion of the presentation, but as you can see, the final total costs are the same, regardless which method you use. So funding collaborations. If you are going to have a sub-award on your application, you're going to want to consider a few things, right? So I these examples, I have designed it from a US organization collaborating with a foreign organization, but the same would be true for a foreign organization collaborating with another foreign organization. So the prime recipient, or in our example the US institution is responsible for the full conduct of that award, including anything at the sub-award level, and any sub-award requires a formalized written agreement, and we'll talk about what that needs to address here in a minute, and it needs to ensure that the collaborating institutions understand what's expected, including the application of the rules and regulations or any terms that might be on the notice of award. And it helps to determine who has the authority to sign for that organization. Definitely with foreign organizations, sometimes they have a higher level official sign than we do in the US. So think about that and think about the timing of that when you're going to put sub-award agreements in place. So here are some of the things you're going to need to decide. So how are the funds going to be distributed, right? Is there anything in that local environment that you need to be accounting for for systems of reimbursement? Are there extra banks that the money needs to flow through? Are there extra organizations that the money needs to flow through because there's a prime site for the university you're collaborating with and they get the money before it goes to a satellite site. What does the salary support for the local investigators look like? What happens if there's project delays and if there's project delays and staff aren't getting paid? How are you paying them, by check or by wire or by electronic funds transfer? So you definitely also need to establish the procedures for reporting progress and the use of funds and the frequency of those things, including, also, above the frequency of the payments, and US awardees would also flow down to foreign sub-recipients the multiple applicable parts the NIH policy statement or applicable regulations. So a vendor agreement is actually a little bit different than a sub-award agreement. In a sub-award agreement, we would expect substantial scientific input, right, but a vendor agreement is really more like a fee for service that doesn't have a significant impact on the science or changing the direction of the science, mostly you're just purchasing a service or a good. So routine goods or services. It's ancillary to the research. It provides a service that you could get at many different places, potentially. You don't need the same written agreement because it's not having the same impact on the science, and then for those you would also need to determine the payment process. So human subjects research. If you have human subjects research that's involved on a foreign award or a foreign component, you're definitely going to want to plan to make sure that the foreign component has Federalwide Assurance, that they're following all of the IRB rules. Just a reminder here that for domestic awardees, any domestic site of multi-site studies that use the same protocol have to use a single IRB. That's not applicable to the foreign sites, however we do get the question often, can foreign sites opt in to using the SIRB? And the answer to that is, yes. Additionally, some countries have additional in-country requirements, right? They might have a second level of review for their IRB, or they might have a second level of review for the whole application, and this is quite a few countries now, so be sure you know that on the front end because those can take a little bit of time to get, and they can sometimes delay your award if you're not aware of them and working through that process. There were some changes recently to human subjects, and I'm sure that you'll probably also consult other things for human subjects information, but this is just a reminder of two other things that change with the common rule that we're getting a lot of questions on. So the exemptions code changed. So they went from E1, E2 to beginning with an X, X1, X2, and they expanded a little bit, and you can go to the resources down here to find more information about that. Also, now, when IRBs review human subjects information, they're not reviewing the application as a whole and providing a review and approval of the application. They are reviewing each research protocol and providing that. So when you are providing IRB information and IRB approval to your grants management specialist, please be sure that you're providing that for the research protocol, and correspond with them if you have any questions about that. Another reminder that NIH discontinued the support of a training module that we had, which was protection of human subjects and research participants. We didn't get rid of the requirement that you have to have training if you're doing human subjects work. We still want human subjects to be protected. It's just that the institution now is responsible for defining what's appropriate to fulfill those requirements and how frequently that training needs to be done. Here are some additional references for you, and also I would recommend reviewing the FAQ page for the OEP website. So vertebrate animals. You would also need to have, just like you would have a Federalwide Assurance for humans, you would need an Animal Welfare Assurance for the foreign site. If you're doing a direct foreign award, you wouldn't need an IACUC approval, but you would need to be able to certify that you have met your local requirements as far as animal subjects go. Monitoring. So I'm going to cover here just a few things that we ask for in the research performance progress report. This is the annual progress report that you would submit after receiving an award, and it lets us know how you're doing with that award, and there's actually three different places in that RPPR that we ask for information that has to do with foreign countries or foreign involvement. One of those places is in E4, which actually asks what dollar amount is being spent in foreign countries. So for this, we're actually looking for the aggregate that's spent by country. These should be total costs for that, and if there were multiple countries that were involved, you would list the aggregate, again by country, and if you are a foreign awardee and are sending money because you have a first-tier sub in the US, that you actually wouldn't report because that money is being spent in the US. So another place that we ask for foreign information is in Section G.9, which is the Foreign Component, and there you're going to provide any significant activity that's performed outside the US, whether or not you've expended funds for that. This is often a place where we see that we're not getting things that are reported as we expect, so one of the things NIAID did recently was begin to add a Term of Award to remind grantees when we expect to see reporting there. If we see reporting there and we didn't expect to, that should raise your eyebrow a little bit. It definitely does for us. The reason for that is if you have added a foreign component, you can only do so if you have already sought and received prior approval to add a foreign component. So I wanted to reiterate that. For all of NIH, you cannot add a foreign component to a grant unless you have prior approval to do so, and then it will only be if it was allowable under the FOA to begin with. And then the last place we ask for information is in D1 participants. So there you would check yes and add the country and organization if the individual's primary affiliation is with a foreign country and they're working in a foreign country. So some other tips. So where to find out information about allowable costs that we spoke of earlier. So section 7.9.1, which is applicable to all grantees, but also in section 16.6 of the NIH grants policy statement lists unallowable costs and some allowable costs for grantees that are foreign. Please don't forget that foreign investigators have a little bit of a different audit requirement. So for everyone, it is ... the threshold is $750,000. However, for US grantees it is $750,000 or more in federal awards, and for foreign grantees it's $750 or more in HHS awards. So that means you need to know who the components of HHS are, so what agencies there are. For example, the Centers for Disease Control and Prevention. That's usually the one we see most frequently. Also the FDA or AHRQ, just to name a few, but definitely if you're unsure, go to the HHS website to determine if the agency is an agency that's a portion of HHS. If you're doing select agent research, I include this as a reference, but I definitely encourage you to reach out of you have questions about this. If you are the prime grantee, you would have to flow requirements down for select agent research, and those requirements would address all safety, security, training, things like that that would need to be addressed for select agent research. So prior approvals. Change in scope. So anybody foreign or not, if you are wanting to change the scope on what you had proposed in the application, you would need prior approval. Any time you're going to change the PD/PI or there will be an absence of the PD/PI or someone named on the notice of awards, you would need to request prior approval. The carryover of a unobligated balance, if the NoA says the you need prior approval to do, and always the addition or change of performance sites, so either to a new foreign country or within a foreign country, you're going to want to check before you make those changes. Always for everyone the transfer of a grant from any organization to another organization is a prior approval. If it is a transfer of a grant either between two foreign organizations or from a US organization to a foreign organization it requires additional steps for NIH, including the requirement to get the approval of NIH and the National Advisory Board or Council as applicable. So please be sure if you are transferring to a foreign organization that you let us know as soon as you know so we can walk you through the process and what's needed so that we don't have additional delays, and if you have questions, contact your program officer or grants management specialist. Your grants management specialist is always the one who will approve your prior approval requests. So project monitoring. Be sure that you are monitoring time and effort and that you are applying the 8 percentage F&A correctly. Also be sure that you're maintaining the funds in an interest-bearing account and that if there is any aggregate interest earned in excess of $500 per year that must be returned to the government. So let's not forget closeout. This is something that all grantees need to address. All the documents are due within 120 calendar days. Grantees must ensure that there's no discrepancies between their final federal financial report, or FFR, and the monies they've drawn in payment management, and I want to underscore this for all the direct foreign grantees because this is often a place where we see discrepancies. So please be sure that if you say that you've expended money on your FFR that you have also drawn all of those funds in the payment management system. If you don't draw them in a timely manner they can be wiped out from that account and we cannot always reinstate those, so when you're submitting the FFR, make sure you're going back and reconciling that at the time you're submitting notes. There's also reporting for final invention and certification and the final RPPR or interim RPPR, depending on if you've submitted a competing continuation. So some takeaways. Be sure that you look at your notice of award. It's going to tell you whether or not you are a streamlined non-competing award process sort of grant. So actually there how frequently you would need to do financial reporting or not, and it will also tell you whether or not you have the authority to carry over. Be sure that you submit your FFRs on time and that you reconcile PMS when submitting those. Consult the grant's policy statement. If you have questions, be sure that you have SOPs in place so that you guys are following your own rules because that's very important, and follow the four cost principles, which you probably have heard about in other ways and also in the grant's policy statement if you've researched that, which are reasonableness, allocability, consistency and conformance. And consistency is usually the one where we see questions. So be sure you're applying all your policies consistently. Communication: Start early communicating with your collaborators and communicating with NIH before an award, communicating with your grants management specialist or your program officer after award. Understand that foreign grantees might have unique policies and regulations in practices that you need to plan for. Be sure that you're involved here for the long-term and be patient because it can take a little bit to work through these things. Here is a resource slide on NIH Grants and Funding website that has a lot of information for foreign grantees. It's particularly helpful for new foreign grantees, so I highly recommend that, and with that, I will end with my concluding slide and my contact information. Thank you very much, and I look forward to the question and answer session.