Advanced Administrative Topics: Post-Award Issues

Crystal Wolfrey: Welcome to the "Advanced Administrative Topics: Post-Award" session of the NIH Virtual Seminar on Program Funding and Grants Administration. We have ... Next slide, Sean. We have several people here that are going to be working with you and talking with you today. I'm going to introduce myself, and then I'll let my partners introduce themselves. My name is Crystal Wolfrey. I'm the Chief Grants Management Officer at the National Cancer Institute. Sean?

Sean Hine: Hello, everyone. I'm Sean Hine. I'm a branch chief within the office of grants administration at the National Cancer Institute, and we have a special guest today, Terri.

Terri Jarosik: Hi. I am Terri Jarosik. I'm the Chief Grants Management Officer at the National Institutes of Mental Health.

Crystal Wolfrey: Great, so a couple quick logistics as we get things started. First of all, I'm sure you realize you're all muted and you are not on video. You can see us. We can't see you. You are welcome to put questions in the Q and A. However, a couple things to remember: This session relies heavily on case studies, so they are real-life examples of things in the session, and we will most likely not have time to cover all of the Q and A. We have some plans for a quick lightning round, but just keep putting them in. They're going to be captioned, and we'll find a way to get answers to you. Next slide, Sean. Okay, so let's jump right into this because, as I said, it's 45 minutes, and we have a lot to cover. So we wanted to give you some examples of things that we believe are aspects of grants that make them complex and that create post-award issues, things like: post-award change of recipient organization, project teams at multiple institutions, delays that happen inevitably in research, significant changes in the research team, significant large balances accruing in the award and unexpected post-award changes. Next slide. So a couple things as we get started, we want to put you into the mindset of thinking like a Fed, so there are a few things to remember. First, federal employees, us, grants and management people, have to support federal policy. We have to enforce applicable laws, cost principles and administrative requirements. We also must support the President's initiatives and policies. We are stewards of federal funds. These are all taxpayer dollars that NIH uses to fund research, and we are the stewards of those dollars. Keep in mind, also, that there are larger ICs at the NIH. There is a lot of ICs at the NIH. I believe there are 24 awarding ICs. Larger ICs have more funds which oftentimes can mean more flexibility. So the correct answer at NIH really is often, "It depends." Next slide. So NIH's perspective when considering challenging, complex situations, a couple things we always ask ourselves. "Have we listened enough to really understand all of the issues and objectives of the situation?" Sometimes the initial question is hard to say yes to, but when we get the details and the backstory, we figure out ways to say yes. "What is in the best interest of the science? What will best serve the investment of the taxpayer in the project? Do we have the funds to even support what's being proposed?" And most importantly or least importantly or however you want to look at it: "How would this play if presented on the evening news or on the front page of, say, The Washington Post?" Next slide. So these are the types of things we're going to try to cover today in our 45 minutes. We have a case study on change of recipient organization. We have a case study on change of principal investigator or key personnel, some topics on changes and delays in the research that create large balances and unanticipated events, aka, stuff happens. And I don't think we have time to get to close out, but we will see. Okay, so change of recipient organization, Sean, that's you, I think, right?

Sean Hine: Absolutely, so hello, everyone. So change of recipient organization, or more classically referred to as the transfer, that definitely is one of the more common and definitely one of the items that has intricacies all over the place, as many of you have probably experienced. So this is where a grant is awarded to a particular grantee institution. It's important to emphasize that point, so this is where the grant if ... I'm sure we have some principal investigators out there. Unfortunately, grant is not yours. It actually belongs to the grantee institution, so the first step is going to be associated with whether or not that grantee institution actually is willing to relinquish that particular grant. So a change of grantee request normally will be permitted only when all the permanent benefits attributable to the original grant can be transferred, so pretty much, "Is most of this grant going with that particular PI, and therefore we, as the awarding IC, can actually say, 'Yep, this makes sense. This is actually in line with everything that we expect this grant to do and they can still be successful based off of their already reviewed and approved aims'?" A change may be made without peer review, provided that the PI plans no significant change in the research objectives. Like I say, this is where we get to some of the heart of the aims issue. This is all prior approval, so this is where it's always good to get in touch with your NIH contacts, branch management and program officials to help kind of ease the process of transfers because they can get rather sticky. So this is where we're going to jump into some hypothetical situations. We say hypothetical because these things really do happen, and to try to help some of that engagement, we're going to kind of walk you through a little bit of a, let's call it, a little bit of a roleplay thing going on here. So in this particular case, a mid-budget-period transfer, the PI is on an application that moves from one organization and wants to take his or her grant with him or her. And so there's always some complications that pop up, and we've seen a few over the years. So let's listen into what a call could sound like between the NIH grants-management specialist and the authorized official for this grant.

Crystal Wolfrey: Hello? This is Crystal Wolfrey at the NIH. How may I help you?

Sean Hine: Hello. This is Sean Hine, the authorized official at Best Research University. You are the grant specialist on our NIH grant with Dr. Stewie as the PI. We have some changes recently that are impacting this grant.

Crystal Wolfrey: Okay. Those sort of changes are pretty common, so I'm sure we can work through your situation. Can you explain what's happening?

Sean Hine: Oh, absolutely. So Dr. Stewie has taken a position at Second-Rate University. I'm not sure why he decided to leave us. I guess it must have been the weather. Whatever. Anyway, he plans on taking this grant with him.

Crystal Wolfrey: Okay. That sounds like a change of recipient organization. Those also are quite common. Do you plan to relinquish the grant?

Sean Hine: Sure. We have no problem with Dr. Stewie taking this grant and going off there. Besides, we were still getting the money out of this grant. Only his salary and fringe benefits are going to be supported from this grant at Second-Rate. They get to manage the grant while we get all the money. Cha-ching!

Crystal Wolfrey: Well, I'm a little concerned with what you were describing. It sounds like your organization will be doing the majority of the work. Is that right?

Sean Hine: Yeah, that's the plan. Yeah, absolutely. We're still conducting all the animal studies as well as the analysis from the benchwork. Even Dr. Stewie's team is going to stay here because they don't want to go to Second-Rate.

Crystal Wolfrey: Ah, so here is the problem. NIH policy states that the grant recipient must perform a sustentative role in the project and cannot simply serve as a conduit of funds. If the plan is to have Best Research University still doing all of the research activity with the only change being Dr. Stewie working elsewhere, I don't think we're going to be able to approve a transfer of this grant. There are options that we can discuss if you'd like, though.

Sean Hine: Okay. Yeah, let's ... You have other options? What are those?

Crystal Wolfrey: Sure. There are several that could be considered. One, for example, would be to set up a subaward to support Dr. Stewie's efforts at Second-Rate University while Best Research keeps the grant. Dr. Stewie even actually could stay on as PI if your institution's policies allow for it. Or perhaps there's a possibility of a multi-PI arrangement. Maybe it would be a good time to set up a conference call with everybody, including the NIH program official, Dr. Stewie, you and me and anyone else at your institution that you think would be helpful, and then we can talk about this more.

Sean Hine: That sounds great. Yeah. Let's definitely do that.

Crystal Wolfrey: Okay, great. We will set something up.

Sean Hine: Great, thank you. All right. End scene. So what did we learn from that particular interaction? So the grant award must be held by the organization conducting the sustentative work and directing the research. So what we just heard in that particular case is pretty much the entire grant was going to stay at the original location. Meanwhile, just the PI was heading out, so that's something we would definitely want to talk about with your NIH officials as far as if you run into that type of situation. There are other options, as was just described by Crystal. So when a PI leaves for a different organization, you can transfer the grant, maybe establish a subcontract to support the PI, maybe even reconsider the PI arrangement. Perhaps establish a multi-PI arrangement. So those are all items that you potentially could talk about with your program official and your grants-management specialist. So another item that comes up commonly is the change of key personnel. So we've all had the opportunity to do this in person, which is always wonderful, and one thing that does come up often is, "So I have a change of a particular individual on this grant, so I need to send that in for prior approval, right?" So we always get to have the fun discussion of, "A change of PI request is required if there is a significant change in the status of the PD or PI or a key personnel that's named on the award." And there's a reason why that's italicized, underlined. We probably should have bolded it, probably should have had it flashing at you, but so that's just one of those items that we want to make sure we really emphasize in this particular case. You may find a lot of people to be key on that grant, and I'm sure they're wonderful and great contributors. However, it's only those that are named that needs to be on there, so ... Sorry. I had just had something pop up on my screen distracting me for a second. So absence for any continuous period of 3 months, reduction of effort devoted to the project by 25 percent or more from the initial competing year. So change of key personnel with multiple PIs, however, so prior approval for single to multi or vice versa is also a prior approval item. So NIH policy allows for post-award PD/PI changes with the prior approval of the grants-management officer if it is expected such requests. However, it is expected that such requests will be rare. It must be obviously substantially supported through a scientific justification, including any changes in the scope or budgetary changes that we may need to account for from the NIH perspective. So a newer revised leadership plan is required, and also prior-approval requests include adding or dropping a PI, and the recipient organization is responsible for securing and retaining the required signatures from all PDs/PIs. So here is another purely hypothetical situation, i.e., this actually has happened. A multi-PI project has been a productive team for years. One of the PI moves in the seventh year, and a large subaward is issued to continue the collaboration. In the eighth year, the PIs have a fallout. The contact PI sends a letter to NIH requesting to change the award to a single-PI project. So the consortium PI, however, again, been a part of this team for a while, contacts NIH demanding NIH hold the prime grantee to the terms of the pre-reviewed leadership plan. We got some problems. So removing a PI from a grant. What might be NIH's response? This is where we could use some help. So in the chat, if you can answer A, B, C or D. So A, move forward with the change of PI. Grants are awarded to institutions, and NIH's relationship is with the prime awardee, or B, deny the request. Recipient must make it work with both PIs. C, terminate the grant. There is no hope. If the PIs can't get along, we no longer want to fund the grant, or D, none of the above. So let's give a second to see how the chats are coming in. Cynthia, how is it looking so far?

Cynthia Dwyer: Well, it was pretty close. I'm going to say the winner is probably D, but A is a very close second.

Sean Hine: Okay. All right. Great. I'm glad everyone is willing to participate. Thank you so much for that. I'm sorry. I need to get this on my screen. All right. So let's talk about A for a second, move forward with the change of PI. So remember, grants are awarded to institutions, and NIH's relationship with the prime recipient. However, all of the named PIs on a multi-PI grant have the same status and level of responsibility. That contact name is just that name in general, so it's the person we would just go to if we need to discuss the specifics of this grant. All of the responsibilities are the same, however, amongst the PI team. So a change of PI is a prior-approval request, of course. The institution must ensure that they have the approval of all PIs for prior-approval requests. We cannot move forward with the requests until we ensure the above. However, it doesn't seem to be this situation. So we also have options B and C, so deny the request or terminate the grant. Neither of these are likely in the best interest of the science or the research NIH is supporting. You may remember way back at the beginning, Crystal detailed out some of the complexities and some of the things we want to account for, which is, "What's in the best area of interest to the science and obviously the NIH and the taxpayers and so on?" So NIH would immediately look to the leadership plan. The leadership plan is going to describe the governance and organizational structure of the leadership team, including communication plans for handling publications and so on, and then obviously the big part is procedures for resolving conflicts, the conflict resolution. So then it gets to option D. So this is most likely the best answer, but why is that? So NIH funded the project for a reason, and we wanted to see it succeed. Crystal said earlier, "We want win-wins out of all of these situations." So we require documentation that the recipient took every step to resolve this on their own through the conflict-resolution plan as stated in the leadership part. Sometimes things, however, can't be resolved, and in those situations ... Hopefully and luckily they're rare. If not, then the recipient took every possible action, and that's what we would want to see, is we would likely honor the request for the change of PI. But the takeaway is to make sure you have a strong leadership plan when you're applying for that particular project and putting forth that proposal. Crystal, back to you.

Crystal Wolfrey: Back to me. So the next topic we want to try to cover are changes, delays and balances. So as everybody knows, biomedical research does not always proceed as planned. Projects are delayed. Balances accrue in the project. Progress points the research in a different direction, changes in scope and so forth that require NIH prior approval. So here is another purely hypothetical situation. How much is too much? During the first year of the grant, the PI has found other sources of funding for a graduate student requested and funded in this application. This results in savings to this grant, which is reported on the RPPR. The PI plans to automatically carry over into the next budget period this balance. Is this a problem? Just can you please enter yes or no in the chat? Okay, I see all ...

Cynthia Dwyer: I know.

Crystal Wolfrey: ... going back and forth, back and forth.

Cynthia Dwyer: I was going to say, "Probably" ... Well, and then there's that good old, "It depends."

Crystal Wolfrey: I love the, "It's depends." I love that!

Cynthia Dwyer: I'm going to say it. The winner is probably yes, but "It depends" is probably a good comeback.

Crystal Wolfrey: It's coming up. That's great. Okay.

Sean Hine: They're learning!

Crystal Wolfrey: Sean.

Cynthia Dwyer: They are learning.

Crystal Wolfrey: They are. Worked with NIH too long. So next slide, Sean. So savings on a grant, so the answer that we have come up with on this one is yes. Although "It depends" probably is right, too. The RPPR reported good progress, including multiple publications. The savings resulted in a balance as reported on the RPPR. Those savings, if we allowed them to be carried forward and used in the next budget period, would be considered an administrative supplement to the grant because progress went fine. The science went fine, and you still didn't need all the money. So it was good. Work was completed. It looks like the funds were not needed, and the NIH-awarding IC might actually reduce the next award by the amount of money that's left in the balance. Okay, next slide. All right. Purely hypothetical situation: A piece of instrumentation essential for the NIH grant has blown up. The PI wants to put the costs for the replacement on the NIH grant. So we've got four answers here. Please enter the one that you think is the right answer. A, this is not possible since the purchase of equipment would require NIH's prior approval. B, this can be done as long as the equipment is needed for the grant's research and therefore fits in the scope. No way! This would probably be greater than 25 percent rebudgeting which would definitely need NIH's prior approval, or you're just simply going to have to wait until the renewal and ask for the money. Good luck with that research project. So please enter your answer in there.

Cynthia Dwyer: They were way ahead of you, Crystal.

Crystal Wolfrey: That's fine.

Cynthia Dwyer: They didn't even wait until the end. B is the clear winner on this one with a few As thrown in there.

Crystal Wolfrey: Ah, okay. Let's move on and see. Yes. This is a very smart group we have here. We need to change our case study, Sean! B is definitely the answer. This can be done as long as the equipment is needed for the grant's research and fits in the scope. So let's talk a little bit about the other answers and why they were not correct. Next slide, Sean. Why not answers A or C? Per the NIH Grants Policy Statement, the acquiring of a piece of equipment and/or the rebudgeting of funds greater than 25 percent are just indicators of a change in scope. It doesn't necessarily mean there was a change in scope. If it is a change in scope, it requires prior approval. If it is not, it does not. In this particular case, there's no change in scope, so it's not going to require prior approval. Next slide. So why not answer D? If the equipment is needed for the grant's research to take place, then the PI needs it, and we need to figure out a way to get it for you. Never feel like you are stuck because of some bad luck, whether it be the equipment or a study behind schedule. Reach out to NIH so we can discuss options. So why is answer B correct? As everybody, I believe, realizes, the equipment is necessary for the project. It's clearly within scope. Apparently, the funds are available in the project because you have money to rebudget for it, and the recipient can make the change without our prior approval, again, assuming that there's no change in scope. The other thing I would add to this, it also assumes that the money that you're rebudgeting was not restricted to a certain activity or cost. Next slide. Is this me or you?

Sean Hine: This is me.

Crystal Wolfrey: Okay, have at it.

Sean Hine: So luckily enough, we had a nice segue into the change-in-scope discussion. So we're going to get into something good here, so we're first going to set the stage for you. So details first because inquiring minds want to know. So we had, actually, an NRSA Fellowship finishing its second year and just submitted their annual progress report to RPPR for the third year of funding. So the NIH program official has been looking it over, and just something's not adding up right now. So let's listen into a call between the NIH program official and that principal investigator.

Crystal Wolfrey: Hello, Sean. This is Crystal, the NIH program official for your NRSA Fellowship. Do you have a minute?

Sean Hine: Oh, sure. Anything for my NIH program official.

Crystal Wolfrey: So I've reviewed the RPPR that was recently submitted, and a few things stuck out at me. First, it looks like you've had a change in your sponsor.

Sean Hine: Oh, yeah, yeah. No. Dr. Dolittle is doing exactly that, very little. It just wasn't working out. So she was requiring all these mentoring meetings and everything. Also, after getting into the research, I found out that what she was working on was really boring. It just didn't speak to me at all. I'm working with Dr. Stark now. The research is more interesting and definitely something I can get behind. Who wouldn't want to find out more on why disco music seems to make everyone dance? Everything is great now.

Crystal Wolfrey: Okay. I'm glad you brought that part up. According to your RPPR, it looks like you did decide to start working on something completely different from what was in your original application. There's no mention of disco music in the original aims that were proposed and reviewed.

Sean Hine: Right. I just figured since the Fellowship is pretty much just supporting me, I could make these type of changes.

Crystal Wolfrey: Yeah. Unfortunately that's not the case. Dr. Dolittle was your proposed and approved sponsor, as was the scope that was originally stated in your application. Changes to your sponsor and research strategy require NIH prior approval. Now, I'm concerned that it appears you made these changes earlier in this past year. Is that correct?

Sean Hine: Yeah. Actually, pretty early this past year if I'm not mistaken.

Crystal Wolfrey: So did you happen to talk about this with your sponsored-programs office?

Sean Hine: Not directly. I don't talk to them much. I did put it on the RPPR, so I figured that was a good way to let them know what was going on. Man, this doesn't sound good at all, but everything is going so well.

Crystal Wolfrey: I'm sure that it is, but not getting approval on such changes is a really serious issue. We're going to need to address this further with the NIH Grants Office. I'll contact them now, and we will be in touch.

Sean Hine: Okay. Thanks for calling, I guess. So, yeah, as you can tell, this doesn't sound very good. So I'm sure you want to hear from the program official and the specialist on what they're going to discuss. You know you want to.

Crystal Wolfrey: Hello, Terri. How are you? Terri?

Sean Hine: Muted. Terri, you're muted.

Terri Jarosik: Forgot to push this thing. Sorry. Hi, Crystal. What do I owe you the pleasure?

Crystal Wolfrey: Well, I wish I had a better reason to call you. I've reviewed the annual progress report for the Fellowship for Sean where you are the grants-management specialist. I noticed that the sponsor has changed and the scope of the project is now different.

Terri Jarosik: Are you sure they didn't just submit the wrong information? I've had some grantees do that where they put it on the wrong grant.

Crystal Wolfrey: Yeah. I was hoping, and I wish that were the case, but I just got off the phone with him, and he confirmed. He's working with a completely different sponsor and changed the scope of the research, researching disco music now.

Terri Jarosik: Wanting to go back to the '70s, huh?

Crystal Wolfrey: Apparently. Who doesn't, right? Anyway, this all happened earlier this past budget period, so I think we got some problems here.

Terri Jarosik: Yeah. Unfortunately we have some serious issues, it seems. It sounds like there's a change in scope. This change in scope is rather significant.

Crystal Wolfrey: Oh, absolutely. It's a completely different grant. If I would have known, there is no way I would have approved these changes.

Terri Jarosik: Okay. We're going to have to put together a formal letter to the recipient. Since the work done this past year is out of scope, we'll most likely need to recover those funds for at least a portion of the past year. Do you know if the sponsored-programs office was aware of these changes?

Crystal Wolfrey: I asked, and he said it was all put in the RPPR. I kind of get the impression that there's not a lot of interaction there between this PI and sponsored programs.

Terri Jarosik: It sounds like the authorized official may not have even noticed that it was out of scope. Perhaps even worse, they may have noticed but didn't think it needed prior approval. We'll need to get more information on their internal-review process as well.

Crystal Wolfrey: Sounds like this is going to get rather involved. I'll e-mail you some information regarding the scope change.

Terri Jarosik: Thanks. That'd be great. I'll get started on the letter now. Talk to you soon.

Crystal Wolfrey: Thank you.

Sean Hine: All right. It's like they didn't even know I was listening. So then what happens? All right. So I'm sure you want to know, actually, what occurred at the tail end of this. So there were definitely some exchanges back and forth, multiple exchanges for that matter in this particular case between the NIH and the recipient. The recipient even requested to change the scope and sponsor after the fact, so more or less acknowledging the fact that definitely something changed, but then they then repitched it back right to us. Ultimately the NCI decided that the new scope could not be approved. The research had to return to the original planned aims, and funds for the past year had to be returned. And also as Terri mentioned, one area that we'd want to zone in on is, "What are the review processes like? How did the RPPR actually make it through the clearance?" So NCI also retaining a copy of the recipient's RPPR procedures to understand those in more detail. All right. So we are ...

Terri Jarosik: I had one ... I just want to add a little ...

Sean Hine: Oh, absolutely.

Terri Jarosik: I had a grant one time where I called the university and talked to the AOR, and the AOR said, "I have it already. It's all waiting for you. It's all signed. I'm just waiting for the science part." So we had a little chat to explain what they were signing.

Sean Hine: I'm sure it's just like we all write our bills out the same way, right? We just write the name, and we let them actually enter the dollar amounts because they'll just do it, but thank you for that, Terri. All right. So we're actually going to do, at this particular point, we're going to do a lightning-round Q and A. So for the next 5 minutes, and we're going to try actually really hard to stay within 5 minutes this time. So the next 5 minutes, we're going to just open it up. Our great moderator, Cynthia, she's going to take care of funneling some questions our way. I will defer all them to Crystal and Terri, and we'll see ... So fire away, Cynthia, whenever you're ready.

Cynthia Dwyer: Oh, my goodness. You have so many questions in this box. Okay. "Do we need NIH approval if a PI wants to change his effort by more than 25 percent? For example, if a PI is listed at 35 percent effort but wants to put in 80 percent towards a grant. Does this need approval?"

Sean Hine: So in this case we're bumping up effort by a substantial amount, correct? So in that particular case, it would not necessarily need prior approval, but it does kick in the pieces where you have to question the scope. You do have to question, obviously, for more budgetary impact because that's a lot of money now going to one individual that wasn't originally planned. So, yeah, so it may seem great on paper that the effort is going to go up by that much and the PI is going to contribute all of that, but that is something I would probably recommend because a couple red flags were bouncing in my head as far as, "How are they going to pay for that type of thing, and how is that all within scope?"

Cynthia Dwyer: Okay, great. And then we have a question that's similar. Oh, I just lost it. We've got so many coming into the chat box, too. We've got both. Let's see. Well, basically, let me summarize. It's already gone on the list, but, "If Dr. X had rats in his proposal and all of a sudden he decides, 'You know what? I want to do mice," is that's a change in scope?"

Crystal Wolfrey: It probably would be considered a change in scope. Go ahead, Terri.

Terri Jarosik: That's what I was going to say. It can very well be a change in scope. You would need to check.

Cynthia Dwyer: Okay. "Does it matter how late in the grant period new equipment is purchased?"

Crystal Wolfrey: Not by NIH policy, no. In the old days, because I'm old, if it was purchased in the last 2 years of the project, it required prior approval, but NIH waived all of those cost-related prior approvals, so as long as it's within scope and you're not rebudgeting restricted funds, it doesn't need prior approval.

Cynthia Dwyer: Okay.

Terri Jarosik: And it's necessary to the project, right?

Cynthia Dwyer: Okay. "When we verify the human subject's education is current, is that specific to key and senior personnel under the NIH Grants Policy Statement definition of key and senior personnel, or does this requirement expand to others, basically anyone working on the grant?"

Crystal Wolfrey: So, yeah, I just love that NIH has multiple definitions for key personnel, but in this particular situation, it's those individuals who are involved in the design and conduct of the human-subjects research. That's who's determined to be key for the human subject's education certification. So it's not necessarily who was named in the award notice, and it's not necessarily by the definition of key personnel that NIH has developed for key personnel. It's individuals involved in the design and/or conduct of the human-subjects part of the research.

Cynthia Dwyer: Okay, and this is basically ... This is a good question for who to contact. "So what if one of the co-PIs to a grant is no longer ... well, passes away, for instance, unexpectedly after the proposal is submitted? There's no clear instructions in the NIH Guide. Do you contact the program manager for that grant, or what are the steps to take if something happens like that?"

Terri Jarosik: Is this prior to review or prior to award?

Cynthia Dwyer: It sounds like it might be before, but I'm not sure. I'm not sure. "No clear instructions in the" ...

Crystal Wolfrey: Well, it sounds like it ... if it's prior to ... It's definitely prior to funding or prior to an award being made, so my recommendation, and then I'll let Terri and Sean jump in, the program official is the person that you get. That's the first name you get when you get one of the grants submitted to NIH, so that would be the person I would reach out to if something like that happened prior to it getting either reviewed or selected for funding. Having said that, if you can't reach that program official, you can always contact the chief grants-management officer because our names are everywhere. We put them all on our websites, and we can make sure that we get you in touch with the right person.

Cynthia Dwyer: Oh, you know what? I bet this is a common question, too. This person, Morris, says, "I've noticed the NIH awards are not necessarily listing the coinvestigator or other key people. Is there a reason for that? Is there any problem with the coinvestigator not being listed on an award?"

Terri Jarosik: There's not really a problem. The key simply means that that person has such expertise that we could not do this award without that person. So just because you're a coinvestigator, you might have other expertise, but many other people in the country or whatever have that expertise and might be able to pick up if that person needed to leave. But if you have a specific expertise that is very specific to that person, we would generally list them as key.

Cynthia Dwyer: Okay, are there any ...

Crystal Wolfrey: It also depends on the type of grant that we're funding, too. So some grants that support specialized centers or specialized networks, there tend to be more key personnel listed in the terms of award than in regular research grants.

Cynthia Dwyer: Okay, and Richard wants to know, "Who, NIH or the institution, actually determines if a change in scope has occurred?"

Sean Hine: All right. So, yeah, so it would begin at the institutional level, so that's where it's going to start, so that principal investigator would have that conversation at the institutional level. What our experience has been, of course, is then if it kind of gets a little wishy-washy, not exactly sure, that's when you want to reach out to your program official, so have that contact and at least have that discussion. If it is decided, however, that this is a change in scope that needs to be formally reviewed and approved, that needs to come through the grants-management office. So it's important that you don't stop just at the program official because you had a wonderful conversation, as I'm sure many of you have had, but you need to finalize this by getting it through the grants-management office, and they must actually get the request and the formal acceptance of that change.

Cynthia Dwyer: Okay, good.

Sean Hine: We can do one more, I think.

Terri Jarosik: I think we have one more, yeah, because its ...

Cynthia Dwyer: Okay. Oh, and I have to tell you that I know we are running out of time. There are so many great questions, and I'm sure that they're not going to get to all of them, but if you have questions after this, then please feel free to go to the exhibits-hall booth, talk to grants managers. There's an NCI booth. There's booths from every institute and center. Okay, so one more question. "Are other support files needed for key personnel that are not named in the NOA on just-in-time and RPPRs?"

Sean Hine: This will probably ... Sorry. I lost track of it.

Terri Jarosik: So in just-in-time for completing applications, other support is required for every one that you have indicated or named as key in the application. In the RPPR, I think this might be something for GMO. I believe in the RPPR, it's only for those individuals we've named as key, but I'm not sure.

Crystal Wolfrey: Terri, I agree with you. Yeah.

Sean Hine: Yeah.

Terri Jarosik: But you know what? We will double-check that answer because I feel like I've had that question before and we might have answered it wrong, so we'll double-check it and make sure that when we post the questions, we'll get answers with them, too. Okay?

Sean Hine: All right. And with that said, we are going to move on. So thank you ...

Terri Jarosik: So thank you, Cynthia, for managing all that.

Sean Hine: Yes. Thank you, Cynthia. All right.

Crystal Wolfrey: Me. Is this me?

Sean Hine: Yep.

Crystal Wolfrey: Okay. Most problems start out small. Only when unaddressed and left unchecked can they grow into ugly monsters. Unanticipated events, otherwise known as, "Stuff happens." Okay, so here is the situation quickly. Five-year grant, no concerns with years 1 and 2. The accrual portion of the grant is set to begin in year 3. The year 3's progress report arrives. Program official notes that thus far only 10 of the planned 100 patients have been accrued and a significant balance is reported. Accrual was supposed to be completed by the end of year 4, but the RPPR indicates that the time line is now showing completion of accrual in year 5. "Houston, we have a problem."

Sean Hine: So first of all, it's pretty obvious that this grant is in a bad spot. So what are some of the initial steps that NIH IC.

Crystal Wolfrey: Okay. It was good to see that the RPPR was detailing the issues that the grant is experiencing. As the grants officer, I would first want to consult with the program official just to get a better feeling of the situation and what he or she knows and then a few questions I think I would be asking. One, was there any indication of progress concerns in the previous RPPRs maybe that went undetected or were not reported? Is it reasonable for this grant's accrual to be completed a year later than planned and still finish on time? How are they going to analyze data and everything else? If not, what's the time line now? We would have to consider how much funding remains in the grant with this new time line, so I'd probably look into the payment-management system to investigate that to see what's reported on the RPPR, what's reported as balances. Is there enough money to support the grant to completion? Is the grant overspent given the rate of progress, and if so, why? I then work with the NIH program official, and what we do is put together a letter, send it to the recipient to detail our concerns and ask some questions.

Sean Hine: So let's say assume that this grant is just purely behind schedule. Many grants, for issue, suffer accrual issues all the time, so especially in light of the recent coronavirus pandemic. Is there a substantial balance? And there is a substantial balance because of the delay in the progress. What are the options there?

Crystal Wolfrey: So there's several approaches that could be taken here. Perhaps if there is such limited progress that it's really difficult to gauge where this grant is currently and where it should go next, NIH may consider extending the grant's current budget period to give it more time before taking any action on another noncompeting award. Maybe a type-five award could be made, but maybe we'd put a requirement on for an interim progress report with milestones. Or I know at NCI because we're a large IC, and as I mentioned, larger ICs have more money and therefore more flexibility, I would think that one of the things we could do is restructure the budget so that it matches the time line a little bit better. What that basically means is we let them use the balance that they have this year to fund this next year, and then maybe we'll add time and money on at the end, so that's something that we could do at an IC like ours. I don't know, Terri, if you want to talk a little bit about that.

Terri Jarosik: Yeah. We utilize all those options, but like you said, because we're a smaller IC, sometimes it depends on what time you are in the fiscal year as far as how much money we have available, what we can do to restructure, what has to be funded, so every one of them would be taken on a case-by-case basis, but we absolutely ... I think pretty much ... I've worked at several institutes, and we all worked towards hoping to facilitate this research, so trying to find the best solution within the confines that we have.

Crystal Wolfrey: Great. Thank you. And then so I get the ... And then at the end, as a last resort, if a situation is not recoverable or if it's a trial that really we'll never actually be able to accrue, it sort of becomes unethical to continue the research, and we might actually negotiate phasing out the grant. So those are the options that we would look at.

Sean Hine: And from what both of you described, it sounds like at the heart of it all, NIH wouldn't simply be looking to save money here in any of these options, right?

Crystal Wolfrey: Right. No, no, that's absolutely correct. Our focus is on what's in the best interest of all parties and science. So we have a lot of options at our disposal, and we will work with a grant recipient to try to pick the best one to move the research forward.

Sean Hine: Yeah, and Terri talked ... I'm sorry. Go ahead, Terri.

Terri Jarosik: I was just going to say, the best thing to do is to give us a call because we really do want it to work just as much as you do.

Sean Hine: Yeah, and Terri had talked about it a little bit as far as there's a variance from institution to institution from an awarding standpoint. So just in hindsight here, what would you like to have seen different from this recipient?

Crystal Wolfrey: The only thing that comes to mind is that there might have been a missed opportunity here, not reaching out to NIH during the budget period when it was known that there was accrual issues. Some options could have been discussed sooner at that time, but again, we're here to help, so even at the RPPR time or even before, our goal is in the best interest of science.

Sean Hine: Okay. So with the progress issues, just as a summary of some of the things we just talked about, so first you get in touch with NIH. The sooner the better. There are options that can be considered, the extensions during the project period, interim-reporting milestones, restructuring the budgets and, of course, the worst case, phasing out the grant. Future year of funds in a grant are not guaranteed. Obviously we need to evaluate the progress and everything that's going on there. However, NIH is here to help in any way we can. We wanted to fund this research. We funded the research. We want to keep going, so ...

Crystal Wolfrey: Okay, so to sum things up a little bit, communication between department and sponsored projects is critical. A lot of solutions are organizationally culture-driven. For example, good communication is part of the culture, then it's more likely to support good management practices, such as work groups across departmental boundaries. Current, written and accessible policies are a must. All parties involved must know and understand and comply with the rules. If not, well, outcomes may not always be positive, but again, we are here to help, and we want you to reach out to us as quickly as possible. Okay, we've listed some resources for you. First and foremost, your sponsored-programs office, if you're not already from there, your accounting office, your internal auditors, IRBs, IACUCs. Please, at NIH, first stop, grants-management specialist. There is a grants-management specialist and a program official assigned to every single branch. They know your grant the best. They are the most intimately involved, and they can answer your questions. There's links here for the Office of Laboratory Animal Welfare, Office of Financial Management and the Grants Policy Office. And then also part of HHS is the Office of Human Research Protections. Resources for compliance, Grants Compliance and Oversight Office, Grants Compliance inbox and NIH's Outreach Activities, like the regionals that we're doing and then additional resources. Please make sure that you read your notice of award. Grants-management specialist is always listed in the award notice, as is the program official. There are some links also for OER, which is the Office of Extramural Research, Grants Information, Grants Policy inbox and the Division of Financial Advisory Services, so we're hoping you just find these resources useful. Any questions? We've given all three of our e-mail addresses. If you didn't get your question answered, I think we have 4 minutes that we might be able to answer a couple more questions. If you didn't get your question answered, I know after yesterday's session, someone reached directly to me with their question, and I was able to answer it. I think that happened to Sean as well. The three of us are absolutely here to help, and as Cynthia mentioned, please use the booths because every IC has put a lot of time and energy into manning those booths, and we are really just sitting there waiting to answer your questions. So ...

Terri Jarosik: I'll be at mine from 12 to 5 tomorrow on the booth.

[ Chatter ]

Crystal Wolfrey: Since we have a couple minutes, do you want to shoot through a few more questions?

Cynthia Dwyer: Okay, sure.

Sean Hine: Yeah, let's do that.

Cynthia Dwyer: Okay, awesome. "For last phase of a center grant, an administrator was listed as key personnel on an NOA. Is this usual?"

Crystal Wolfrey: An administrator was listed?

Cynthia Dwyer: Mm-hmm.

Crystal Wolfrey: I would say that's not usual from our perspective. Terri, is that something you would know?

Terri Jarosik: Not from us either. I could see if they needed someone definitely coordinating it, so they would list an administrator as the role as key, but not necessarily the person.

Crystal Wolfrey: Yeah. That's when I think I would reach out to grants management to ask some questions about.

Cynthia Dwyer: Hmm, this is a really good question, especially with a lot that's going on in our universities right now. "A university initiated a hiring freeze due to overall budget issues," and I'm sure there's other things going on out there. "This resulted in taking 6 to 9 months to hire staff. Would that be a legitimate reason to request carryover of over 25 percent?"

Crystal Wolfrey: I'm going to start, and then I'll let others jump in. It's certainly a legitimate reason to explain why there's a significant balance, so that's the first part of that over-25-percent question is explaining why there's a balance and where the balance came from. The next part of that is, what are you going to do with that money, and how is it going to be used in a bona fide need way over the next budget period? So I know at NCI if there's a hiring freeze and you haven't been able to hire and you're still not able to hire, this is a situation where we may consider restructuring the budget to match better the time line, so we may not provide the full funding in this next award notice because you have so much of a carryforward. We would let you spend down that carryforward and then maybe build out an out year to realign the time line of the project with the money that you have left. So that's what we would do. I don't know, Terri, if you have other thoughts.

Terri Jarosik: Yeah. We would be definitely doing an analysis on what money is needed. Are you going to be increasing total effort on the grant? So maybe you need that money coming forward with the people that you currently have on the grant to make up for those you couldn't hire, things like that. There are definitely different things we are looking at to see which way would be best to handle it.

Crystal Wolfrey: Thank you. So I saw something really quick, Cynthia, before you go, jump up on the chat saying, "Restructuring is a pain. Let us just keep the money and do a no-cost extension at the end." And I absolutely appreciate that. I will tell you that. Many of my staff will tell you restructuring is a pain, and, "Why do I have to deal with that?" But what I think it's really important that you understand is part of what ... Remember the very beginning when I said we were stewards of federal funds? One of the things that we absolutely have to adhere to is what's known as the bona fide need rule. We cannot provide money in an award unless we have a reasonable expectation that you can spend that money in that time period for that award. So if you have a significant balance and we issue another award, we have, in effect, violated the bona fide need rule if you can't use all of that money in this next budget period. So from our perspective, I know it's a pain, and I understand it's a lot more work, but it's the better way to do the award because it actually shows on paper the restructured time line and the restructured budget.

Cynthia Dwyer: I've got a question. "What happens if our grantee community has grants- management specialists that are not responsive to questions?" Do you have some advice as grants-management officers for that person?

Crystal Wolfrey: Absolutely.

Terri Jarosik: Yes.

Crystal Wolfrey: Please, we all have our organizational structure ... What do you call it? Org charts on our websites. Contact a supervisor. Contact their team lead or the branch chief and always feel free to contact me, not in a way that you're trying to get somebody in trouble, but in a way to get you an answer. I'm always happy to help in those situations, and I think all of us ... Terri, you agree?

Terri Jarosik: Yep, absolutely.

Crystal Wolfrey: Yeah. We are here to help. Trust me. Sometimes we get busy, but we are here to help.

Cynthia Dwyer: Great.

Sean Hine: We're up to 4:45.

Cynthia Dwyer: We are at 4:45, and I'm so sorry that I probably didn't talk fast enough to get to all these questions. There where just so many wonderful ones. We did have a question about what booths should people go to, and so we do have an exhibit hall and general-information desk that you can go to, and they can help guide you to one or more of any of our 45 booths that are available. If you're interested in a specific institute or center, then we also have all of our funding ... We call them ICs, but our institutes or centers available with grants managers there, with program, with review, so don't be shy. Go there. They're open. They're staffed between noon and 5. Almost every booth is, so that's a good place. We also have a policy booth. It's called Ask an NIH Policy Officer. We have a training booth. We've got just numerous, so check it out, and then ... I have to go, but thank you so much to our presenters, and thank you to our interpreters and all of you for joining us today. Appreciate it.

Terri Jarosik: Thank you.

Sean Hine: Thank you.

Crystal Wolfrey: Thank you. Thanks, Cynthia. Thanks, everybody.

Sean Hine: Bye, Cynthia.

Cynthia Dwyer: Bye.

Terri Jarosik: Thank you.

Crystal Wolfrey: Bye.