**Advanced Administrative Topics - Post-Award**

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Elyse Sullivan: Thank you for joining our presentation, Advanced Administrative Topics Post Award. My name's Elyse Sullivan, and I'll be your moderator today. And joining us to present, we have two experts from the National Cancer Institute. Crystal Wolfrey is the Chief Grants Management Officer, and Sean Hine is the Deputy Chief Grants Management Officer. These two have a lot of expertise to share, so I'll let them take it away.

Crystal Wolfrey: Thank you, Elyse. Hello, everybody. Welcome to our session on Post Award Advanced Administrative Topics. For those of you that attended the last session, it is definitely live, so anything can happen. Well, my name, as Elyse said, is Crystal Wolfrey. I am NCI, the National Cancer Institute's Chief Grants Management Officer. I have been doing this .. . For those of you that didn't come last time, I'll fill you in on me. I have been doing this for 36 years, so I've been in Grants Management a long time. I've learned a lot, and I'm very much hoping to share some of that with you today. And I'm going to let Sean introduce himself.

Sean Hine: Hello, everybody, Sean Hine, the Deputy Chief GMO. And if you joined last session, you saw how I quickly get out of work. So I'll skip the niceties. I've been here for about 20 years, and we're just going to get rolling. So the logistics, Elyse already covered, so we'll just skip right on past that. So let's get into post-awards. So what's the period of time that we're talking about with post-awards? So and that's any time after the initial competing award is made. So that competing award gets fired through, and then we pick up post award at that particular point. So this also includes any point of annual reporting. So if you're doing the RPPR, your IRPPR, your FRPPR, you name the RPPR, it all falls in that spot. And then, we lovingly joke that this is kind of where a lot of the quote-unquote action happens. So a lot of stuff can happen during the post-awards phase. So a few things just to keep in mind. So we'll just kind of roll through these really briefly, which is we're here to support federal policies, enforce the applicable laws, procedures and principles, acting as stewards of federal funds. And it's always really important to keep in mind, too, that some of the ICs have a relatively broad mission. Others have a little bit more of a narrow mission. So some of the flexibilities will be dictated based off of that as well. Larger ICs have more funds, so more flexibilities, and not all the ICs fund the same mechanisms. And the classic NIH, the correct answer is usually, it depends. So a couple other items that we want to try to account for in any of these post-award discussions is, have we listened enough to you through the entire process? Have we listened to the issue? Do we get an idea what you're trying to get at? What's in the best interest of the science? But then also, what's in the best interest of the taxpayer into the project? So we always keep that in mind, that steward of federal funds piece. And do we have the necessary funds to support what you're looking to do, and how would this play out if it were to pop up on, you name it, news? So, and then lastly, we're really looking at the idea, can we get to a win-win that works out for everyone involved? Okay, so a few of the discussions, the items and things that we're going to cover today is results reporting with clinical trials. That's always a hot topic. So foreign components, so getting in a little bit of that prior approval space. Flip-flopping back and forth between an R01 to U01. Can that even happen? And drawing down funds, albeit a little bit late. And the last one, which we hope is a really cool case study for you, will be what to do with a major change in plans?

Crystal Wolfrey: Okay, so we're going to jump right into this because we ran out of time last time. So first topic, clinical trials results reporting. This been kind of a big topic lately. There are enhanced efforts to ensure that the results of clinical trials are widely available to the public. That includes what's known as the Final Rule, which is the CFR that is referenced here, which clarified and expanded legal requirements for registration and results submission of clinical trials, results reporting of FDA-regulated products. And then, NIH's Policy on Dissemination of NIH-Funded Clinical Trial Information. It expanded the requirements in the Final Rule to cover all NIH-funded clinical trials whether or not they're subject to that regulation. I'll jump. That's okay. Oh, we both jumped. Sorry. Sean, you do it. Okay. So really quickly, all NIH-funded clinical trials are expected to register and submit results information to clinicaltrials.gov, as per the NIH policy for competing applications and contract proposals that were submitted to NIH on or after January of 2017, that proposed clinical trials that started after that date. Both the NIH policy and the federal regulation aim to increase the availability of information to the public about clinical trials, information that's not systematically available from other public sources. Sean, are you frozen?

Sean Hine: No, I think I'm good. So quiz time. So we're going to jump into a little quiz for everyone to kind of get you engaged. So Crystal didn't trust my Internet connection there. So to comply with NIH policy, what is the standard timeline for submission of results information after the trial's primary completion date? Go ahead and enter that in the chat, and let us know what you see, Elyse.

Elyse Sullivan: All right. In the chat, we see a lot of A and a lot of C, some B. We're actually pretty .. . Yeah, we've got quite a variety here, so I think we're not sure.

Sean Hine: Very good. So the Cs would've got it. So you got 1 year in order to get that taken care of, so that's .. . I like the variety. That means this was helpful, so hopefully good information for you. All right. Crystal, time for some back-and-forth on this one.

Crystal Wolfrey: Okay, sounds good.

Sean Hine: All right. So my understanding is that NIH has been sending out letters for this .. . to the awarding institute .. . from the awarding institution or center about results reporting concerns. What's this all about?

Crystal Wolfrey: Yup, that's right. NIH has been very active in sending out letters to the recipient organizations where it looks like results reporting hasn't been submitted as it's required by the NIH policies.

Sean Hine: So to back up for a moment, so how are recipients certifying that they are compliant with the NIH policy?

Crystal Wolfrey: Okay, so it starts with the competing application that requests NIH funding to support a clinical trial. That application needs to include a plan that will address how they will meet the NIH policy expectations for clinical trial registration and results reporting. That plan, then, becomes a term and condition of the award.

Sean Hine: Ah, so, all right. So let me guess. So when the authorized organization or representative, the AOR, signs off on that Research Progress Report, that RPPR, they are confirming they are complying with the terms of award, so including clinical trial registration and results reporting requirements and the compliance with those FDA regulations if that's applicable. Is that correct?

Crystal Wolfrey: That's it. Exactly. So when NIH issues an award, our award system checks to see if there's a clinical trial that's more than 1 year past the primary completion date and that if it's not reported results, and those results are required, then it flags it for us. And if that happens, NIH will send a letter to the recipient requiring that they come into compliance with the policy.

Sean Hine: That makes sense, and sounds like some checks and balances in place from a system perspective. Validations. That's awesome. So the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information became effective with applications submitted after January 18th, 2017, correct?

Crystal Wolfrey: Correct.

Sean Hine: And so why have I heard about letters being sent to recipients on trials that started before that date?

Crystal Wolfrey: Okay, well yeah, it's definitely true that the NIH policy was effective with applications submitted after January 2017, that proposed trials to start after that date. But remember, the requirements for registration or results reporting of clinical trials subject to the FDA Amendments Act, that regulation, often are called applicable clinical trials, that goes back much further. So it's possible that the trial falls under those requirements, and that's why a letter would be sent out.

Sean Hine: Got you. Okay, so that sounds complicated. So what happens if the study doesn't have any .. . doesn't come into compliance?

Crystal Wolfrey: It can be complicated, but there's a lot of information out there that explains the policies, and NIH will help recipients figure it out. We'll also give time for the study to come into compliance, but eventually if it does not come into compliance, then we may take enforcement actions. And for applicable clinical trials, there could be financial penalties that can be enforced by the FDA.

Sean Hine: Wow, that's pretty severe. So thanks. I think being aware of the requirements is really important. And in the end, disseminating clinical trials information, so including results reporting, the NIH mission is to advance translation of research and results into knowledge, products and procedures that improve human health.

Crystal Wolfrey: Right. Okay, so in summary, if you've heard from NIH about potential noncompliance, the NIH needs you to confirm results reporting. It's really important that results reporting concerns are addressed immediately. As I said before, there can be substantial consequences if you are found in violation of the regs and policies. Reach out to NIH if you have any questions about this.

Sean Hine: All right. That was a lot of heavy stuff right there. Now that's not easing into this at all, so we just needed you all hanging out from the last one. So all right. So we're going to switch gears to a different topic, foreign components. So prior approval requirements, this is a quick refresher. So I know you all are savvy to them, so we'll just roll through these. So there are a couple few situations that come up pretty commonly for prior approval. We list them here, just as far as extensions, that's the additional time with and without funds, change of recipient organization or lovingly referred to as transfers, adding that foreign component and the occasional change in approved aims. So just as a reminder, go check out that Grants Policy Statement Section 8.1.2 for more information on prior approval requirements. But specific to foreign components, let's .. . We're going to walk through an interesting situation. So we have an ongoing cooperative agreement that recently entered into its fourth year of a 5-year project. The grant struggled with enrollment a little bit and has very recent specific segment of the population that would pretty difficult to get to, and so it's causing a little bit of an enrollment issue. So in conversations with NIH grants manager and the program official, it was determined that it would be beneficial to add another site. So now we're going to listen into on a call, however between an AOR and the grants manager. Hello, this is Sean Hine at NIH. How can I help you?

Crystal Wolfrey: Hey, Sean. This is Crystal from Splendid University. Do you have a few minutes to discuss a situation we're in?

Sean Hine: Absolutely. What's going on?

Crystal Wolfrey: Okay, so we have a U01 with Dr. Biscott as the PI. Things were not really going particularly well. Dr. Biscott and the NIH Program Official have been in contact. They're trying to figure out alternatives to our enrollment issue.

Sean Hine: Understood. Yeah, no, enrollment has been a particularly tricky topic in the last couple of years with COVID and everything.

Crystal Wolfrey: Yup, you're spot-on there. If I had a dime for every instance where I had a PI bring up enrollment with me, but anyway, that's not important. So here's our pickle in this. We brought on a new site back in November, and all is looking good. Things are set up, and everyone is already moving on it. We think this could be a real game changer for the project.

Sean Hine: That sounds great. So sounds like the program official is involved. I've heard about this loosely as well, so what's the problem?

Crystal Wolfrey: Well, the problem is that it's a foreign component.

Sean Hine: Oh, okay, well you said November that the site was brought on, right? Did you happen to send in a prior approval request for that?

Crystal Wolfrey: So I said it was a pickle, right? So Dr. Biscott was working closely with the NIH Program Official, and I guess the thought was that given those discussions, we were good. So no, we did not get that request in until the beginning of January.

Sean Hine: That is definitely a pickle and not the good kind. Is it good that it is now .. . It is good that it is now with NIH to act on it, and the final approval needs to come from a NIH Grants Management Officer, rather than the program official. I see in the system that it was cleared by all the departments on January 15th, so we could wrap up the review on that and get a response back to you to that request.

Crystal Wolfrey: Okay, that's great. And yes, I think everything's in place, but the question is, what about charging the grant for expenses back to when the site came on in November? Any chance?

Sean Hine: Huh, so that's a little bit on the trickier side. So unfortunately, that was all done before the request was even submitted, so sometimes we can provide retroactive approval, but adding a foreign site requires clearances outside of NIH. The clearance didn't even come through until January, so the best I can do for you there is probably approval of charges to starting around January 15th when the clearances were provided.

Crystal Wolfrey: Okay, I had a feeling. Like I said, it's a pickle. Okay, we will go from here, and we'll work to make sure this is better understood with our PIs. Thanks a lot. I appreciate your help.

Sean Hine: So what did we learn from all of that? So any time you're dealing with a foreign component being added, you're in a prior approval situation, just across the board. So if you get in that space, just reach out to the grants manager and have that conversation. Make sure that's being covered. So there's always additional clearances required to make sure that this is in the right spot across the board as well. In some of those, depending on the foreign component that's involved, can take a while, so it's best to really lean into the prior of that prior approval space. And in this case, the best that could be done, as was described, was the authority to charge the grant funds no earlier than the date of the actual clearance, which is when the NIH Institute and Center could approve the actual involvement. So again, that prior approval piece is really important here. All right. So we're going to test them at this point, Crystal.

Crystal Wolfrey: We are going to test them, so another audience participation. So critically important to understand what needs prior approval. For example, true or false? Do you need prior approval from NIH if a rebudgeting between costs categories on an R01 would be more than 25 percent?

Elyse Sullivan: All right. In the chat, we're getting a lot of yes, yes, yes. We got some, "It depends," but mostly yes or true.

Crystal Wolfrey: The it depends have to be NIH people. Okay, the answer is maybe. Yes, it definitely .. . It depends. So rebudgeting greater than 25 percent is a potential indicator of a change in scope. The rebudgeting alone would not need prior approval from NIH, but if that rebudgeting results in a change in scope, then yes, prior approval would be required, but of the scope change not the rebudgeting. So I believe now we've created an incredibly busy slide, that we will not read, but the bottom line is this is from policy on what constitutes a change in scope. And there are number of things that are potential indicators of a change in scope. Things like, you'll see in there, significant rebudgeting. Another question we get a lot of is purchasing equipment that exceeds $25,000. There's a couple .. . There's another one in here we get a lot of transfer of the performance of substantive programmatic work to a third party. Those are all potential change-in-scope indicators. If it is because of a change in scope, the change in scope requires prior approval. If you're doing any of this stuff, and it's not a change in scope, then the action itself does not require prior approval. So it depends. Oh, okay. we're at lightning round. Good timing. Do we have anything in there, Elyse, that we could do?

Elyse Sullivan: We have a few. Our Q&A folks have been answering a lot in the chat, but let's see what we have here. Okay, so we've got a budgeting question. "If a PI has an appointment with both the parent and the subrecipient, and the subrecipient's invoice contains the PI's salary charges that's part of the amount invoiced, does the invoice require the parent," are you following? "To have a one-over-one approval before the invoice can be paid?" Did you get that? I didn't.

Crystal Wolfrey: I got that.

Elyse Sullivan: Okay, good.

Crystal Wolfrey: Do you want to go, Sean?

Sean Hine: Go right ahead. I insist.

Crystal Wolfrey: Oh, yeah.

Sean Hine: I'm still processing.

Crystal Wolfrey: So first, I will say highly unusual, and we would ask a lot of questions. If the PI on the parent award was also the PI on the subaward, that does present some concerns because it is clearly less than arm's length if it's the same individual, and that individual really should be paid on either as the prime or the sub. If, by some way, we've worked it out, and this is allowed to happen, yes, absolutely. You would need a second set of eyes on that invoice. The PI could not be the approver of his own invoice on the subaward, but again, that would be really unusual. If you have a situation like that, I really recommend you reaching out to NIH to talk about that before it happens.

Elyse Sullivan: Great. Thank you. All right. Let's do one more, and then you guys can move on to it. Okay, so I got a question about a public university located in Europe asking about the PIs who are submitting other support. "Does that need to include a copy of the university employment contract? They're obviously foreign in the eyes of NIH, but this is the PI's domestic appointment. With the same question about whether the PI needs to provide a copy of an award contract with our funding agency?" So I guess the question is, if you're a foreign component, what do you need to report in your other support?

Crystal Wolfrey: In your other support. Okay. So if the application is coming from a foreign institution, and the investigator is employed by that institution, no, we do not need a copy of that employment contract. The fact that you've submitted an application with that individual listed as the investigator implies that there's an employee-employer relationship with that individual as an investigator at that institution. I can't remember what the second part was. What was the second part?

Elyse Sullivan: Do you need .. .

Crystal Wolfrey: First part, no, we don't need that contract.

Elyse Sullivan: Do you need to provide a copy of an awarded contract with other funders?

Crystal Wolfrey: No. We would need a .. . . Well, so now we're going into the weird other support space, right? So you do need to report all other sources of support for the investigator. If the investigator is engaged with a different foreign organization as part of their other support, then yes, we would need to see that contract, but we don't need to see a contract with other organizations that just provide funding for you. So that's a really weird one, but the bottom line is, generally speaking, you just need to report everything in your other support. And we will go .. . We will ask you if we need any more information other than that. Good?

Elyse Sullivan: Great.

Crystal Wolfrey: Elyse is nodding. She's from OER, so I'm guessing I did.

Elyse Sullivan: I'm on board.

Crystal Wolfrey: Okay. So we moving on?

Elyse Sullivan: Great.

Sean Hine: All right. Moving on. So this .. .

Crystal Wolfrey: Is this you, Sean, or is this me? Is this you?

Sean Hine: I believe this is actually me, if I'm not mistaken, Crystal. You can yell at me if it's not. So flip-flopping of a situation. So we have a grant situation where a grant competes as an R01, during which it's identified that there's plans to have an NIH Intramural Investigator substantially involved. But before the initial award, the grant was converted to a U01, so now in year 3 the NIH Investigator is no longer involved. So what happens now?

Crystal Wolfrey: Okay, Sean, you peppered me with questions resulting .. . about results reporting, so now it's my turn. What's your take on this situation? Oh, and you made me answer both of those Q&A, so what's your take on this situation?

Sean Hine: I did make you answer both of those Q&As, so I gave you a thumbs-up in the middle one though, so that was good. So this is what I would call a not uncommon situation, but uncommon enough. That's very .. . If anybody worked with me, that's very me speak right there. So we do commonly see the first part happen, a grant gets converted to a cooperative agreement at the time of the initial application.

Crystal Wolfrey: Okay, so can I stop you there for just a second? How does that even come up?

Sean Hine: So it's typically not done with the intent of trying to get a cooperative agreement kind of snuck in the door. The application is reasonably submitted to an R01 funding opportunity, for example, and there just happens to be the involvement of, say, an investigator at the NIH Clinical Center. In those instances, NIH officials will work with everyone involved to land in the correct spot before an award is made.

Crystal Wolfrey: Okay. Okay, so back to this scenario. That involvement would just go away?

Sean Hine: So it really .. . Here's the NIH answer. It kind of depends, right? So it's very possible that this was actually planned from the very beginning. There was definitive plans already in place, that in instances like this, where the NIH involvement was going to cease at a particular point. In this case, maybe it was going to cease after year 2. Also, there can be changes over the course of the research that may result in the involvement no longer being necessary.

Crystal Wolfrey: Okay, so is there anything else that should be considered in those situations, specifically where it was a change that was not necessarily planned?

Sean Hine: Oh, most definitely. So this gets in the sublayers of consideration, actually. So what was required in the funding opportunity, for instance, does this impact the scope of the grant? Is that work being replaced in some way? So if it's an unexpected change, is work going to be replaced by somebody else? Maybe a foreign component, for instance. If so, then a lot of things need to be considered. So anything to consider with the new participants of the organizations are going to be involved. All of this would be part of the analysis that goes into this sort of a change.

Crystal Wolfrey: Okay, well that makes sense. Okay, so this situation, if it was a plan change, what happens next?

Sean Hine: So NIH Grants Management and Program Officials would work with the recipient to discuss the plans, so to convert this back to an R01. So again, it went from R01 to U01 back to an R01. The terms that were previously included to reflect the substantial involvement from the NIH would be removed, and it would be treated as R01 moving forward.

Crystal Wolfrey: Okay, that's super interesting. Seeing that a grant can adapt throughout the life of the research is important and to consider, since so many things change as research goes on. So thanks. That was great. Okay, so as you heard, options abound. So in summary, because of the proposed substantial NIH involvement in the original application, NIH negotiated with the recipient to convert the award to a cooperative agreement, and then we added terms that described that involvement. When the substantial involvement ended, NIH then renegotiated, and we removed the terms. And we converted the award back to a grant. All of it was done based on the evolution of the project and the research. So the take-home, really important that the actual activity code and terms of award are correct for the work being conducted and who will be conducting it. But we know, and you know, things can change throughout the life of the project, so the activity code and the terms of award could change too online. All right. I think this is another multiple choice for you all, so let's talk business and money on drawing down funds. Multiple choice. Up to how many days past the period of performance end date does a recipient have to request payments from the Payment Management System and file the FFR? Elyse?

Elyse Sullivan: All right. We've got a lot of Cs, some B. Yeah, we're split between B and C. We're split between 90 days and 120 days.

Crystal Wolfrey: Great. So to draw down from the Payment Management System, it's 120 days. Good for those that got C. Very good. So the requirement, including the timing, has actually been around forever, and we actually, hopefully, gave you the CFR link to it. Admittedly, NIH has not always enforced it as strongly as we are now. So what is happening is things are coming up outside the 120 days, and the question is, "Can I have an exception to that regulation to draw funds down beyond 120 days?" And the answer is, yes, but with some qualifications. First, we need a request to draw down the funds beyond 120 days would have to be submitted to the institute, to the NIH Institute or Center, because it requires our approval. Included in that request, you have to give us some specifics, the Payment Management subaccount, the grant number, the amount of funds being requested. Additionally, you really need to provide a justification for the late payment request. And finally, and probably most importantly, you need to tell us what actions you're taking to avoid this in the future, so that you can be compliant with that regulation. If we get all of those pieces, and we can approve it, then we can approve it. I think it's on the next slide, Sean. If we do approve it, we will notify the Payment Management System that we have approved it, and then you can resubmit that request and PMS will approve it. The one thing .. . There's a lot of details. There is a guide notice that provides all these details, in large part because we do know that it was not as enforced as carefully before as it is now, so a lot of institution were kind of caught by surprise by this. But just know, we consider these requests on a case-by-case base, and if organizations have repeated instances, then I think you can expect to hear eventually from NIH about what you're doing to improve systems so that you can meet that 120-day deadline. Thanks. Oh, yes. What is going on here, people? Okay, Sean, I think this is you.

Sean Hine: it is. So, all right. So last story, so we're going to walk you guys all through. So, all right. So here's what's going on in this particular one, and we think it's a good one. So this is a big change in mid-project, and you'll understand that a little bit more here in just a moment. So we have an NIH P01, so multi-project grant is wrapping up in year 2. Has a clinical trial involved, delayed onset as was initially established as the protocols are still being .. . were still being developed. However, a very significant event has just occurred, and so we're going to drop in on a call between the PI and the NIH Program Official.

Crystal Wolfrey: Hello, this is Crystal at NIH. How can I help you?

Sean Hine: Oh, thank goodness. You picked up, and you may single-handedly calm my nerves.

Crystal Wolfrey: Oh, I hope so. How can I help?

Sean Hine: Crystal, this is Sean. I'm the PI of the P01 where you are my program official.

Crystal Wolfrey: Oh, yeah. I'm familiar, of course. I'm really looking forward to seeing your upcoming progress report wrapping up on year 2, correct? Really excited to see how things are progressing.

Sean Hine: It's about that progress thing. So we've run into a significant issue. As you know, we have multiple studies going on in this, that we're looking to conduct since we were covering this from so many different angles, but here's our rather significant issue. We lost the use of the drug we were going to use. Therefore, we don't have FDA approval, and we are literally at a standstill.

Crystal Wolfrey: Okay, that is a significant issue, but one that actually we hear happens. So I recall that year 1 was primarily for getting preliminary data in place, so that early in year 2 was going to be set up with the protocols and obtaining the necessary approvals, right?

Sean Hine: Yeah, that's correct. And we were able to get a good but of prelim work done in year 1, albeit I'll admit we're a little bit behind even schedule on that as we even reported last year. But the issue is, we had an ambitious schedule this year to catch up, but we literally have been struggling all year just to get everything in place. So we're hoping to keep things moving, but I honestly don't even have a timeline at this point.

Crystal Wolfrey: Okay, I understand. Okay, so I'm going to recommend that we set up a call. Let's include NIH's Grants Management as well as the grants people from your side, sponsor programs office, any associates you need on the call. I do believe a written statement ahead of time would be beneficial too, so we have a better understanding of the situation, what's been done and when.

Sean Hine: Okay, I'll get on that right away, so I really appreciate it.

Crystal Wolfrey: Thanks. Looking forward to getting it.

Sean Hine: So there we have it. Yikes, right? So a lot of going on in this particular one. So a lot of conversation had to take place between just purely amongst NIH officials. So really, what can even be considered in situations like this? So, Crystal, let's say this hits your desk as the Grants Manager. What are you thinking at this point?

Crystal Wolfrey: Okay. Well, one, this is a worst case scenario. The grant's at a total standstill, and because the difficulties, little to nothing was accomplished in the past year. And worse, they may not even have a path forward without access to the original drug.

Sean Hine: So just curious, should the PI have potentially reached out sooner than what they did?

Crystal Wolfrey: Ideally yes, but also it may be fair to say that they were trying to work through the issue with due diligence. We would want to hear about what was being done when during the follow-up calls, but the focus now, though, needs to be is whether or not there's a path to success. Are there options, scientifically, that could be considered that could keep this P01 still within the aims that were originally reviewed and approved? How long were the studies to be conducted? Is there any chance for achieving the goals? Keep in mind, they've already lost pretty much a year.

Sean Hine: Yeah. No, that's a big part too. So in this case, let's say there is a potential angle that literally everything else would need to fall in line perfectly. What else would be the next steps here?

Crystal Wolfrey: Okay, so first we would want to consider the option to give them a little more time on year 2, but we'd need to build in some safeguards that we could put in place with terms of award, maybe require specific milestones, what needs to happen and when that needs to happen. That all needs to be clearly stated and agreed to by everyone. This is an area of increased risk for the NIH awarding agency. So it'd be really important to carefully document all the steps taken, put the negotiations in formal letters, provides the award to include more time in the terms and beef up the terms of award of what we're going to need see. Then also, we might have to recognize that things may not work out and other actions may be necessary.

Sean Hine: Thanks for your insight, Crystal. So let's see what happened in this case.

Crystal Wolfrey: Okay, so months of negotiation, including multiple phone calls and discussions of options. What NIH did was negotiated a mid-project extension for year 2, adding 9 months of time to give an opportunity for the recipient to adjust and come up with another time table and plan. We negotiated milestones, and we added those to the terms of award. Again, the plan was to give the recipient very clear expectations from NIH as well as what the next steps might look like in order to keep this project going. And then, an update on the progress was due the standard 60 days before the new budget period cycle date. So this is actually still an ongoing situation. So as of right now, the recipient did continue to work through all of the approvals, trying to obtain the necessary FDA approvals. A couple of the protocols were cleared; others were still pending. How this could ultimately end? Hopefully, the work can continue to get all the protocols in place and approved. The project just continues, albeit behind schedule. Unfortunately, though, we my have to consider a revision to the plans as well as the budget. And honestly, if all else fails, we might have to consider the prospect of bilaterally phasing out this grant. A lot of depends on, as you said, everything falling into place. So bottom line, take-home message. Changes, delays and balances. Biomedical research, as we all know, is not always proceed as planned. That's science, right? Projects can be delayed. Balances can accrue. Progress points in research could point the research in different directions. There could be changes in scope, or there could be things unanticipated that research from even actually progressing. So we know this happens, so what are our options? Here's what can be done. First of all, from your side, get in touch with NIH, the sooner the better. Bring us on board, so we can talk about. Again, increases our flexibility. Here are some of the options that we can consider. Mid-project period extensions, which is what has happened with this P01. Interim reporting/milestones that we would put on the terms of award, so we can keep tabs on the progress as we're moving forward to make sure we're still .. . we're moving on track. Restructuring the budgets, which would account for the new timeline, so possibly giving less money this year, letting you use up your balance, adding money into a future year when the research catches up. And again, as I mentioned, worst case would be negotiating a bilateral phaseout of the grant. Future year funds in a grant are not guaranteed, but NIH is here to help any way we can. That's what we're here for, facilitating science, and we want to be there. So even with a complete mess, the NIH IC will still seek to find a win-win in these situations. We want to try everything. Houston, we might have a problem. We are going to try to fix it. All right.

Sean Hine: That's it.

Crystal Wolfrey: We actually got through on time. That's great.

Sean Hine: I know. Go figure, right? When my Internet hangs around, we actually get through the slides the way we wanted to. So I'm going to bring us to the end. So the good part for those that were in the pre-award session, the primary piece you missed was actually the resources. So if there's a saving grace to all of that craziness, that's the piece. So use these slides and just duplicate. So here's just a few resources. There's a ton of information out there on the OER pages, at the IC pages. There's a lot of information that you can find that will hopefully help you through whatever questions you may have. So we're all here to help out. Again, I've been here for 20 years, and I'm always amazed the teamwork that goes into just helping lift grantees forward. So please feel free to engage with any of us as we go along. So resources for compliance. Post award, in particular, really does bring in the compliance space. I know there was another session here at the regional seminar about compliance, so just a few reminders. When it gets into the compliance area, so there is a grants compliance inbox, for instance. So if things that come up that you may want to try to ping NIH about, there's an opportunity for that. There's also outreach activities. So if you're relatively new in this world of NIH grants, you may want to just check out some more outreach activities and ones like this, so it's great that you all are here for that as well. And then just a few select resources. Like I said, there is a ton of resources out there, so we just grabbed a few, just highlighting at the top one of the primary resources. Yes, this is a shameless plug on our part, is, please reach out to the Grants Management Office and the Program Official on your particular grant. So the post-award space, that's your starting point, so definitely reach out. And I just highly recommend check that eRA Commons, so just see which .. . who the person may be. So there's, luckily enough, a lot of retirements that always take place, and so names do change around. So please feel free to reach out to make sure that you have the right person. And then OER pages, NIH pages, the Grants Policy inbox, for instance. And even for some of the other organizations here that are newer in the for-profit world, Division of the Financial Advisory Services is out there too. So just again, just a plug for a few of these places that will be very helpful. Questions? Feel free to contact us. This is a slide that we did not get to in the pre-award, and so now we really are on blast here, Crystal. So whoops. So just reach out to us if you have any questions.

Crystal Wolfrey: Please do. Absolutely. We have a few minutes for questions now. Usually, we do this sometime during the conference, so then we go to our meet the experts and our booth, and you can reach out to us that way. I know this is, I believe, the tail end of this conference. So if you think of things that come up, feel free to reach out to Sean and I to our e-mail. But, Elyse, do we have any Q&A that we want to .. . I think we got 5 minutes.

Elyse Sullivan: Yeah, yeah, we've got a couple minutes. So I've got some questions for you. So as a follow-up to the prior approval and the rebudgeting piece, the question is, "If you're rebudgeting, for example, funds out of patient care costs, does that ever require prior approval as long as there's no change in scope?"

Crystal Wolfrey: So here .. . Patient care is a really interesting topic, and I'm glad somebody asked that. Generally speaking, no. Unless it's a change in scope, it doesn't require a prior approval. However, often patient care costs are a restricted item in the terms of award. So if you have a cost category that has a term that restricts it specifically to that category, then you would need prior approval to rebudget out of it. So you really do need to make sure you read the terms to make sure that there aren't any restrictions in the terms.

Elyse Sullivan: Great, thank you.

Sean Hine: And if I may just interject, Elyse. That's a really good one, especially if you're the PI with that type of project. Get in touch with your Program Official. Just get it kind of sliced as to what's going on there because they can at least kind of help you gauge a little bit. "All right. We're dipping out of patient care." "Is there a reason why you're dipping out of patient care? That was requested and included in the first place for a reason." So again, gets back into that funding opportunity, so it's just important to keep that in mind.

Crystal Wolfrey: Absolutely. Just a plug, only Grants Management can give you the prior approval, though, right? Okay, everybody remember that. Okay. Okay.

Elyse Sullivan: Wonderful. A couple questions about no-cost extensions. One of them, "Are there special award conditions that remove the ability to request a no-cost extension without prior approval?"

Crystal Wolfrey: So generally speaking, except for individual fellowships, all grants at NIH are eligible for the first no-cost extension through the eRA Commons, so it doesn't need prior approval.

Elyse Sullivan: Okay.

Crystal Wolfrey: There are certain situations where something might have happened during that project period that would take that grant out of the ability to do a no-cost extension, and then when you look at the Commons account, it doesn't give you that option to do it. So if you do have that situation where it's a grant that's in its first budget project period, you haven't extended it yet, you think you should have the first no-cost automatically, and it doesn't show up, reach out to your Grants Management Specialist or Officer and try to find out what happened. But generally speaking, all grants get that first time no-cost extension.

Sean Hine: Elyse, if I can add one item in this. A common item that does come up, back in the day when we used to get in person, this was almost a consistent question that would come up is: If you do miss that automatic first no-cost extension by a single day, it now becomes a prior approval request. So that's when you do have to engage with the NIH Grants Management Office in order to get that taken care of. I will freely admit, it is not a long, arduous task for the most part to get in touch with us in order to say .. . to give us pretty much the whole kit and caboodle as to why. It's just more just something came up. You missed it by a day, and we'll work with you on that. So just reach out to us if that does occur.

Elyse Sullivan: Great, thank you. All right. We've got a couple more minutes. So there is a question about reporting other support for key personnel. "So must you report in a RPPR changes for all key personnel or just key personnel that are named in the notice of award because we know that sometimes those are different things?"

Sean Hine: Should I .. . You want me to take it? All right. Cool. So I was watching her hand to see if she was reaching for the mute. So yeah. So this is pretty much a consistent item that comes up. So it is other support for the key personnel as it's identified on the recipient side. So that's really what it gets into in that space. So the instructions in the RPPR, I usually guide people actually to that pretty consistently. Check out the instructions on the RPPR. It actually walks you through a lot of these instances as far as trying to decide, "Okay, am I in the spot where I just need to report on the PI, or is it everyone? Where's it kind of landing?" So in that case, I would definitely defer to the RPPR for those type of nuances, so that way it helps you out, guide you through that. Because the other question we get often is, too, which is "I'm going to now change effort on X person. And no offense to X person, but that person is not listed as key for us." And so that's why the RPPR actually provides guidance, which is the PI and anybody named to identify them as key.

Elyse Sullivan: Wonderful. Thanks so much. All right. And I think we should .. . Let's try and squeeze in one more. "Is there a difference between a foreign component and a foreign subaward? How are they similar? How are they different?"

Crystal Wolfrey: So a foreign subaward is a foreign organization that receives funds from the prime recipient through a subaward, so that is a foreign subaward. A foreign component can be a subaward, or it could be an unfunded component of the project. But a subaward defines the fact that money is going between the prime and the sub.

Sean Hine: It doesn't change the clearances process and everything like that. So whether you have a foreign component that's not receiving funds and everything like that, get in touch with NIH. Make sure you always get in touch with NIH on that, but yeah. If you establish international subcontract, that's a different space.

Elyse Sullivan: All right. Well, thank you all.

Crystal Wolfrey: Are we good?

Elyse Sullivan: It looks like our Internet stayed stable the last hour, so thank you, Sean. Thank you, Crystal, and thank you to our lively audience. We had about 1,200 of you joining us this afternoon. So in closing, the slides will be posted after this. We didn't post them ahead because it had some spoilers for some of the questions and answers, so they will be posted in the conference area. The video will be available in a few days, and we really hope that you enjoyed your conference experience and that you were able to get your questions answered, and that you were able to visit the booths and to meet the experts and all of those wonderful things. So we thank you all for joining, and we super-thank our presenters. So we hope you had a wonderful experience and hope to see you next year.

Crystal Wolfrey: Thank you all. It was great.

Sean Hine: Thanks, everybody.

Crystal Wolfrey: Bye.