Elyse Sullivan: So now we're going to get started.

Crystal Wolfrey: Are you ready for me?

Elyse Sullivan: Thank you so much ...

Crystal Wolfrey: Go ahead.

Elyse Sullivan: Thank you so much for joining our session on advanced administrative topics, post-award. So many of you joined us for the pre-award edition, and now this is your 2.0, your follow-up class. My name is Elyse Sullivan, I'm the moderator for today's 45 minute session, and today presenting we have Crystal Wolfrey, the Chief Grants Management Officer at the National Cancer Institute, and we have Sean Hine, who is a branch chief at the National Cancer Institute as well. So our format today includes interactive, case-study-driven presentation from Crystal and Sean, and we're going to have a lot of time to ask you some questions, we want to answer your questions and so we're going to be kind of kicking this off in a fast-paced way. So go ahead, put your questions in the chat, and let's go.

Crystal Wolfrey: Okay, now it's my turn, yes?

Elyse Sullivan: Yes.

Crystal Wolfrey: Thanks. Thank you, Elyse. It's a pleasure to be here. I'm sort of distracted by the chat and seeing where everybody's from. It's so great to see all the places that everybody's saying hello from. But as Elyse mentioned, my name is Crystal Wolfrey. I am the Chief Grants Management Officer at the National Cancer Institute. Sean, you want to just say hello so they can hear your voice?

Sean Hine: Yes, hello, everyone. I'm Sean Hine, the deputy chief grants management officer with the National Cancer Institute as well.

Crystal Wolfrey: As Elyse mentioned, there's a few logistics on this slide, I won't go over too much. Please, just as a reminder, if questions could go in the Q and A, and then we have staff that could try to answer them, and Elyse will be monitoring. We have a lightning round halfway through, that we'll try to answer as many as possible. So if you can keep the questions in the Q and A and then responses in the chat to our questions, that would be perfect. Thank you so much. Next slide, Sean. So we wanted to start a little bit with a discussion just to make sure that we put this into context. As Elyse mentioned, I think many of you probably attended our pre-award session yesterday, so this session is really focused on post-award, and the time that we're considering post-award for the purposes of this discussion is, anytime after the initial competing award is made, annual reports are considered a post-award period, and this is the time where a lot of things happen, and a lot of the action happens, so that's what we're going to focus on in today's session. So I apologize if you did see this yesterday, it's a little bit repetitive, but I want to go over this a little bit. Just a reminder that we're doing this from the NIH perspective, so there's a few things to remember. First, we are required, and we must support federal policy. We have to enforce applicable laws, cost principles and administrative requirements, and we do have to act as stewards of federal funds, so know that that's the perspective we use when we answer some of these questions. A couple of reminders about NIH, there's a lot of ICs in NIH. Some of them have a relatively broad mission, and others by comparison are relatively narrow. Some are large, and some are small, and larger ones often have more funds, which means they have maybe some more flexibilities. We'll try to point out where that's a little bit different as we go through our cases. Not all ICs fund the same grant mechanisms, so some of the things we talk about might apply to some and not to others, and my favorite thing in grants management, the correct answer often really is, it depends. So some other things that we consider is, we want to make sure we've listened enough so that we really understand all the issues that are going on in the situation. We look for the best interest of the science, what will serve the investment of the tax payer and the project in the best way. Do we have the necessary funds to support what's being requested or support what's being proposed? How will this present on your evening news or the front page of your local paper or a national paper? Is there an opportunity for a win-win, and again, last but not least, and my favorite, we try very hard to say, can we get to a yes? We try hard not to start with no but to start with, how can we get to a yes? So what are the issues that we're going to try to talk about in today's discussion? We're going to cover change in scope, we're going to cover the NIH human subjects system and you, effort changes on grants, scientific and budgetary overlap, and changes and delays in the research and large balances. Case-study-driven, as was mentioned, so let's get started. So the basics, what is scope? So not exactly what we had in mind here, Sean.

Sean Hine: I like to have fun.

Crystal Wolfrey: Okay, scope and NIH grants. Scope is the direction, aims, objectives, purposes or type of research training identified in a project. Stated and identified in the original peer reviewed application so it undergoes peer review. It's the basis for which the budget is requested and awarded, and unless we negotiated otherwise, when we issue an award, we've approved the scope that was presented in the actual application. Change in scope requires prior approval. It's stated in the NIH grants policy statement, and I won't read the part in italics, I know that you can read it, and many of you are aware of it, but it is a prior approval item, so if you do plan to change in scope, you must go to the IC to request prior approval. It is the grant recipient's responsibility to initially assess whether a plan will result in a change in scope that requires approval, and then after that assessment, to come to the NIH for approval. So here's a long list out of NIH policy that are a number of potential indicators of a change in scope. I'm not going to read this list, it's a long list. I will highlight a couple. Change in the aims is an obvious one. Shift in research emphasis, application of a new technology, change in personnel, significant re-budgeting, things like that are indicators of a possible change in scope. Okay, so I believe we are now going to listen in on a conversation between a grants management specialist and an investigator about a possible change in scope in their research. Hello, this is Crystal Wolfrey with the NIH. How can I help you?

Sean Hine: Hello. This is Dr. Despaired. You are the grants management specialist on one of my grants. We had some changes recently that are impacting the grant.

Crystal Wolfrey: Okay, well post-award changes are pretty common, so I'm sure we can work through your situation. Just tell me a little bit about what's happening.

Sean Hine: Well, as you know, COVID has been rough on so many things and research is no exception. COVID has definitely hit our project pretty good. We had to shut things down for a bit, but are working to ramp back up now that things are also opening just back up across the country.

Crystal Wolfrey: Well that's good, that you're able to ramp back up, and I know your situation is like so many others. I can't tell you the number of grants that have come in in the past year noting very similar problems. So what specifically is going on in this situation? How are things going?

Sean Hine: Well our project, it's really dependent upon recruiting patients to trial, and that's been really rough as pretty much has been put out in the news everywhere. We are way behind where we were hoping to be at this point, but who knew, right? That leads to why I'm calling. I have a colleague that can help by opening a new recruiting site. We're working through things, but we'll need to throw some money his way for that work.

Crystal Wolfrey: Okay, well it's good that you're considering options here.

Sean Hine: Yeah, well, I would imagine you government folks need all those details. The who, what, when, how, all that type of stuff, because why not throw more paperwork at you.

Crystal Wolfrey: Well, as you know we are from the government, we're here to help. But actually, no, that may not be necessary.

Sean Hine: Really? I thought you guys had your hands in like every step of the grant here.

Crystal Wolfrey: Well, in general we do need to be kept apprised of what's happening in your grant, and I would definitely recommend reaching out to your program official to discuss the progress on your grant, but typically, most changes or many changes fall within the authority of the grant recipient, and you would just need to include such items in your annual report. A couple of questions. Are you seeing this as a change in scope? For example, are you adding animals or human subjects?

Sean Hine: No, all that's pretty much the same. It's pretty much what we put in the original application. Bringing on the site will just help us ramp up outside out of our current [Indistinct]

Crystal Wolfrey: That's good to hear. How about the location? Is this a domestic US site, or are you looking at a foreign location?

Sean Hine: We're planning domestic, but foreign location may be something we'll consider at some other point. Does that matter?

Crystal Wolfrey: Well, definitely. Adding a foreign component is a prior approval item, so what I would recommend what we do now is discuss further with your sponsored program office to see if anything needs to be done on your side. If it does not constitute a change in scope in the grant and you're not adding a foreign site then nothing is needed on our end, you can just include this change in your next annual report. If this is a change, and/or if you are adding a foreign site, you sponsored programs office should submit a request to the grants management specialist and we can work through that. Make sure please that they copy your program official.

Sean Hine: This is great. I was figuring I would have to go fill out a ton of information to get this moving. I'll get in touch with our sponsored programs office today, and I really appreciate the guidance.

Crystal Wolfrey: Not a problem, always glad to help. End of skit. So Sean, I'm a little confused here. We just showed a slide with a bunch of indicators of change in scope, and adding a third party or transferring substantive work to a third party was one of them. It sounds like it can be a bit of a murky subject, right?

Sean Hine: You are correct, Crystal. There's definitely some gray area. As Willy Wonka's expressing here, or the classic answer from NIH, it depends. It does apply at times to scope discussions.

Crystal Wolfrey: Okay, tell me then about this phrasing. Potential indicators of a change in scope as stated in the policy. The grants policy statement has all of these items listed. Does this mean that if any of these boxes are checked that it's a change in scope and requires prior approval?

Sean Hine: Yeah, and I just flipped back to that screen just so that everyone can see again that long list of all of these potential indicators. So the worst potential indicators is key to this conversation on a change in scope. The list of the items that we were just showing on the screen, are right now served as a guide or tool to grant recipients. MPI to assess whether the plan change may be considered or result in a change in scope. A very common example is the changing third party enrollments we just discussed in that case study. The addition or removal of a third party would not necessarily mean that NIH must be contacted for review and approval. If that addition or removal does, however, directly impact what the grant stated it would achieve or how it would go about the research from what NIH was anticipating, then yes, that would be something that we would be brought in. But just note, the only time transferring work to a third party always needs prior approval if the third party is outside of the US, which is why we brought up that little extra piece about the foreign component.

Crystal Wolfrey: Very interesting, thanks. So one that comes up all the time, the whole re-budgeting question. The policy talks in detail about what is considered significant re-budgeting, so I assumed that re-budgeting 25 percent or more always needs prior approval, right?

Sean Hine: Yeah, so I'm glad you brought that up. Way back in the day when we used to have regionals in person this was the number one question that would come up, I know for multiple sessions that you and I have been in over the years. So when that question comes up the big part to remember is does the 25 percent threshold mean I have to request approval for re-budgeting? That's what we always get asked, so this is just again, a potential indicator of a change in scope, not necessarily that it alone means we need to seek approval. The thought from NIH is that if you have that big of a change in money that the scope should be considered here and whether it should be discussed with NIH prior to making that change.

Crystal Wolfrey: So could a PI or an AOR discuss the change in scope with anything at NIH? Grants management or program?

Sean Hine: Absolutely. While program is the PI's counterpart, the key is to open lines of communication with the NIH, so the PI should feel free within institutional policies of course to contact them. We'll make sure everyone is looped into that discussion. But it is important to remember, however, is that any prior approval requests, and I just want to emphasize this part. Is any prior approval requests including change in scope must be submitted to the grants management office, and only the grant management officer can formally approve. So if you do have that, for any PIs that are on this particular citing is, if you do have that great conversation with a program official and it sounds all good, you still need to formally take that step with your sponsored programs office to request that change. Each grants management office will work closely with the program on the review of any proper request.

Crystal Wolfrey: That's a great point. Good example of how important communication between NIH and the grant recipient is.

Sean Hine: Great. Thank you so much for that. So we're going to now switch out of that, out of change in scope, and get into something else which I'm sure everyone on this call loves, which is human subjects reporting. And yes, we will just admit, it's the best. So did you know, so a little bit of a chat question for you, so everyone's reading ahead before I even get [Indistinct]. This is one of the major issues with human subjects reporting that occurs on an annual progress report and drives NIH officials a bit batty. What is it? A, IRB approval date is not included on the page. B, the Human Subjects System, HSS and CT.gov records do not match. C, the inclusion table is not included. Or D, excessive use of memes and gifs, which obviously that's not the answer because there's an appropriate amount in this presentation. So I'll give a second here for everyone to enter in the chat.

Elyse Sullivan: We're pretty split here, we've got some Bs, some C, yeah. There's no real ... We've got some A, a few Ds. So I think we may have an all of the above.

Sean Hine: Interesting, I actually wasn't anticipating that, so very interesting. And the answer is B, the Human Subjects System and CT.gov records do not match. I'm sure as many have seen over the last few years as the reporting requirements have tightened around this particular space with human subjects, a lot of correspondence has occurred from the NIH program officials. Sometimes the grant management specialist with the sponsored programs office or PIs. So those are particular areas that have fairly become highlighted over the past year, and hence the love that we all have for the Human Subjects System in particular. So how can we make HSS and your relationship with that hopefully a little bit easier? And this is all from experiences that each of the ICs have had over the last several years. So first and foremost we ask to check you're records, just ensure everything is up to date and matching up prior to you submitting the RPPR. So that's really one of the big things that come into play. Also, it's just really important and we'll provide, obviously, these slides after the fact, is that NIH has a great user guide out there. So, and here's a link to that particular PDF document. I highly, highly recommend and I personally have sent this user guide out in multiple instances to try to get HSS and CT.gov discrepancies resolved. The best advice that comes up pretty often is remember to populate HSS with what you have in CT.gov before you submit the RPPR. This is actually included on the user guide as far as how you can do that. If you kind of goof on that part and you need to do it after the fact there is also a process in which you can do that too. But what is really important that we want to emphasize is this last bullet. It's just critical that the registration in CT.gov is done in compliance with the regulations. So if you're getting in the path of moving forward on that trial, you have to register in CT.gov. I can comfortably tell you, big heads up as far as how we go into this year is we will not be able to make awards if that CT.gov registration is not done, so there's no kind of finding a way to work around that or anything along those lines. We will get what is held on our end, a red bar, and that's never a fun bar to deal with.

Crystal Wolfrey: And just to add, you won't be able to submit RPPRs either, so ERA had put in a validation on the submission of RPPRs. So if you have registered the patient and you've gone past the 21 days and that trial is not registered in CT.gov, clinicaltrials.gov, thank you, Elyse. It will definitely cause a bar of being able to submit the RPPR. So this is all just really very important.

Sean Hine: Yeah, great add-in, Crystal, I appreciate that that so much.

Crystal Wolfrey: I think this is me. So we're going now ... We're supposed to have page numbers and we don't. A twist on a transfer situation. How about this, so a grant transferred in March of 2019, the previous grant recipient relinquished $185,000. Funds were moved from the old to the new recipient via notices of award issued by the IC. So the old recipient was reduced 185,000, the new recipient was awarded 185,000. So far so good. So then the previous institution contacts the NIH IC later saying they relinquished too much, rather than 185,000 being relinquished it should have been 150,000. What can the awarding IC do? Tell the previous recipient too bad, so sad. Restore the funds by moving money back to the previous recipient from the new recipient. Start a GoFundMe page for the previous recipient, or D, it depends. Enter in the chat. I think we have a lot of Ds. There's one GoFundMe, I like that one.

Elyse Sullivan: We've got a lot of Ds, it's tonight's just favorite answer, right?

Crystal Wolfrey: Absolutely. When all else fails, if you say it depends. And the answer is it depends. Why it depends? So timing matters a lot in these situations. If it's reasonably close, within a month or 2 or so, to the time of the transfer, a negotiation can be worked out with all parties, and we would move the money from the new recipient to the old recipient. But if it's too far removed, say, multiple months or even possibly into the next year, it's likely that the new recipient already spent the funds. So that could be a problem, and we would have to do a different negotiation. And also, depending on the timing, if it really took months and months and months for the old institution to realize this mistake, it could bring into question the previous recipient's financial management standards, and it's a conversation that we would probably start with that institution about how they manage funds and how they didn't realize this mistake until it was too late.

Sean Hine: Yeah, just to add in there, Crystal, I remember distinctly a situation where it was about a year and a half after the fact that we got an e-mail from former recipients saying whoops, looks like we've got an old subcontract coming through to invoice, can we have some money back? And we immediately went after that last bullet that you just mentioned, and they quickly tried to backtrack to say oh, nevermind, we're fine, don't worry about us. And we're like, well, hold on a second, we still need to talk to you about this point. So we still pursued that particular item. So just again, real life examples on what we run in to from time to time.

Crystal Wolfrey: Okay, so, Elyse, I only see 5 things in the Q and A, so we might not be ready for a lightning round, or do you have questions that we can answer?

Elyse Sullivan: I've got a couple if you guys are ready. Okay, change in scope. What if there is no change in scope, but I asked for 50K and now I need 100K. Will I need to do prior approval? I need more money.

Crystal Wolfrey: Requests for more money are always a prior approval item and definitely not a guarantee. But certainly if you under budgeted or you have cost over runs, or you have something, a piece of equipment broke and you need to replace that, there's always the ability to submit a request for an administrative supplement. And again, some ICs have funding for that and can provide it, some ICs don't. But I'm a big believer of if you don't ask you definitely won't get, so I would suggest reaching out to see if there's a possibility, but that's a great question.

Elyse Sullivan: Great. So sort of the opposite here. I've got an R21, one of my aims can't really be completed because of COVID delays so I've actually got a decrease in scope. Do I need prior approval to decrease my scope?

Sean Hine: I'll jump in on this one, Crystal. So that would still constitute a change in scope, you should still have that conversation. I would really recommend for any of the PIs out there, have that conversation with your program official first and foremost, explain what's going on as you've seen within your grant, and then also see what potential options that may be out there. Some other items that you could potentially pursue and consider. And then yes, then that's when you want to work with your sponsored programs office and get in touch with the NIH grants management office about what that impact may look like and formally request that. I will say one item that we'll have to talk about, and just is it what it is, it's business on that part, is also the level of funding that you would get. So we would have to go down that path too to fully understand if you're not going to do a particular aim and yet you still want to probably keep the same amount of money is what are your plans as far as associated with that change.

Crystal Wolfrey: And I think we also have a case study coming up that kind of goes into this area little bit and the COVID impact on research. So that's a perfect question for that.

Sean Hine: Somebody saw our script.

Elyse Sullivan: Great, well I'll kick it back to you guys, that's all for me.

Crystal Wolfrey: Great, thanks.

Sean Hine: All right, so we're going to go into a different space now. The change in effort for key personnels. So this is another situation that comes up very frequently, and we thought it would be a good one to really highlight here from a post-award standpoint. So in this case the competing R01 application lists the PI with a 2.4 calendar month effort. The PI's effort on the subsequent RPPRs as described below and from the participant table is 2.0 in year 2 and then 1.6 in year 3. So true or false, the recipient did not need to request prior approval for a reduction in effort of more than 25 percent?

Elyse Sullivan: We're getting a lot of false. Most people are saying false.

Sean Hine: Ah, looks like we have a savvy group.

Crystal Wolfrey: Or the question was way too easy.

Sean Hine: It was probably, I would put the blame on the person who wrote it. But yes, the answer is false. So why is this false? And I say savvy, it's rather interesting because this comes up fairly frequently when we're actually analyzing RPPRs. We kind of get into this oh, I didn't realize that. In this case the approval level, again, was set at the competing year so year 2's RPPR does not represent a resetting of that approved level. You can drop down as was described in this particular case to that 2.0 number, however, that's less than 25 percent reduction, therefore doesn't need our approval. Year 3 however, is a great than 25 percent reduction because we're going to go back to what that approved level was in the very first place. So that 2.4 calendar months in the competing to account for that reduction down to 1.6 calendar months in year 3. So great job for everyone being in tune with that one. But in this particular case, so what would the NIH IC do, however, if we did run into this type of situation? So what would occur on the RPPRs, so we would be looking at year 3, which is the table showing 1.6. We're going to contact the award recipient organization, first to confirm what was reported, a large percentage of the time, and I hope I'm not over speaking here for the grants managers that are on this call, but a lot of the times it's going to be a whoops. Actually, that was supposed to have been reported at a different level versus the one that actually we included. So we'll document the file and we'll move to the next. So that way we can account for that from a documentation standpoint. If the report is accurate, however, NIH will still need to address this as a retroactive request [Indistinct]. So the grants management and program officials would need an official request, and then what would be considered that particular change so we can evaluate it. And also at the same time, as you can kind of tell from the post-award standpoint, is we're still probably going to have the extra little kicker then, which is if you missed it in that case, and it was an accurate reduction, and it did drop to 1.6 and we're finding out about it in the RPPR, we're going to have a conversation with the institution as far as how the policy procedures work in terms of valuing and effort. So that way we can just, maybe potentially work with you all and refine those processes, refine those practices so that way we can avoid the retroactive piece on this request in particular. All right, onto the next one. Crystal? Never mind, this is me, so, shoot ...

Crystal Wolfrey: I didn't think that was me, but ...

Sean Hine: I messed up my own notes. So all right, so I just want to read the header here first, just to kind of tease everyone. So are you ready for something really good? All right, this is a juicy one that we into actually just this past summer. So competing R01 is funded in fiscal year 2020 for Dr. Slick. That is not the person's real name. The year 2 RPPR comes in, the other support is showing some interesting items. So an RPPR comes in fiscal year 2021. So a previously unreported DOD grant that was funded in FY2020 is listed showing the same title as a P20, also included in this RPPR and the other [Indistinct] was also funded in FY2020. So we have three different grants going on, RO1, the DOD and a P20, all of which was funded in 2020. Dr. Slick must be very good at writing us applications. Even better, there may be potential overlap between all three of these funded applications. So not only was it previously unreported, it's also now showing up in a potential of all three of these applications. Yeah, we're getting into some good stuff. Oh wait, there's even more. We find out NIH policies also became involved in the conversation. So specifically because this is another supportive, and as the slide says, other support is no joke. So and Michelle Boles gave a presentation on this just earlier today. These grants crossed awarding agencies and programs, so we have a lot of different moving parts going on here, and so we're now going to sit back and relax and hear what the conversations were like between the NIH grants management and the program official. Hello, this is Sean Hine, NIH branch management. You're on mute, Crystal.

Crystal Wolfrey: I do that every time. Sean, this is Crystal, NIH program official for Dr. Slick's RO1. Can you believe what's going on with this one?

Sean Hine: I know, it's all over the place. I have been doing this for quite a bit and it's not too often you have a situation where you have completely different agencies, NIH and DOD and multiple grants with two in NIH, and the fact that this wasn't reported is just mind-boggling.

Crystal Wolfrey: Well, it gets better. I put all of these together to compare the aims, and it's not pretty. For the two NIH grants, the R01 and the aim one of the P20 are the same and two is alike for both projects and with a couple of a subtasks on the DOD project. I shared this with a program official for the P20 and they couldn't believe it.

Sean Hine: What you're describing is really concerning. I'd imagine it was probably a pretty significant budget overlap here as well, right?

Crystal Wolfrey: You can bet their last dollar there is. They are both definitely planning similar items so the expenses would have to be the same. For example, 96 samples for genome Y genotyping and molecular agents, definitely in both applications. I'm also having a really hard time understanding the logic in the budgets, too. The RO1 was slightly more samples for a subcontract that is doing some of the work that the P20 is doing, but the budget is four times as much.

Sean Hine: Anyway, I'm looking at the file as we're talking here and I'm not seeing any of these projects being reported on the other support at all.

Crystal Wolfrey: Nope, none of it was disclosed to us.

Sean Hine: This is a serious problem in itself, the update of other support is a vital part of the Just-in-Time process. Not only for us to ensure commitment, but for also the reasons such as you've described, to learn about potential overlaps that may exist.

Crystal Wolfrey: When I obtained the information on the DOD project I was told that they had reduced down the aims of the DOD project to avoid the overlap.

Sean Hine: Well, I guess that's good to hear, but we're just finding out about that now? I don't think we've received anything from NIH grants, however, right?

Crystal Wolfrey: No, nothing has been stated for the NIH grants.

Sean Hine: Okay, so what I would recommend here, we put together a letter to state our concerns like you laid out, discussing the scientific and budgetary overlap. I've heard that NIH policies also enrolled in this discussion, that conversation did not even start with us, so something else is brewing that we don't even know about potentially. If you can provide the side-by-side comparison you did that would be helpful so the recipient can follow the review and understand our concerns. Additionally, you have to learn from them how they're valuing their other sources of support.

Crystal Wolfrey: Okay, that sounds like a plan. I will get that information to you by the end of the day. Okay, so where did this one end up? What we ended up doing is the NIH program officials conducted a thorough side-by-side analysis of the all of the projects, where a lot of exchanges occurred via e-mail between NIH, the grant recipient, and all the program officials involved. The recipient previously negotiated with the DOD to reduce the scope of that award to resolve the overlap with the two NIH grants, and NIH was able to obtain a copy of that negotiation. So we sort of were able to solve the DOD issue. However, there was still existing overlap between the two NIH grants, the RO1 and the P20. So here's what the NIH IC decided to do, fund the P20 per normal, it is a shorter project period and a multi project grant, and would've been more complicated to end, and we delay funding on the RO1. An extension for 3 months was provided to allow the recipient time to address the overlap to the IC, a plan's going to be submitted by the deadline, and then we're going to make a decision. If they don't submit a plan then the grant will have to be ended. So it's important to note even with a complete mess, the NIH IC was still seeking to find a win win, and that's how we were able to do it. We want to try everything. Okay, is this me? Changes, delays and balances. The biomedical research does not always proceed as planned. We've actually talked about that a little bit today. Projects are delayed, balances accrue in the project, progress points the research in a different direction, changes in scope require a prior approval per NIH. We've talked about all of that. AKA stuff happens. Most problems start out small. It's only when unaddressed and/or left unchecked that they grow into ugly monsters. Can anyone think of some widespread something that happened in 2020 that may have caused issues? I'll give you a good half a second. Okay, am I doing the situation or are you ... Am I doing it?

Sean Hine: This is me.

Crystal Wolfrey: Okay.

Sean Hine: All right, so we're going to kick into some progress issues, and this is obviously a particular case, however as mentioned earlier, we saw a number of instances like this throughout the course of 2021 in particular. So, all right, so here's the situation. We have a 5 year grant, so there's no concerns that were brought up in years 1 and 2. The accrual portion of the grant is set to begin in year 3. Year 3's progress report arrives, so the 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 timeline is now showing completion of accrual in year five. So as you can tell, a lot of things going on in terms of trying to get patients enrolled and accrual is definitely in [Indistinct]. Houston, we definitely have a problem. But now we're going to jump in on a call between the NIH program official and the grants management, so.

Crystal Wolfrey: Hello, this is Crystal, can I help you?

Sean Hine: Hi, Crystal, this is Sean Hine, I'm the NIH program official on Dr. Lagging's RO1. I believe you are the grants management specialist on it as well.

Crystal Wolfrey: Yeah I am, Sean, glad to hear from you. I have a feeling I know what you're calling about.

Sean Hine: Dr. Lagging's grant is in rough shape, right?

Crystal Wolfrey: Oh, I thought it was for my pumpkin pie recipe. But oh, yeah, Dr. Lagging's RPPR didn't paint a good picture. Just looking at the financials, the balances skyrocketed, and as I have seen on a number of grants this year, COVID appears to definitely have had an impact. Have you seen anything in the past that would've indicated progress issues on this grant?

Sean Hine: No, I actually double checked the RPPRs for the last couple of years and so far years 1 and 2 were pretty good, so a little bit of a delay in year 1, but nothing out of the ordinary. But that was just getting everyone in place, so they made up for it in year 2.

Crystal Wolfrey: Year 3 for this grant had a June 1, 2020 start date, so the timing of the grant award would've fallen really shortly right after things were shut down.

Sean Hine: Yeah, they definitely did in this [Indistinct]. All of their enrollment sites closed down. They started to slowly reopen them over the course of the year, but a very limited capacity, and as with so many trials, patient enrollment is way down. This trial was included in that.

Crystal Wolfrey: Did they have any progress over the past year, or was the total year just a whole loss?

Sean Hine: Well, it's interesting you ask that. There was some, but that does that really impact what we may consider here?

Crystal Wolfrey: Oh yeah, definitely. So for example, if there was little to no progress being reported, we really wouldn't be able to pay a type five because there's no progress on which to build that next type five, so it might make sense to consider giving more time to the current budget period before we issue a type five. In other words, we could extend the current budget period for some number of months to let them catch up. But if there was some reportable progress, and now it's just really that their timeline's not aligned with their budgets, we could look at maybe possibly restructuring the budget. It's not something all ICs can do, but something we can explore. But before we get there, I need to ask you if you feel like this study can still be completed. It sounds like not on time, right?

Sean Hine: The chances of them finishing on time are the same as the Washington football team's chances of making the playoffs. Absolutely none. As for whether they can get it done at all, that is hard to say without talking with them. It is a tough population to enroll for sure, they got some bench work that they did this past year, and they did enroll some patients, but they really are behind where they were hoping to be. Only 10 out of 100 patients enrolled this past year.

Crystal Wolfrey: Okay, I would recommend then that our next steps to be get in touch with them. Let them know our concerns and set up a meeting.

Sean Hine: Great, hearing from them on what their plans are to make up for this time will be huge. I would love to see them be successful, they really have a cool grant project. There are not many grants out there evaluating this particular idea. This could really have such an impact.

Crystal Wolfrey: I hear you. We can't delay on this one at all. I'll reach out to the AOR today and get this ball rolling. Thanks a lot for the conversation. Okay, progress issues, what can be done? First, get in touch with NIH, the sooner the better. There are options that can be considered. Mid project extensions, which is what we talked about when there's just literally no progress at all in the current year, we could consider extending that budget period to allow more time to sort of catch up or show some progress. We could issue the award and require some interim reporting, or milestones that need to be hit. We could potentially restructure the budget, which is a way that we are able to, some ICs are able to move money around so it actually matches the new timeline. So don't give new money this year, allow the grant to use the money that's sitting in the account, and then possibly building out an out year or increasing the [Indistinct] for the out years. In the worst case scenario, if it cannot be done ... For whatever reason it's determined that the project just can't be done, the population can be approved, or things have gotten so out of whack, it can't be finished we could potentially negotiate phasing out the grant. That would be a negotiation though, we would never do that unilaterally, in this case. Future-year funds on grants are not guaranteed, just as a reminder. And apparently there are a lot of NFL fans. However, NIH is here to help in anyway we can. That's what we're here for.

Sean Hine: So I could say just from the NCI perspective, we did pretty much all of that included in these slides. So, again, trying our best and getting really creative as we worked with the recipients. There are a lot of folks out there that are trying their darndest in order to do everything they possibly could do maybe things work, so they're great in terms of just working with us, and some of the negotiation stuff led to some time, and kudos to all involved especially our grants managers out there that helped get this all worked out. And, again, as Crystal mentioned, one thing to keep in mind too, not all the ICs have the same flexibilities, so it's really important just to engage, again, back to that first point. Get in touch with the NIH as soon as you may possibly run into a space where you're like, "Oh, this is not going the way we really hoped it would go."

Crystal Wolfrey: And so one thing I ... So back on that other slide. One of the things, and just a previous, so if you come in spring, one of our cases is definitely going to be about what happens now. So we have the COVID shut down year, we've had an entire year of progress being completely disrupted because of the COVID shutdowns and the different things that we were able to do to try to help make grants successful. The big question's going to be in 2022, what do grants look like? And what are our options for some of those grants that we pushed out and now maybe still aren't caught up because of the COVID thing. So cases will change, and we will definitely be building some around that for the spring seminar.

Sean Hine: We had a record number of restructures and extensions, Crystal, I don't think we'll have to go very far for those case studies.

Crystal Wolfrey: I don't think we will. So I think that's it. The rest is resources that we have provided for you. I think we've left at least maybe 3 or 4 minutes if there are any additional questions or if we want to try to get to the chat, however you'd like to handle that.

Elyse Sullivan: I can take a few questions here. Our Q and A folks in the background are getting to a lot of them, but we're going to ... If my Q and A folks can stop, I'll just ask some of these out loud.

Crystal Wolfrey: Great.

Elyse Sullivan: Let's see. Oh, I think some ...

Crystal Wolfrey: While you're looking we're going to put a plug in. If you want to talk to us in-person or we don't get your questions answered, check out the NCI booth. Sean and I both have times for one-on-ones, and we'd be happy to meet with people and talk with you. Okay. Oh, shoot.

Elyse Sullivan: So Crystal and Sean, what if there's a progress delay due to COVID like we're all experiencing and an RF1, which states in the notice of award that no cost extensions are not allowed, do we have any opportunities there?

Crystal Wolfrey: So, RF1s I'm not familiar with, I have to say I don't know what IC funds it. So if it states no, cost extensions are not allowed, it is definitely a problem. I do know last year because of COVID, we were able to make some exceptions for things that required no-cost extensions that didn't allow them. So I don't know if we'll be able to have that same flexibility. What I can do is research RF1s and research some answers, and we'll be at the booth if you want to come stop by and look at those, but RF1s are not something that we fund, so I don't know. We do have some grants, like our R35s, no, cost extensions are not allowed. Last year we were doing extensions if COVID did cause the problem. I haven't heard how flexible NIH will be in 2022. A lot depends on what happens with COVID. We have a lot of problems with ... so RF1s are ... So we multiyear-fund grants that ... Thank you so much, that's very helpful. So we multiyear-fund grants but we don't use the RF1, we just keep them at whatever their activity code is. So if it's a multiyear-funded grant that was funded for 5 years, there's really no way to do an extension because that money does expire. I will say, though, in 2021, we got approval from HHS to allow an extended draw on those, so it may be possible in 2022 that we could request that same flexibility. So stay tuned, if you have one of those I would reach out and see what happens with that. Thank you so much whoever put in the chat what an RF1 was, that was usually helpful.

Elyse Sullivan: So, Crystal and Sean, when you extend a budget period to allow the awardee to catch up, do you always also extend the project period as well?

Crystal Wolfrey: Sean, go ahead, you want to ...

Sean Hine: Yep, so I'll jump in on that one. So generally speaking, yeah. We would always extend it. So if we're looking to extend a budget period, we have to add on that time to the project period for sure, and I'll also comment this, so in some cases we'll also run into, again, what we call, what we refer to as restructures, so when we reshape the budget around that timeline, there's sometimes actually ... They'll say, "Well, actually, we still want to stay within our current project period, we just don't need as much money this year. Can we work with you all in order to quite frankly avoid having to provide a bucket of information on the RPPR next year to pretty much say the exact same thing. We couldn't spend all the money you gave us." So we're going to try to work with any of the applicants along those lines too. So again, kind of one of those it depends kind of space. So the more you talk to us the more we can come up with ideas. We have a lot of creative people out there, so hopefully we can work together on that.

Elyse Sullivan: All right, we're at about time. Thank you, Sean, thank you, Crystal. Thank you to our Q and A folks on the back end for answering all these questions. Thank you all for attending. Just a plug to visit our exhibits, get some more questions answered, and also leave us some session feedback. So there are session feedback links associated with each session in the auditorium. Let us know what you liked, what worked for you, what didn't. We really pay attention to those, so please give us feedback. I know that everyone will give this an A plus, so give Crystal and Sean their big ups.

Crystal Wolfrey: I was going to say, only if it's positive. No, I'm kidding. The only thing I will say, I want to mention, we do have some people that are capturing the chat and capturing the Q and A, so we will go through and make sure that we didn't miss any questions that didn't get answered and try to make sure that we're ready at our booth if you still want to get your question answered. So please feel free to join us there if you didn't get your question answered.

Elyse Sullivan: Wonderful. Thank you all, enjoy the rest of the conference.

Crystal Wolfrey: Thanks, everybody.