Advanced Administrative Topics: Pre-Award Issues

Session Transcript: 2022-2023 NIH Grants Conference

Elyse Sullivan, PhD: Thank you all for joining today's presentation, Advanced Administrative Topics Pre-award. My name is Elyse Sullivan, and I will be your moderator today, and presenting today we have two dynamic experts from the National Cancer Institute, Crystal Wolfrey, who's the Chief Grants Management Officer, and Sean Hine, who's the Deputy Chief Grants Management Officer. These two have a lot of experience to share with us, and I told you they'll make it fun, so I'll let them take it away.

Crystal Wolfrey: Thanks, Elyse. That's a big build up. I hope we can live up to it. I haven't been called dynamic in a long time, so it was nice, but, yes, my name is Crystal Wolfrey. I am NCI's Chief Grants Management Officer. I have been with NCI for 36 years now, I believe. So I have lots of experience in the grants management world. I'm still learning, but I do have some things to share, and so we're hoping today we'll be able to share some of our knowledge with you in this advanced administrative topics session. So I'm going to let Sean introduce himself. Sean.

Sean Hine: Yeah, hello, everyone. So my name is Sean Hine, Deputy Chief GMO at NCI. Been here for about 20 1/2 years, and for those 20 1/2 years I have never been called dynamic. So that would be a first for me. So thank you, Elyse, for building that up. So .. . But, yes, welcome, everyone, and hopefully this will be a fun session for everyone and really informative.

Crystal Wolfrey: Okay. Sounds great. So I think the logistics, Elyse covered. So I think we're good, Sean. I think we can move on from that. So let's talk .. . We're going to get things started here. For those of you that have done this session in the past, this might look a little bit familiar to you, but we want to start out kind of giving you an idea of what our perspective is from the NIH when we look at what we call interesting situations, is what we're going to do in this advanced administrative topic. So a few things to remember from our perspective. One, we, as federal employees, have to support federal policy. We are charged with enforcing applicable laws, cost principles, administrative requirements, both from your side and from our side. We are stewards of federal funds, taxpayer dollars. We take that very seriously. A couple things to remember, there are a lot of ICs, institutes and centers, at NIH. Some have a relatively broad mission. Others have by comparison relatively narrow mission. Some have significantly more dollars than the other, and the nice thing about having more funds is it can mean some more flexibilities are afforded to some ICs than others, and remember always, not all ICs fund the same types of grants, so some of these scenarios that we're going to walk you through may not apply to every IC at NIH, but they're kind of broad brush and apply to many of them. So a couple things that we consider when we're making decisions on tough situations like the ones we're going to talk about. One, we really want to think about, will the action create a precedent? What are the potential consequences if it does? Is an action consistent with policy, both NIH, HHS, other federal policies and regulations, and how would this play if it was presented on the evening news or on the front page of the "Washington Post" or the "New York Times" or any newspaper that you can think of? Some other things that we want to do when we're working through complex situations is we approach all of them with several basic questions that we want to ask. One, what's in the best interest of the science? Next, what's in the best interest of the grant recipient? What's in the best interest of the agency, NIH? Is there a way that we can get to a win-win so that both the agency and the recipient get what we need and the science moves forward? And from our perspective, we try very, very hard to see if we can get to a yes in any of these situations. So that's kind of how we come at it and what we're looking for when we deal with these complex situations. So here's what we're going to cover in these next 45 minutes. This is the pre-award session of advanced administrative topics. We're going to have a discussion on application submission. We're going to have a quick discussion on changes that might happen prior to the initial award. We're going to talk a little bit about grant deal making and negotiation time and what that looks like. We're going to talk about what happens if there's substantial federal involvement in a research grant, and for those of you that are brand-new applicants to NIH, we're going to talk a little bit about what you can expect if you submit an application and it gets selected for funding by one of the NIH ICs. Okay, application submission roulette. All right. So, Sean, let's get this warmed up a little bit. Let's say I were a prospective applicant. How do I get an application in the door?

Sean Hine: So that's a great question, Crystal, especially for any new applicants. So all applications to NIH are in response to what's called an NIH Funding Opportunity Announcement, and all of those applications are also submitted electronically. So each funding opportunity provides those details to what systems can be used to submit. So for any principal investigators that are attending today, be sure to work with your organization's sponsored programs office so that you know exactly what options are at your disposal.

Crystal Wolfrey: Great. Very important notes for sure. Thanks. So I know a common concern is about what an organization needs to do to make sure that they're set up to submit applications. Is that right?

Sean Hine: Yeah. Now, this is a critical point, actually, and I recently helped a whole bunch of organizations get this done in a big program that we launched this past year here at NCI. So ensuring that your organization has all the necessary registrations in place is critical. So this includes ensuring registration with eRA as well as with grants.gov and what's called the System for Award Management or sam.gov. I'm sure many people are familiar with that one. So for small business friends that are out there, so there's also a need to be registered with the Small Business Administration Company Registry. I'm not going to lie. I read that one to make sure I got it right. Organizations want to make sure they start this process really early on. It does take a little bit of time, so it's really important that applicants definitely consider that in your deadlines for your funding opportunities. Oh, and I should say, for any prospective PIs that are out there, there's also a requirement for you as well, so from a senior and key personnel perspective. So you need to make sure senior and key personnel, other significant contributors and other individuals you plan to name as senior key personnel on the forms in your applications are also registered with eRA so they can get their own Commons ID.

Crystal Wolfrey: Okay. Covered a lot of ground there. So let's switch gears a little bit. Something that I know that I receive a lot of questions around are on requests for applications or RFA, and specifically the money that's listed that NIH intends to commit, sometimes we call that a set-aside. Does that have any impact on what an applicant can request in an application?

Sean Hine: RFAs actually will exactly list how much they can request. So that is an institute or center is planning to spend a particular amount of funds to support however many number of grants. So this does not directly impact, however, what an applicant requests. For an applicant it is important to focus on whether there are any direct cost limitations. So they may say, "Hey, we want to set aside $3 million in this particular one," but the direct cost for you as the applicant specifically is going to be listed. We'll talk a little bit more about one very common money-related question that comes up and funding opportunities in just a few moments.

Crystal Wolfrey: Okay. A nice teaser there. Okay. So another question that comes up is let's say an original application does not score well enough to be funded. The applicant wants to take some time, reconsider the approach, respond to reviewer's recommendations and stuff. How much time do they have to resubmit that application as a resubmission or amended application?

Sean Hine: Yeah, so the applicant would have up to 37 months to submit that amendment, so science moves very quickly. So what may be relevant today could be not so much tomorrow. So any longer and it may be worth considering a new application. In those instances where it's been a little bit of time, my recommendation would be to have a discussion with the NIH program official just so you can get some guidance in terms of what's maybe the best step for you.

Crystal Wolfrey: Okay, good. Thanks. I'm glad you mentioned reaching out to the NIH program official. It is important for any prospective applicant to know that they can reach out to NIH to get help. The officials listed in the Funding Opportunity Announcement are great resources. For administrative questions, they can reach out to the grants management person listed. For scientific questions, they definitely should contact the NIH program official.

Sean Hine: Yeah, and if you're not sure where to even start with your idea, so an item I actually just came across the other day, there's a lot of great resources that are out there, but one in particular was actually something called NIH Matchmaker, which is a great tool for someone that may not know exactly which area you want to go into or really even to get started with your research, so just something to keep in mind.

Crystal Wolfrey: Yeah, indeed. NIH has a lot of tools and resources for everyone to use, and we hope that they will guide applicants on their journey. I know that this conference has lots of booths from the ICs at NIH to give lots of resources, too. So thank you so much for the information and the discussion.

Sean Hine: Mm-hmm. All right. So in summary on that one. So there was a lot going on there. We tried to cover a lot of things, hence the roulette style. So a couple main items that we lifted from there. So just if you got a question on your Funding Opportunity Announcement, I actually had a one-on-one just earlier today with an individual, and one thing I brought up is, "This is a great spot to talk to your program official. This is a great spot to bring in your Grants Management Official." So just always keep those things in mind. It's administrative in nature, grants management. Definitely reach out to us here at NCI or any ICs. We're here to help you out with those prospective applications, and from a scientific perspective, definitely get in touch with that program official because I am not a scientist, so you're better in those hands. So what if you are looking to apply for, say, for instance, the parent R01? So NIH has the parent R01 announcement, and you're not quite sure who to talk to. Again, that NIH Matchmaker tool that I personally just found the other day was really neat. So I just recommend to check out some of the resources that OER has. The Funding Opportunity Announcement, we talked about that a little bit in terms of what's being listed on that FOA, what we refer to as the FOA, in terms of the dollar amount. So if an applicant is looking to adhere to .. . Really the important part of all of that is an applicant adheres to direct cost limitations that are provided in the FOA. So if nothing is listed, that's actually shifting it back to you as the applicant and the investigator to make that decision on how much to request. You don't need to average. So if you see X amount of dollars and Y number of grants that they're looking to support, you don't need to average those two. So no worries there. And last thing is how long to submit the application, again, just a reminder on that 37 months.

Okay.

Sean Hine: So that gets us to our first one to fire off to you all. So, Elyse, this is where we're going to test you on this one, too, just to see how fast things can go. All right. So here's a scenario. This is when we were doing that back and forth, I mentioned that there's a very common money-related question that comes up. So I'll let you all read it for the most part, but just a quick little overview. The plan is that you have a prime, Great Dane University in this made-up scenario, be the applicant, but there's an important subcontract with Chihuahua University because, why not? So the RFA indicates that the direct cost is $600,000. So true or false, does the indirect or facilities and administrative cost for Chihuahua University count in that $600,000 cap?

Elyse Sullivan, PhD: All right. So we've got responses coming in the chat. We've got the majority of people saying false. Got a lot of false here, and we do have one suggestion, Sean. You're hyped up. You're amped up. You're talking a little quickly. If you could just turn it down just ever so slightly, I think people would be able to follow.

Crystal Wolfrey: That usually, comes to me, so I'm really [Indistinct]

Sean Hine: Oh, man. That's just .. . I appreciate the thoughts, but all right. So all right. So I heard from you, Elyse, a lot of false. So nicely done, everybody. So, yes, that is false. That is a very common question that we get here at NIH when it comes to those. I'm not joking how many times that question comes up is .. . It says $600,000, but I have a third party. I even may have more than one, and do those indirect costs count against that cap? And the answer is no. And just in general, indirect costs in general do not count against the NIH direct cost cap.

Crystal Wolfrey: Okay. I think this is me.

Sean Hine: It is. The slower of the two.

Crystal Wolfrey: Okay. So we got another one to play with you guys to get you guys involved. So we've got another true or false. So here's the scenario. A PI with ESI status submits an application for funding that is not selected for funding by an NIH IC. Institution resubmits the application as an amended application or resubmission, but the PI's ESI status has expired. NIH will not give special funding consideration to the amended application because the PI is no longer an ESI, true or false? Enter into the chat.

Elyse Sullivan, PhD: We've got a little bit of a mixed bag here, Crystal. So we've got a lot of trues, but I see some false as well.

Crystal Wolfrey: I like it. So nobody knows for sure. Okay. Sean, you want to go? All right. Oh. Okay. Mostly false. As long as the application is resubmitted within 13 months the application will be flagged as an ESI application and funded as such. There's a couple exceptions, though. If the PI has received another NIH award in the meantime in between getting the submission and the resubmission, then they are no longer considered ESI for that application. If the resubmission is not submitted within 13 months, again, it won't be treated as an ESI application. And then if the resubmission is not funded, so both the original and the resubmission are not funded, and so then the institution resubmits that application as a new application, that also will not be considered an ESI application. So mostly false on that, but there's a couple exceptions. Nice job, folks. Okay. So let's talk a little bit because this comes up a lot in questions, so we wanted to go over it just really quickly and having to do with the timing of ESI status and some reminders. So sometimes what will happen is a principal investigator, an institution with a PI, will submit an application, and then after the application is submitted they will update their ESI status or they'll receive an extension on their ESI status. And a lot of times investigators aren't sure what happens to that application. So here's what happens. The application will be reviewed as it was designated when it was submitted. So if the investigator did not have ESI status or they had expired, it will be reviewed as not being an ESI application. However, if they update their status or they get an extension, after the review, after the summary statement is issued, then the status will be updated. So the application should be flagged as an ESI application, which means it would be considered for special funding consideration by the NIH. Quick note, though. Sometimes the updates don't work perfectly, and the application status is not updated. A lot of times I see that happen when there's a long time between this application submission and the update, so best bet, here's a tip. If you think your application should receive ESI special consideration because you are now an ESI and you aren't sure it does, call the NIH awarding IC to talk about it. We get those calls all the time, and we're able to shift things in and out of that pool depending on what the status is. So that's a little tip for ESIs.

Sean Hine: So I'm going to just take it for a minute here, Crystal, just to kind of round out this discussion. So just a fun story for everyone because, again, all of these case studies that we talk about today did happen in some way. I joked the other day with Crystal, I was like, "We probably should just call it as based on a true story." So actually this one just came up just recently. So we were talking about application submission. So as many people know and as all of us have been impacted with the pandemic a couple years ago with so many people going home and working from home for quite a while. So just the other day we just happened to come across a package was sent to us at NCI, and included within that package, which was originally sent to a building that we have not been in in over 10 years, but that's neither here nor there, is it was actually information about an application submission. So it was looking to submit an application to a very specific program that NCI actually no longer even supports, but then extra component to that which was it was actually asking for information back from us, and so .. . And the date on that was in 2021. So it's been a little bit. So really the whole point there is kind of get at the idea of .. . Oh. Is remember, you got to be in response to something. So definitely make sure that you always respond to some sort of funding opportunity, and we would love to be helpful for that, and definitely reach out to us. I would recommend via e-mail. I'm not trying to squash down the whole paper submission. It's something that's a lovely letter, but definitely I'd recommend e-mail there, too. But highlighting my point, this includes supplements. So there's a notice that came out not too long ago that actually requires all supplements to be submitted electronically as well. So just, again, those fun grant stories that we all have, but we're going to keep on rolling now. So we're headed off into the prior approval world or the prior-to-award world. So again, the beauty of this is it's a really well-constructed process that NIH has. Well, a lot of time can pass, and a lot of things can change during that time. So again, approximately 9 months between the submission of application and to make it an award. So in those 9 months a lot of things can change. PIs move. They get new jobs, changes in the science itself. So we're going to take you through a little bit of a story, and as we mentioned .. . We know it's a little bit later in the day. You all have had wonderful 2 days of this conference, so hang with us. Hang with us just for a little bit longer. All right. So here is the situation. So a PI submits a competing application to the NIH parent R01 announcement. No biggie there. The grant reviews well. It scores a two. Fantastic. It's doing really well. Things are looking on the up at the moment. However there are some changes that need to be dealt with. Again, that 9 months of time, a lot stuff can happen. So the PI contacts the NIH program official. So let's listen in to that call. Hello, this is Sean Hine at NIH. Oh. You .. .

Crystal Wolfrey: Sorry. Thank goodness. I got the right number. It's not the pizza place again. Sean, I really need your help. This is Crystal. You're my program official on my pending R01.

Sean Hine: Happy to help in any way I can although I really want some pizza now.

Crystal Wolfrey: Okay. So here's the deal. My R01 scored really well, and I'm very hopeful it will be funded, but we have a big problem. The materials that were related to aim two simply will not be available to us for an unknown amount of time. It could even be years from what I'm hearing. It sounds like it's all supply chain issues, so I'm really worried we may not even be able to do aim two.

Sean Hine: Okay. So all right.

Elyse Sullivan, PhD: I think we lost Sean for just a moment.

Crystal Wolfrey: Yeah, I think he is frozen. So we'll give him a second.

Elyse Sullivan, PhD: Maybe he went out for pizza, so .. .

All right. I'm going to move on. We'll see if he jumps in. So I think he was going to ask me if we were planning to start aim two and when we were planning to start it, and definitely in year one. It would continue into year two. The data resulting from it would have been partially used for us to proceed with aim four. So it's hard to do this without him on there. So as the investigator I am really freaking out about this. What I need to know, do I need to withdraw the grant? What do I need to do? So I'm going to read Sean's. He said he would say, "I'm not sure if we are at that point yet. We can consider some options here. It sounds like those materials are crucial to that aim, so it would need to be dropped. We can look at the rest of the application, consider the funding opportunity it responded to, and if that aim were removed, would it change the grant enough to where we would need to consider whether it would have scored the same?" So of the four aims, not the most important one. We, I am the investigator, think it's valuable, but I do think that we can make do with the rest of the grant. So obviously the implications to aim four are important here as well. We would need to look into what we could accomplish towards that aim or maybe even consider whether we can obtain data from another source that may come close to fitting what I was originally trying to achieve here. So it's a good idea. We have to look into that, and so the recommendation is that we write up what we want to do, submit it to NIH, loop in grants management because there are options on the table here, and if we end up having to remove that aim fully or even a partial aim, that could be a lot of changes that we would have to consider, and from a scientific review and budgetary standpoint. So the investigator would have to go back, put this all together and try to figure out what they could do. So after that scenario, here's the question: Can an application have a change in the proposed aims? Time for the classic NIH answer, it depends. So a few of the items that we would need to consider: one, responsiveness and requirements of the Funding Opportunity Announcement. Would the application as changed still meet those requirements, still be considered responsive? Is the application still .. . Is the new revised application still the same as the application that was peer reviewed, and if so, are the changes significant enough that it would have impacted the score that the application received? So it's important, takehome message, contact NIH program and Grants Management Officials early in the process so we can talk through and let you know what we could do and what the options are. So I don't see Sean back, so luckily this is another one that we're going to bounce back to you all, so hopefully while he's logging back on, let's go with this multiple choice question. A U01 application was reviewed and scored with a multi-PI arrangement. Shortly after one of the PIs blissfully heads to retirement. What needs to be done? A, the grant will just need to remove the person resulting in one less PI, the grant must go back through peer review, C, a request to remove or replace the PI can be submitted to the NIH institute or center or D, the grant must replace the PI since it was originally submitted as a multiple PI arrangement. So if you want to .. . I don't know if, Elyse, if you're on we're going to [Indistinct]

Elyse Sullivan, PhD: Yeah, yeah. We've got mostly C, here. We've got .. . Yeah. We've got mostly C, that the request to remove or replace can be submitted.

Crystal Wolfrey: Okay. So luckily I have control of these slides. I think Sean is rebooting his computer, so I hope he'll be here soon. So, yes, absolutely. The answer is C. It is a prior approval request, but it could be requested. It is possible to remove or replace that PI, and you would need to send it into your .. . the IC that funds it that's going to fund the grant to the grants management person and the program official. A couple reminders to include in something like that. If you're changing a mutli-PI arrangement, either by adding or removing a PI, but you're keeping it still an MPI grant, you will need to revise the multi-PI leadership plan, and you'll have to submit that revised new leadership plan to us. If you're just dropping the PI and the other investigators are going to absorb those responsibilities, you'll have to explain to us how that works. What that PI was originally supposed to do, who's going to do that now? Who's going to take that on? And then finally we really would need an explanation on the impact on the proposed research. So again, mantra all the way through, communicate with the NIH officials as early in the process as possible. That's the best way to ensure that we can get things done in a smooth fashion. So he's still not here. Oh, yay. Go get more time. So we are in the lightning round. Do we have anything, Elyse, that we can try to answer?

Elyse Sullivan, PhD: Yep.

Crystal Wolfrey: Okay.

Elyse Sullivan, PhD: Yeah. We've got a couple here. So we know that the data management and sharing policy is a hot topic. We've had a session on it at this conference.

Crystal Wolfrey: Yeah.

Elyse Sullivan, PhD: But there is a couple of questions regarding the data management and sharing policy, and totally fine if you have to defer them to the group.

Crystal Wolfrey: I was going to say, thank you so much for a question that's not in my .. . No, it's fine. I'm going to give it a shot. We'll see.

Elyse Sullivan, PhD: So there's a question about if a DMS plan is required for a supplement application for a project that was awarded previously.

Crystal Wolfrey: If it's an administrative supplement application, no, it is not required. If it were a supplement application that is what we used to call competing supplements, but I think they're called revision applications now. If it comes in for peer review then, yes, it would require .. . It would fall under the policy if the requirement is there.

Elyse Sullivan, PhD: Yeah. So only competing, not anything noncompeting.

Crystal Wolfrey: Yes.

Elyse Sullivan, PhD: Right. Great. Let's see. Can you discuss some of the nuances of the other significant contributor, how someone might be designated that versus some of the other designations?

Crystal Wolfrey: Oh, my. Thank you. That's seriously testing my years of knowledge. So .. . And I would highly recommend that you go back and look at the 424 and the definitions of it, but another significant contributor is not somebody who's listed as key personnel and not somebody .. . not the principal investigator or one of the multiple PIs, but somebody like a consultant or somebody like that who is significant to the project but not to the level of key personnel. Then you could definitely test me on that, and send me an e-mail if I got that wrong, but I'm pretty sure that's what the definition is of an other significant contributor.

Elyse Sullivan, PhD: Great, and we have a question .. . It may have just gotten answered, but it's about salary caps, and can you request salary that is over the NIH designated cap, and what happens there?

Crystal Wolfrey: Absolutely can request it, and in fact I recommend that if your investigator salary exceeds the NIH salary cap that you do indicate that in the application, right? So the application, the 424, should come in with the institutional base salary of the investigator. I do know that if the investigator salary exceeds the cap, oftentimes the institutions will just put the cap in. If you do that, that's fine, but please indicate somewhere in that application in the budget justification that the investigator salary does in fact exceed the cap because the NIH salary cap goes up almost every year. We cannot provide that increased salary if you haven't noted to us in that competing application that the salary actually exceeds the cap. So it's always in your best interest to note it. I have a Chief Grants Management Officer colleague who says, "If you don't ask, you don't get." And that's really what we always say. Ask for it. We will give it to you if we can. That's a great question.

Elyse Sullivan, PhD: Great, and even better news, we've got Sean back. We missed you, Sean, but .. .

Crystal Wolfrey: Yay.

Elyse Sullivan, PhD: .. . Crystal has been holding down the fort.

Crystal Wolfrey: Doing my best. Can hear us, Sean?

Sean Hine: Yes, I can hear you. I think I'm still here. So .. .

Crystal Wolfrey: Okay. Do you want me to advance the slide?

Sean Hine: You all wanted me to slow down. That was one heck of a way to have that happen, right? So .. .

Crystal Wolfrey: Oh, you going to advance the slides then? Okay. You take over. Okay. Great.

Sean Hine: I don't have the [Indistinct]

Crystal Wolfrey: Okay. I will do it. No worries.

Sean Hine: Yeah, go for it.

Crystal Wolfrey: Okay. All right.

Sean Hine: They don't trust me anymore with the remote.

Crystal Wolfrey: All right. So I think this is you. Do you want to start?

Sean Hine: This is me, and since you've been doing pretty much the lion's share of the work, nice test for you, right? So that's going to show up in my evaluation. So sorry about that, everybody. So, yeah. So we're going to move on to negotiation of an award. So getting into really the thick of it and towards the tail end of that preaward process. Next slide, please. All right. So [Indistinct]. All right. So we're going to paint a picture for you. So here's a good one that has also we've come across. So R01 application has been reviewed. Again similar instance like we did before, so I got a four in this particular case. So again, score really well. So everyone is really excited. Everything is looking pretty good. So it's gone through council, and Grants Management and Program Official are conducting their reviews. So it's kind of at that tail end of the line. It's already gone through the initial review. It's gone through council. Things are looking really well. The Program Official identifies a rather interesting thing, however, during their review. The investigational new drug, the IND, which is needed in year one, will definitely not be improved until some time in year two. Go ahead and .. . Perfect, Crystal. Thank you. So all right. So that's not good news. So all right. So let's listen into a conversation between the specialist and the Program Official, and hopefully I don't drop off in this middle of the back and forth, Crystal. So we'll see.

Crystal Wolfrey: Hopefully not. Okay. Hello? This is Crystal at NIH Grants Management. Can I help you?

Sean Hine: Hey, Crystal. This is Sean. It's been a minute. How are you?

Crystal Wolfrey: I can't complain. It's almost baseball season. I've been rewatching the Nationals' run of the World Series. Magical time. But anyway, how can I help you? You've got to be kidding me. Oh, my gosh. It's almost inevitable. Okay. So I'm going to try to do Sean and me until he gets back. So Sean, "Well, I've encountered a situation with Dr. Magic on this R01 that you are the Grant Specialist on. I've been talking to them, and it sounds very likely that they will not have the investigation of the new drug until year three." Okay, when were they planning on having it? "Funny you should ask," this is Sean. "They were really hopeful I guess because it would have been in the middle of year one." So I respond. Yikes! That is a problem. I'm assuming everything in the application, the time line of the research, the budget were all reflecting this plan? So for Sean, "Yes, the budget was definitely loaded in year one and two to move along with the trial. The analysis work was later. Overall the whole thing is a bit of a mess right now." So I can see that for sure. Is this grant still viable? Do they have other work not related to that study while they wait for the IND approval? So the response is, "I think they do, a good amount of bench work that they could move up, but I don't think it will be nearly as expensive." So my response is we could consider working with them to lay out the plans. They could send us a revised budget and a revised time line that will fit the fact that the IND study won't be done much later. It would be really good to hear from them on how they think they could still accomplish the original aims in this grant, and then we can talk about whether we can meet those needs within the policies. Okay, so Sean thinks that's really interesting.

Elyse Sullivan, PhD: Sean is back. We've got Sean. Sean, do you want to come off mute and relieve Crystal of the two-sided conversation?

Sean Hine: Yeah. So awesome job, Crystal. I completely agree with everything you just said. I apologize, everybody.

Crystal Wolfrey: Do you know where I am? You're at the, "This is really interesting."

Sean Hine: All right. So this is really interesting, actually, interesting in so many ways right now. So .. . But .. . So pretty much it sounds like from what you described they're recrafting the budget before the grant even starts. I didn't even know that was option.

Crystal Wolfrey: Okay. Well, it's possible. It's definitely case by case. There's a lot to consider here, including whether this adjustment meets the funding opportunity announcement and the requirements and what was looked for. Also we got to make sure it doesn't change the project so much that it could have impacted the score that the original application received. So they can't rewrite the science. Don't get me wrong, but they might be able to restructure the time line and still meet the original objectives. I think a call with them so we can discuss the options would be a really good idea.

Sean Hine: Sounds good. I'll work to set that up. So thanks for your help.

Crystal Wolfrey: I am happy to help. If you drop off again .. . Anyway, so there's a lot to unpack there. All right. So in this case, what we did, the grant was restructured prior to award. The institution submitted a revised budget with a new project time line. We redistributed costs in the project period. So year one became significantly less, and then the out years increased as they could bring on that study that needed the IND, and the award was ultimately released, so we were able to work it out. So remember, thing come up. Reach out sooner rather than later. Gives us time and flexibility to work through things. We do have a lot of options at our disposal to try to make these things work. Also keep in mind something I said earlier: Not every institute and center is going to be able to meet your needs because of their own limitations, but discussion should happen so you can consider options. Again, if you don't ask, you won't get. And again, we are always looking for a win-win because our goal here is facilitating science. All right. You want to try to take this, or are you going to freeze again?

Sean Hine: I'll give it a shot. So just purely for humor, I had a pop-up show up on my screen that says my Internet is unstable. I'm like, "Yeah, no joke." So .. . But so .. . All right. So again, the question for you all. So R01 application is submitted to the NIH parent R01 again. It's done well in review and meets the NIH institute's or center's funding policy. The NIH Program Official and Grants Manager note that there is an intramural involvement. So can the award still be made as an R01? We'll give it a second. Elyse, what are you seeing?

Elyse Sullivan, PhD: I'm seeing a lot of yes. I'm seeing yes. I'm seeing some maybe. The good old maybe that NIH always likes. I'm seeing mostly yes, and I'm seeing some, "It depends."

Sean Hine: Go ahead and click when we're there, Crystal. Likely with this particular case it would be a no. So in this particular situation because there is intramural involvement going on .. . So do click one more. There we go, Crystal. Thank you. Really the question, is the involvement of the NIH investigator substantial? So that's pretty much the starting point of this is really evaluate, is there substantial involvement going on with that NIH investigator? If it is, then it does require a changeover to Cooperative Agreement. So we're out of the R01 space. We're hopping over into, in this case, a U01 space. So there will be discussions around that. And then would that result in cooperative agreement .. . And that would result .. . I'm sorry. That would result in cooperative agreement terms being place on the actual award. So that would be negotiated between the organizations, the applicant and also the institute. Alternatively, from those negotiations, and we all have seen this, actually, where it gets into the thick of it, and the PI goes, "You know what? Actually, that intramural investigator wasn't really that critical. So let's just work on actually just .. . Let's get that person out of there." So they actually look into the idea of removing that investigator. All right. So I think this is still me, Crystal. I'm still out of whack on my numbers.

Crystal Wolfrey: No, you're .. . Go. You're good.

Sean Hine: All right. Cool. So all right. What if you're a new applicant? So this is, again, like we said at the very beginning, there may be prospective new applicants out of the order of 1,300 people that are watching my Internet crumble beneath me. So there's a lot to consider here. So you got the UEI, the SAM, the eRA, FWAs, Animal Assurance, all these things that you need to account for, all of these policies and procedures that you need to know about, and so all that applies as soon as you apply, and then reporting requirements, even if you get an award. So we're going to walk you through a purely hypothetical, as in it's not, situation for a new applicant coming into NIH, eligible to apply for a funding opportunity, and the company has a couple years of operation, but has yet to receive NIH funding up to this point. I think overall we're looking pretty good so far. Not a big deal. So application is reviewed and gets a good score. Great. It meets the IC's funding policy, even better, and no issues with the IC's council review. So it's moving right along through the process. NIH has reached out to start negotiation. So Program Official, Grants Management Specialist involved. So the application now arrives at the specialist. So the Grants Management Specialist has this, and one of the responsibilities of the specialist across NIH is for evaluating the applicant's ability to manage the federal award. And this is regardless whether you're new or existing. So that's one of the requirements. So new NIH applicants and awardees do not have any track record at the NIH. Therefore there's an inherently increased risk associated with that, and then so we're going to listen in on a call, and hopefully it won't be Crystal just talking to herself back and forth, but we'll see. And so listen in on a call that takes place between the specialist and the Authorized Organizational Official. All right. For the last time, I do not need to extend my car's warranty.

Crystal Wolfrey: So is this Sean from New Discovery Inc.? This is Crystal from NIH Grants Management.

Sean Hine: Oh, sorry about that. Man, I tell you, those calls. They frustrate me a little bit there.

Crystal Wolfrey: I can tell. Do you have a minute to talk about the documentation you recently sent to me regarding your company?

Sean Hine: Sure do. Gosh, I hope we're not in trouble.

Crystal Wolfrey: No, no. No concerns. We just need to talk through something that came up. So as I explained in my e-mail, as yours is a new organization applying for NIH funding, I needed to review some information about your company, ensure that I've mitigated risk to the federal government prior to making the award. The documentation you sent me, which included your most recent financials and some of your internal policies along with your last audit, was really helpful. So thank you for sending all that in. But because you're very new to NIH, I also consulted with NIH's Division of Financial Advisory Services. They noted a couple of things. First, there was an audit finding in your 2020 audit, and then additionally your 2021 audit does not appear to have been submitted as of yet. Was that audit completed?

Sean Hine: Oh, right. Yeah, so that audit finding. Well, it was a .. . We switched over our systems at that point, so then our procedure documents weren't quite lined up, so we definitely weren't able to provide those documents the way we were hoping to, so that demonstrated how we were handling expenses and invoicing as we would like. So we were definitely admittedly, we were a little mixed mess on that, but we definitely fixed all that.

Crystal Wolfrey: Okay. That's great to hear. Can you send me the procedures that you put into place in a letter addressing the situation? I'm not looking to approve the procedures. I just .. . It's really important that I have an understanding on what steps you've taken to address the audit finding and to avoid something similar from occurring in the future.

Sean Hine: Yeah, that's not a problem at all. We can definitely get that over to you. So as for that other situation, yeah, the audit reporting. COVID? So can I just go there? Just kept us from getting that done.

Crystal Wolfrey: Yeah, so, yeah. COVID definitely disrupted a lot of things, and NIH even provided a lot of flexibility, but I'm a little confused at this point. The audit was due in 2021. We're now in 2023. Can you clarify with me why you haven't had that audit completed and reported yet?

Sean Hine: So really it was a .. . We were simply not able to pull all the information together for quite some time, and now we're just trying to get back up and running within the past several months, and we lost some people around that time too just being kind of new to all this and still a fairly new company. So we lost some people that would have helped us with that as well.

Crystal Wolfrey: Okay. Well, I appreciate the need the to balance priorities, but I got to say, it's a little bit concerning that this is an outstanding item. What's your plan at this point?

Sean Hine: So our plan is definitely to get that addressed right away. So let's see. Today is Thursday. So we can get going on that audit, make sure that that's getting taken care of probably within the week?

Crystal Wolfrey: Okay. Great. So I will look forward to your follow-up. For right now I'm going to have to put a hold on additional actions on this award until we can get that resolved. I'd also really like to see your internal policies for complying with regulations and requirements and any other reporting requirements and stuff.

Sean Hine: That makes sense. I will definitely work on getting all this covered within the week and get back to you with an update on how we stand.

Crystal Wolfrey: Great.

Elyse Sullivan, PhD: All right. Thanks, Crystal and Sean. We are just at time now. So unfortunately we're going to have to cut for now, but we really appreciate everybody joining and .. .