Elyse Sullivan: So, thank you for joining our session on Advanced Administrative Topics: Pre-Award. My name is Elyse Sullivan and I'm going to be moderating this 45 minute session today. And presenting, we have Crystal Wolfrey. She is a chief grants management officer at the National Cancer Institute, and we also have Sean Hine, who is the branch chief, also at the National Cancer Institute. So today our format includes a case study driven presentation. We're going to try and get very interactive. We want it to be fast paced. We're going to be asking you for your feedback within some of these cases and we're going to be doing some intermittent Q&A lightning rounds. So put those questions in the Q&A and we're going to get to you as many as we can. And with that, I'm going to turn it over to our presenters. Take it away.

Crystal Wolfrey: Hi. Thanks, Elyse. Thank you very much. I think, Sean, you can move to the next slide. I think Elyse covered much of this. As she mentioned, I am Crystal Wolfrey. I am the National Cancer Institute's chief grants management officer. And, Sean, do you want to quickly introduce yourself?

Sean Hine: Hello, everyone. I'm Sean Hine. I'm a branch chief, also with the National Cancer Institute.

Crystal Wolfrey: Thanks. Next slide. We did another--We also did a slide with some quick logistics just to note you are all muted and with no video. As Elyse mentioned, please put questions in the Q&A. We have three of our staff members monitoring to try to answer some of the ones that they can answer. We are going to have a lightning round where Elyse is going to try to read some for us to answer quickly. Couple notes, as Elyse mentioned, this is a case study driven session. It relies very heavily on it and these are real life examples of things that have actually occurred, even in this last year. We do try to cover a number of topics directly and indirectly and we will most not, as we mentioned, likely have time to answer all the Q&A. We're going to do the best we can. We'd like to encourage you to go to one of the booths. NCI has a booth as well as many of the other ICs and NIH also has a booth. So if you don't get your question answered, it's a great place to go because all of the booths are monitored by staff of the NIH. Next slide. So a couple things we want to start out with, just a couple reminders that we, Sean and I, come at this from the NIH perspective. I have been doing this, grants management, for a very long time, over 30 years. Sean's been doing it for about 20 years. So together, we have about 50 years worth of experience in this. So we are NIH employees. We must support federal policy. We have to enforce applicable laws, cost principles, administrative requirements. We also have to be stewards of federal funds. Some of the ICs, just as a note, have a relatively broad mission. Others are, by comparison, relatively narrow, and larger ICs might have more funds which can mean more flexibilities. So not all ICs fund the same grant mechanisms, not all ICs do things in the same way. We do try to point out where things might be different compared to a large IC like ours and some of the smaller ICs. Next slide. A couple of other additional considerations when you ask us something or we come across a tough situation. We try to ask ourselves, will the action create a precedent which will limit flexibility in the future? Is the action consistent with NIH, HHS, federal policy regulations, laws, legislation and so forth? And most importantly, or somewhat importantly, is how would this play if presented on the evening news or the front page of whatever paper is in your local area? We also ask ourselves a couple things, and this is something that we talk to our staff about a lot. When we're considering some of these things, we try to say, what's in the best interest of the science? What's in the best interest of the PI and the recipient? Is there an opportunity for a win/win? And most importantly, we really do try to say, can we get to a yes? We try very hard not to start with no. How can we get to a yes? Next slide. So let's get right to it. We've got a couple situations we're going to explore as we go through this day. Sean and I are going to trade off. We're going to run some case studies. We're going to do a little role play. We're going to involve you so hopefully it will be a fun and interactive session. We're going to talk about human subjects and single IRB policies. We're going to talk about some of the changes that happened prior to award and how we handle that. Understanding a funding opportunity announcement before you submit an application, submitting a competitive renewal, and we have a couple discussions and a case study about brand new applicants to NIH and what you can expect the first time you get an award from the National Institutes of Health. Next slide. Okay, first question that we would like you to enter into the chat. Today, a Grants Management specialist is reviewing a competing R01, which has three performance sites and human subjects research involved as a multisite study. How many performance sites will need to provide certification of IRB approval to NIH for the award to be issued. We'll give you 5 seconds to answer in the chat. And I actually can see the chat, Sean. I can see it, so it's happening.

Sean Hine: I can see it.

Crystal Wolfrey: A lot of ones, a few threes, and it depends. Oh, our favorite answer, "It depends." And a four. We have a four. Okay, I'm going to go to next slide and we'll get to the drumroll, please.

Sean Hine: Okay, drumroll, please.

Sean Hine: The answer is one. So in this case of the single IRB policy, it was a multisite single study. So in this case, it was due to the single IRB policy which is one IRB would be serving as the IRB of record for this multisite study. But it gets me thinking, Crystal, which is what if we had other situations, other scenarios that could point come up on this. So let's say each of the performance sites are conducting unique studies. So what could we run into there?

Crystal Wolfrey: So if each performance site is conducting a unique study and it's not a multisite study? Is that what you mean?

Sean Hine: Absolutely.

Crystal Wolfrey: There's one site per study? Then as many people had mentioned, we would need to get their--each IRB at each site would have to review and approve the study.

Sean Hine: Interesting. Okay. So single but multi in an interesting little way. What about if only one site is conducting multiple unique studies?

Crystal Wolfrey: So if there's only one site conducting multiple studies, each study would require IRB approval. Some ICs would require certification of each, approval of each study. Some ICs, like ours, would require certification of one with a statement that the other studies had been approved by the IRB.

Sean Hine: Awesome.

Crystal Wolfrey: Did you learn anything, Sean?

Sean Hine: I did learn something. I appreciate that. I actually took some serious notes down there so I can actually answer some questions to staff. So there's actually a lot of information out there, too, for NIH's pages for single IRB. So what we've provided here and obviously it's a part of the resources and these slides will available afterwards, so is the information on the single IRB policies that are out there for NIH.

Elyse Sullivan: And Crystal and Sean, some folks mentioned a couple other variables. What about if you have an exception or a waiver? What about foreign sites?

Crystal Wolfrey: Foreign sites do not--the single IRB policy does not apply to foreign sites. That's a great question. There are limited waivers or exceptions but they have to be approved ahead of time. So it would need to come through the process for approving an exception. Great studies, great questions. Sorry.

Sean Hine: And for anybody that's looking for more information on that, actually, this page that I included here actually provides a lot of that. So I would highly recommend just use Google, Yahoo, Bing, any of the search engines that you prefer, not that I'm advocating for one over the other. So just a recommendation on that too. So there's a lot of information on that. So how about we jump into another situation human subjects related? So the research plan for an application describes preclinical research that must be completed before the human subject research can be fully planned and described. What is this called? Go ahead and enter in the chat. And I cannot see the chat, so I will act oblivious, as always.

Elyse Sullivan: Let's see. We're seeing lot of B. We're seeing a lot of B here. We're seeing a lot of the delayed onset of human subjects research.

Crystal Wolfrey: One or two As, mostly Bs. Clearly no one thinks C.

Sean Hine: No one went for C?

Crystal Wolfrey: I was going for C.

Sean Hine: So we have a savvy group, it looks like, Crystal. We have delayed onset of human subjects research. So let's talk about why that is. So in this particular case, an award can still be issued with a late onset for the very reason that the clinical studies aren't fully developed yet. So they really don't know exactly what they're going to do but they have a lot of work that they can still do. So can an award be issued? Sure, yeah. We can work that out. That's where you're going to work with the NIH IC to actually flesh all of that out. You're going to detail that out in your human subject section. This research will be--the restriction of an award, for instance, will allow for the release of award funds, the PI to start working without the need for, say for instance, FWA or an IRB review and approval. When all of that does come in, what's really important in the delayed onset space, because none of that was reviewed up to this point. So that's all got to be provided to the IC at that point. So completed protection of human subjects section, the FWA number, if that actually hasn't been established already, the IRB approval date and documentation of human subjects education by key personnel. So a lot of information needs to be provided after the fact, but the nice part is, by working with the IC and one of the allowances of delayed onset is that you can get going so you can do all of that important work prior to, hence the reason preclinical, prior to actually establishing what you're plan to do within human subjects activity standpoint. And how is this different, for instance, from delayed start? So the other option, we're going to just chop C out of this because, obviously, that was just for fun. So because the application did not include definitive plans for human subject research or definite plans, NIH must review and approve all of that. So in a delayed start situation however, all of that would still be provided in the application of the primary submission. In delayed onset, you don't necessarily have all the information, so awardees must submit a new or revised human subjects section that clearly describes risks, protections, benefits and importance of the knowledge to be gained by the revised and new activities. And then the initiation of the human subjects research requires NIH prior approval. So, again, all of that is really important to keep in mind when you're in these particular spots. Reach out to the IC if you have any questions ahead of time. if you're not exactly sure where you're flowing. And, again, there's a lot of really useful information out there, but what's important is, in this case with the delayed onset, it's not just submission of IRB when it's approved, but just some information that you want to account for. So Crystal, did you want to provide, add anything here? Very good. Just wanted to make sure. All right. So we're going to switch some gears. So onto some other topics of discussion here. So change happens all the time. Obviously, as many of you already know, or I have a feeling a lot of you already know, it takes a little while from the time that you submit that application to the time that, potentially, you get that award. So in that particular range of time, we're talking about 9 months and a lot can go down in this particular time frame. So we're going to ask you to sit back for a second. And depending on where you are, you may not want to do that because you'll fall asleep real fast. So let's just close your eyes and imagine the following. So here is the situation. So a PI submits a competing application to an R01 request for application, an RFA, from an Exemplary University in New Jersey. Why New Jersey? I have no idea. Just randomly picked it, I'll freely admit. Six months later, the PI lands a fantastic job out on that West Coast. Heading off to the sun, sunny California or wherever you'd like to go. Maybe you would love the Northwest. The PI tells all in his lab about the move and the grant is going with them. Everything sounds fantastic. People are rah-rahing around and everything. How wonderful for this PI? So the PI contacts the NIH program official. So let's listen in to that call.

Crystal Wolfrey: Am I starting? I'm so sorry.

Sean Hine: Yep. Yes, you are.

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

Sean Hine: Hello, there, Crystal. This is Dr. Naive. I hope all is well with you. You're listed as my NIH program official on my competing R01. I'm the PI for that one that is researching why dark chocolate is simply better than milk chocolate.

Crystal Wolfrey: Oh, right. Yes, I recall that one. That may be a game changer. How may I help you?

Sean Hine: I'm excited to tell that I got a new position, actually. Headed to Second Rate University on the West Coast. I'm finding Exemplary University's standards to be a bit, well, let's just say too high.

Crystal Wolfrey: Congratulations, I think. I'm glad you contacted me though. This sort of thing can really impact an NIH grant application. There are several steps we need to get through.

Sean Hine: That is what I thought. That is what I thought, but don't you worry. I have a lot of that already well done.

Crystal Wolfrey: Great to hear. So Exemplary University is relinquishing their interest in the application?

Sean Hine: Wait, what? Their interest? I mean, that's my research. So what do they need to do?

Crystal Wolfrey: Oh, yes. I can understand why you would feel that way, but the grant application was submitted by the institution with you identified as the principal investigator. The applicant institution has the rights to the proposal and and possible award we might issue. So we would need a statement from them that they are withdrawing their interest.

Sean Hine: Oh, okay. Well I didn't think of that one.

Crystal Wolfrey: Also, the research plan talks about interviewing the population in the Northeast. What are the plans if you're going to be out on the West Coast for that?

Sean Hine: No worries there. All of that is still going to happen at Exemplary. A lot of my team is actually is staying behind so they'll take care of all of that. I actually didn't feel like paying for all them to move out. So I'm the only one. I'm the only person moving, actually.

Crystal Wolfrey: Okay. So that might be a bit of an issue. So I think, at this point, we really should think about engaging with NIH grants management at this point. I'm a little worried that what you're describing is that Second Rate would not actually be performing a significant amount of the research. How about this? Let's set up a call with grants management as soon as we can?

Sean Hine: Oh, man. This is more complicated than I thought. I thought this would be an easy call, so glad I called then. I really thought that just getting Second Rate to agree to take this on was it.

Crystal Wolfrey: Transfers like this, prior to a competing award, they do happen. They happen all the time, but it's really important that we all work together so we're on the same page. How about this? I'm going to e-mail the grants management specialist right now. We'll set up a time that all of us can get together and talk.

Sean Hine: Sounds fantastic. Thank you very much. End scene.

Crystal Wolfrey: End scene. Okay, so can a PI move prior to making a competing award? Sure-ish, as we said. Typically it is possible to change a grant recipient prior to award but it's important to understand a couple of things. What's allowed for the funding opportunity announcement? Also, it's really important to consider what the grant will be doing and where that research will actually be happening. It's really important to contact your NIH program and grants management officials early in the process so that things don't get delayed. Remember, the applicant must relinquish their interest and a transfer application must be submitted from the new institution. Okay, Sean, I'm going to ask you this question. What if the move is outside the US? Is that possible?

Sean Hine: Well, it is, actually possible, but, as the slide indicates, it's pretty darn complicated. So, one, it absolutely needs to be permitted by that FOA. So it's really important, as you'll hear throughout this, so hint, hint, that reading the FOA and understanding what the FOA allows is really important. The grant still needs to be relinquished by the original applicant, so the same story here in this case study, which is a true life case study, it also needs to be accounted for. Prior approval requirement, the change of recipient organization and adding a foreign component. So it's really important to emphasize that particular piece. Even though the grant award hasn't been made yet, it still falls into that prior approval space, the fact that it's a change of recipient organization and a foreign component. You need to consider the scope of the originally submitted application. Obviously, in this scenario, it is very much within the domestic US, but depending on the type of population, for instance, that may be enrolled. So that needs to be accounted for in the scope of the application as well. And lastly, it must go to the IC's council of review and approval. So what's really important here is that last point, which is it's really, really important if you're in a space where you're going to potentially look to move a grant to a foreign organization, non-domestic US, is that you get in touch with the IC, the NIH IC as soon as you possibly can. That needs to go to their council and the councils only happen so many times throughout the year and we can't make that award until that council meets and hopefully approves. So that's all just items just for you to keep in mind, that last point being really important.

Crystal Wolfrey: And one thing, Sean, I want to add, the other thing that's also really important that didn't make it onto the slide. There's a foreign justification required for when a grant is going to be funded in a non-US site and it has to address why the domestic site isn't appropriate and why the facilities are the foreign site are. So all things that are really important, go back to, please reach out as soon as you know this could happen so we can walk you through the process. Thank you. Next slide. Okay, I guess we're at the lightning round. Do we have enough Q&A, Elyse, to do like 5 minutes of questions?

Elyse Sullivan: So, you know what? Our Q&A folks in the background are getting to a lot of them.

Crystal Wolfrey: Good.

Elyse Sullivan: So let's hold off.

Crystal Wolfrey: Okay.

Elyse Sullivan: Because a lot of these are already being answered in the Q&A.

Crystal Wolfrey: Okay.

Elyse Sullivan: But what we can do next time you stop us, we can summarize and reiterate some of those for folks who have been not able to multitask.

Crystal Wolfrey: Perfect. Yeah, no, that's great. Okay. That's good. That saves us some time anyway because this 45 minutes is going to go like that. Okay, next slide, Sean. Is this me? Is this me?

Sean Hine: It is.

Crystal Wolfrey: Okay. So let's talk about another situation. Completely different situation, changing gears. An application is submitted in response to an NIH funding opportunity announcement with very specific requirements. For example, since we're from the National Cancer Institute, we're going to use an NCI FOA and NCI's outstanding investigator award. The application is reviewed, scores well and meets the IC's funding policies for the program. The application is being reviewed by the grants management specialist, who reaches out to the AOR to discuss. And I believe we're ready to go into that, right? So it begins, the greatest negotiation of our time.

Sean Hine: Indeed. We'll let you all stare at Gandalf while we do this. So, hello, my name is Sean Hine, and I'm the grants management specialist assigned to Dr. Outstanding in their Field R35 application. I am calling to begin negotiations on the award because it has been selected for funding by NCI.

Crystal Wolfrey: Wow, thank you so much for calling. This is great news. They will be very happy to hear this application will be funded.

Sean Hine: Great. As you know, this is an unusual award that was designed to provide long-term support and increase flexibility for the investigator to continue a research program of unusual potential. One of the requirements of this award is the institution agreed to relinquish the PI's single PI, single project grants funded by our institution.

Crystal Wolfrey: Yeah, thanks. We do know that, but I will say the PI is hoping we can negotiate a little bit on that last piece.

Sean Hine: Negotiate a little? How do you mean?

Crystal Wolfrey: Well, as Dr. Outstanding in their Field, or OTF as we like to call him, is very accomplished. They have several funded grants from your institute and we are hoping that they can negotiate keeping one of them along with getting this award.

Sean Hine: I'm not sure which grant you mean. Looking things over, it appears that all the existing grants are single PI, single project grants. All of them fall under the requirements of this FOA.

Crystal Wolfrey: Yes. Yes, no, we agree with that, but we also believe that Dr. OTF can meet the effort requirements for this award, still keep one of the other awards. The grant they want to keep does not scientifically overlap with this application, I promise.

Sean Hine: Okay, well, I am sorry, but as you know, with this award is a longer duration. So it's seven years, so it's a little bit atypical in that sense and the application did not require specific aims based off the nature of this particular grant. So as to provide the investigator maximum flexibility to pursue their research program. So the research in the R01's could be conducted under this award.

Crystal Wolfrey: Okay, yes. We understand. So quick question. Would it be possible for our institution to propose a change of PI on the existing award? We could switch Dr. OTF to, maybe, a coinvestigator so they could still participate in the project, but not be named PI?

Sean Hine: Unfortunately I have to continue to be the bearer of bad news. That is not possible. It does not meet the intent of this program. The FOA specifically states that NIH will not approve a change of PI on other grants to avoid this requirement.

Crystal Wolfrey: So there isn't any way to make an exception for this application?

Sean Hine: Unfortunately, in this case, no. It would be unfair to any of those who did not apply and that's really important for us to always keep in mind when you apply to this FOA. Because of the requirements described, the only way we would be able to award this application is if your institution complies with requirements of this FOA.

Crystal Wolfrey: Okay, well thank you. I'll speak with Dr. OTF, but it may be that we have to decline this award.

Sean Hine: Okay. Well, that would be unfortunate, but if that is the decision, I would need a written request to withdraw this application from funding consideration signed by an authorized official.

Crystal Wolfrey: Okay. Thanks very much. I'll be back in touch. So what did we learn from this? Sean, what did we learn from this? Read the FOA carefully. Many FOAs have very specific requirements for the award, things like a requirement to relinquish other funding, like we just described. There are requirements for time and effort of the investigator. There's limitations on the use of foreign components. Sometimes the requirement is for attendance at meetings, et cetera. Cooperative agreements also have special terms and conditions. So an IC may not be able to ignore, in fact, IC won't be able to ignore or waive those requirements at the time of award. So please make sure that you know what's in the FOA before an application is submitted.

Sean Hine: Okay. So thanks for that discussion. So hopefully that was helpful. Jumping into a different space now. So here's a situation that comes up every once in a while. So a recipient had received an award to support their last year of the competitive segment in FY 2021. So this actually occurred just this past year. The start date was December 1st, however they are anxious to not have a gap in funding. So the question to the audience, so can they submit a competing renewal early, knowing that if it reviews well, it would be in the wrong fiscal year?

Elyse Sullivan: Got a lot of yes. A couple no's, we got a lot of yes.

Sean Hine: And the answer is ... Too bad I didn't have a little drumroll sound effect . . Yes, but there are some things to consider here. Funding a Type 2 in the same year that the Type 5 was funded would, for all intents and purposes, be funding more than 12 months from one appropriation, which is generally not allowed. And typically, the IC should allow the support of the Type 5 to continue and consider the Type 2 the following fiscal year. So here at NCI, we actually ran into exactly this particular situation, and a couple instances over the FY '21 where this flared up. So we allow for the Type 5 to continue and then look at the possibility of funding the Type 2 the following fiscal year in FY '22. But as you said at the outset ... I'm trying to tie that back to the first couple points ... Not all the ICs work the same. So it's really important that the applicant should contact the IC to discuss the potential impact of submitting a competing renewal early. So, as you can tell, there's a theme going on here which is, get in touch with the IC for these type of potential atypical situations, things that aren't really necessarily normally understood.

Crystal Wolfrey: So what I would also say, in an IC, it's not always the same answer. So a lot of times it depends. So for example, the outstanding investigator award that we had our last case study on, that is not one where we do allow it to move into the next fiscal year. So that is one where we actually require that the institution relinquish that last Type 5 so that we can fund the Type 2. So it is really dependent on the situation and it's really important to reach out to the IC with the one that you have before you decide to do that.

Sean Hine: Yeah, and well see occasionally flare up with even T32's, for instance, and those are other instances where we would want to account for that based off the program it supports. So again, that theme that we'll keep just driving right into the ground, is reach out to that IC, reach out to that program official, the grants management officials, to make sure you have a full understanding as to what you're applying for and how that may work. All right. So we're going to roll into another situation, which is a pretty prominent discussion point here at NIH. So we're, hopefully, giving you some cutting edge stuff going on. So what if you are a new applicant to NIH? There's a lot of things for you to know, I'm sure. I've never personally been an applicant to NIH, I've only worked here. But from everything I've heard from personal conversations over the years, whether it be at NIH Regional Seminars together in person or in other forms. There's just a lot to know. So whether it's DUNS, SAM, eRA, FWAs, Animal assurances, IRB, IACUC, and so on, and so on and other acronyms that I could easily just fill up the entire page here for. All of those type of things that you need to know about just trying to apply, all of the policies that may potentially apply to you or impact you based off the nature of the grant, and then reporting requirements if you get an award, even say, for instance, back to that R35 discussion that we just did a case study on, fully understanding all the intricacies of that FOA that would be expected of you as an applicant, whether you're new or more experienced. So a purely hypothetical situation, an applicant is a small business concern. We'll be apply to the NIH small business program. It's a brand new company, got up and running in 2020, lucky them starting off in a very interesting calendar year, but feeling good about what they're doing and the research that they are proposing. So far it's looking awesome. So moving right along, so the application is reviewed and receives a good score. So it meets the IC's funding policy for SBIRs, the small business program, and up to this point, no issues with the IC's council review. Things are going well, can't complain. So after that particular point, the application is going to arrive to grants management specialists and also the program official. So a grants management specialist is responsible, by policy, for evaluating the applicant's ability to manage the federal reward. We're not asking questions just for fun, it's actually based off the fact it's by policy. It's our job to do it. The new NIH applicants and awardees do not have a track record with NIH, so there is inherently a greater risk when you're working with a brand new applicant. So all the history, for instance, that we have with University X or Hospital Y, all that is not really there in play, so we have to rely upon brand new information and that correspondence and that interaction. So what we're going to do now, is we're going to jump in to Crystal and I reading a script. I know, lifting behind the veil, right? So we're going to listen in on a call that takes place between the specialist and the authorized organization official. Yeah, who is this?

Crystal Wolfrey: Sorry, I had that on mute. Hello. So, sorry, this is Crystal Wolfrey, NIH grants management. Is this Dr. Hopeful?

Sean Hine: Oh, absolutely. Sorry about that, Crystal. I thought you were calling about my car's extended warranty expiring. My fault, how can I help you?

Crystal Wolfrey: Great, glad we got that resolved. So I'm calling to continue our discussion on NIH potentially funding the grant your organization submitted. As you know, your organization has not previously received NIH funding, and for one of my responsibilities, is to assess your company's ability to manage federal awards. I ask for a number of documents to be submitted to me, some recent financials of your company, a chart of accounts and some internal policy documents.

Sean Hine: Oh, right, yeah. Those financials, they were a real bear for us to pull together.

Crystal Wolfrey: Yeah, about those financials, I'm a little bit confused on your balance sheets, specifically it doesn't balance. Also, the income statement is showing that the company is incurred some debt but has yet to generate any revenue.

Sean Hine: Right. I'll have to talk to my Chief Financial Officer on that part.

Crystal Wolfrey: Oh, you have a CFO? Oh, that's great to hear. Since the documents provided were pretty sparse and didn't describe the organizational structure for the company, I wasn't sure.

Sean Hine: Yep. No, no, we definitely have a CFO. Actually, it's my son. Do you want to speak to him? We were just sitting down for dinner so I can actually throw him on speaker.

Crystal Wolfrey: Oh, maybe another time. Thanks, though. So wait, let me get this straight. You're the principal investigator and the Chief Executive Officer and the CFO is your son? I'm a little concerned about that organizational set up, specifically whose responsible for monitoring and evaluating the company's financials? For example, if you receive the grant award, can you walk me through who you envision signing off on expenses that you would incur as the principal investigator?

Sean Hine: I guess I was planning he would, but I definitely see what you mean. I mean, he works for me and I am the PI and he still lives under my roof. That doesn't look like a separation from duties there, does it?

Crystal Wolfrey: No, no. It really doesn't. So what would be ideal is some sort of oversight between the CEO, the CFO and the investigator working on the project. Let me ask you, is there anything written down in your company policies about how this would work with the existing staff?

Sean Hine: Well, it's interesting you bring that up. Not really, with all the application process and making sure we did all that right, we were just going to figure that out based on with what policies we needed after we got the award.

Crystal Wolfrey: Oh, I've heard that before, but unfortunately it can't really happen in that order. This does explain why I only got a page or two of your organizational policies. So the reason I'm pressing on this is because NIH policy states that one of my responsibilities is to ensure, the best I can, that you're organization has the financial and management standards in place to manage an NIH award.

Sean Hine: I hear you. I'm just worried that we don't have things separate at all. The financials were pretty much worked up in an Excel sheet and we were putting so much into what we were going to do on the research and application, I did not really think about the policies that we would be needed.

Crystal Wolfrey: I completely understand what you're saying and I want to help out in any way I can. The NIH is considering funding this grant because the research is really important. So perhaps we should set up a couple of calls where we can walk through more of what you would need to do and what you have in place, what you don't have in place, so I can further explain what needs to be done. I cannot tell you how to write your policies, of course, but hopefully the conversations will get you down the path so we'll be able to make this award and you can start your project.

Sean Hine: Thanks, that would be awesome.

Crystal Wolfrey: Great. So I will be in touch and we'll set up some meetings, okay?

Sean Hine: Fantastic. Thank you, much.

Crystal Wolfrey: Great. So my mind is blown. So how did this get resolved. This was an actual case that we just recently finished up this year. Requires a lot of communication between the NIH officials, program, grants management and the AOR. The applicant putting together policies and procedures that can be followed in their management of the award. So we worked with them. They helped put together policies. Reminder, we don't need to approve those policies or those documents, but they need to be available if requested and we are happy to help with giving samples and so forth for putting these things together. Financials may be limited or not available at all. We know, that's okay. Small businesses, especially, but new organizations just getting set up, you might not have financials that you can send to us. But NIH could consider special award conditions to help mitigate the risk for all involved. We are here to help. Sean, next slide. And we want to help you get on the road. Some additional considerations, we are required to assess not only the merit of the application, which is peer review and scientific merit, we also need to consider the ability of the applicant to manage grant funds. Things we look at are financial management standards, policies, audits, things like that. We will request financial records to assess the capital ratio. We will ask for documentation on the organizational structure, who reports to whom. Is there a board of directors? Is everybody related and how does that structure work. Other policies and procedures that may be dictated based on the nature of the grant application. If you're proposing to do travel, we may ask if you have a travel policy, what your travel policy is. If you're going to have consultants in your work, we'll ask about consultant policies, how you're going to review what consultants do and how you're going to pay consultants. And there are other requirements for the NIH application, bottom line: we are here to help. There are a lot of resources available, technical assistance, site visits, we go out sometimes and visit places to help get things set up. Now we probably do most of that virtually, but we can certainly do that. As I mentioned, templates are out there. Bottom line, we want to get to a win-win for all involved. So we will work with you to try to get everything in place so that you can get the grant.

Sean Hine: And the small business, if I just may add, the small business program, in particular, it happen a lot in new organization applicants, so that's where we would definitely be looking to help out in any potential way that we can. The sooner that we can start those conversations, the better. Actually, just this past fiscal year, I was hit up directly by a potential applicant with a lot of these type of questions. They just simply said over e-mail, hey, can we talk about this? And we had multiple phone conversations. No idea whether this applicant was even from NCI or how this was all going to work, but I was just trying to help out.

Crystal Wolfrey: So--And there's some great--I have to just read some of the things in the chat because they're hilarious. It definitely did not pass the smell test. Somebody wanted to know how old the son was. Somebody said the CFO was under his roof. Sniff test, no policies yet, very common. Yes, very common, and they got a university to participate with them. Remember, in the SBIR world, universities don't have to participate. That's the STTR world. However I will say, we actually--This isn't only the small business program. We've had small grants that have come from organizations that have very little things. Questions if you can ground your CFO it may be a conflict of interest, which I agree. And somebody said, LOL, yes, but the cousin did a great job with the website. And, yes, seriously, this really did happen and I agree. Applying for an NIH grant is incredibly confusing and unless you have the backing and infrastructure, you get the grant in the door and you're like, I'm ready to go. I really want to work on the science but we've had a lot of interesting things happen with CEOs not understanding how to use money in some of these grants. I had one CEO tell me that they just put all the money that they got in a bank account and when they ran out of money, they just drew down more funds. And I said, well, how did you, what were you spending it on? "Well, I don't know, I just ran out of money and the only thing I did was this grant, so I just drew it down." So a lot of crazy things happen. We very much are here to help and somebody said that they got financial management questionnaire from Sean. We do have a financial management questionnaire. We have a new organization questionnaire that we're happy to share. Actually I think I have it posted on our website, so it's really useful information. If you're working with something or you are from a place that's applying for NIH grants for the first time and you've never received one before.

Sean Hine: Yeah, and as I mentioned at the very onset of this, which is this is a hot topic across NIH. Obviously it's risk mitigation across the board. Federal tax dollars are being used for this so this is where we really try to make sure that we are honing on that stewardship of funds and then going all the way back to the beginning, we're trying to look for a win here, so make it work for everyone. The case study was a perfect example where having those conversations is going to take some time. Definitely for folks that are really, really busy, on your side and ours, but that's where we're just here to help out in any way that we possibly can.

Crystal Wolfrey: Absolutely. So those that are asking about the new organization questionnaire, maybe we could make sure that's posted in our booth and you can sort of navigate your way through the lobby to the NCI booth and we'll make sure it's there for you as a resource so that you'll be able to get that. Will the Q&As be available for us to read through? That's a great question, Elyse. I don't know if we have any questions you would want to answer because I think we have a few minutes and I don't know if there are going to be questions.

Elyse Sullivan: Yep. I can roll over. We've got just a couple minutes left. You guys, there has been a lot of activity in the Q&A. A lot of questions are being answered by our wonderful Q&A helpers. I have been checking on the back end and it doesn't look like there's very easy way to export the written Q&A, unfortunately. There's a lot of really good stuff in there. I know that. The video recording and the audio recording will be retained but unfortunately, the Q&A won't. If you can find a way to copy paste, go for it if there's any certain nuggets that you want to take out of there, but unfortunately we're not going to be able to export all of those in bulk. It looks like some folks said they were able to copy and paste it into a Word doc. So I would suggest going ahead with that.

Crystal Wolfrey: Okay. Yeah, no, I also would ask our staff that are answering, if you guys could, before this goes away, if you could cut and paste some of it into that. What we might try to do is sort of consolidate this into common themes. Sean and I have been talking about this and maybe posting some frequently asked questions on our own external website to help things from the regionals in our session so people can go back to. And yes, somebody said is Sean's still at NCI. As far as I know, Sean's still at NCI. I haven't been in the office for almost 2 years. I haven't actually seen him in person, but you're still with NCI, right, Sean?

Sean Hine: Unless you're about to drop some news on me in front of over 2,000 people. So I think I still am.

Crystal Wolfrey: So we don't have a transcript for this session. I know there was closed captioning and I don't know if they will save that as a transcript because this is case study driven, it's less like that. Go ahead, Elyse, I'm sorry.

Elyse Sullivan: So, yeah. So there will be transcripts and close captioning embedded into the video recording. So hopefully you were able to find that, if anyone needs it. But we will have it available afterwards as well. There was one softball question but we say contact the IC, contact the IC. Are you talking about the grant management specialist? Are you talking about the program officer? Does it matter? What do you mean when you say contact the IC?

Crystal Wolfrey: That's a great question. It doesn't matter, necessarily. Our formal lines of communication is if you're from a business office, we would normally expect you to contact the grants management official and if you're an investigator, we would expect those informal lines of communication to be with a program official. The one thing I do say, I do ask, and I ask this of my staff as well, is to try to copy both so that we all sort of know the conversation is going on. Now if it's clearly just a science issue, the PI should definitely be discussing it with a program official. But if it gets into what can we do, what can't we do in our approval, it's better to keep everybody in the loop so that we're not sort of talking across purposes, but that's a great question.

Elyse Sullivan: Wonderful. And then, in one of your first case studies about the PI transferring, there were some questions about the scenario of a resubmission. If a PI has just transferred, does that affect the ability to do a resubmission versus having to start over and do a new submission.

Crystal Wolfrey: No, it doesn't affect the ability to do a resubmission. You can still do a resubmission but I believe that NIH does require something from the old institution relinquishing, indicating that they don't plan to resubmit that application. Same way with renewals. So if it ended at one institution and you wanted to submit a competitive renewal, they would require something from the old institution indicating that they aren't going to also renew that grant.

Elyse Sullivan: And we've only got a couple minutes. I know other support is a whole session on its own. Is there anything quick you wanted to address about some take away points of what do you include in other support, what do you not include?

Crystal Wolfrey: Well, yes, there's a session. I would recommend you go to that session. We're all learning this as we go because it really implemented in January. I would say be as comprehensive as possible and provide as much information as possible. We have a couple scenarios that we had run through in the past about overlap and our problems with that. In fact, I think if you want to come tomorrow afternoon, I believe we have a session on overlap and reporting and other support. So we'll talk about that as well. Oh, yes. Thank you, Sean. And these slides will be posted. Our skits aren't necessarily posted but the slides are reposted and we'll figure out a thing for the chat. Feel free to reach out to one of us. We are always around and happy to answer questions. That's what we're here for. That's why I've been doing this for 30 plus years. I love helping and being a resource. So I'm happy to be able to do that, and Sean as well.

Elyse Sullivan: Wonderful. Thank you guys so much. We're right at time. I wanted to do another plug. Thank you, Sean. Thank you, Crystal. You were able to keep this moving. I think we all learned a lot. So you guys are around at booths? Can people make appointments with you? Can people reach out to you with questions?

Crystal Wolfrey: I know I'm at the booth from 1:00 to 5:00, I think, on Wednesday. And Sean, you have some booth time too, don't you?

Sean Hine: Yeah. If you go to the NIC booth, you can set up a one-on-one expert discussion and both Crystal and I have times available out there. And if we're not available, a lot of other grants management staff are available as well as a lot of program staff are available. So depending on the nature of your question, all of NCI staff there helping out are awesome. So they're here to help out as much as we possibly can. And then there's a lot of staff just at the booth, just for just general chats. So if you want to touch base on that too.

Elyse Sullivan: Yeah, after that plug, visit our booths. Visit the exhibit booths. Every IC, I think, at NIH has a booth, has chats, has one-on-ones. Take an opportunity to get that interaction and also take the opportunity to meet us all back here tomorrow for the post award version of this session. We hope to see you all there and thank you so much and enjoy the rest of the conference.

Crystal Wolfrey: Thank you. Thanks, Elyse. Thanks, everybody. Hopefully see you tomorrow. Have a good one.

Sean Hine: Thank you, everyone.