Advanced Administrative Topics: Pre-Award Issues

>> Crystal Wolfrey: Okay, good afternoon, everybody. Welcome to our regionals topic, "Advanced Administrative Topics: Pre-Award." It is nice to virtually see 1,000 people logged into this, which is a little terrifying, but we're very happy that you're here, and we are going to get started to so we have plenty of time to finish. Sean, you want to advance? Okay. I'd like to introduce myself, and then I'm going to introduce you ... let my coconspirators introduce themselves. My name is Crystal Wolfrey. I am the Chief Grants Management Officer at the National Cancer institute. Sean?

>> Sean Hines: Hello, everyone. So I am Sean Hine. I'm a Branch Chief within the National Cancer Institute, and I'll also introduce our special guest. So, Terry, go ahead. You're muted, Terry.

>> Terri Jarosik: Sorry, I forgot to unmute. I'm Terri Jarosik. I'm the Chief Grants Management Officer at National institute of Mental Health.

>> Crystal Wolfrey: Great. Thank you, guys, very much. A couple quick logistics while we get started. So as everybody realizes, this is the first time we've ever done a virtual session like this, so there's going to be some interesting things that we are trying to accomplish here. As a note, you're all muted, and you do not have video. In other words, I can't see you. So I'm going to pretend that you're actually not there. You are welcome to put as many questions as you need to in the Q and A. We do have a moderator for this session. She will be capturing questions, and we have a plan for dealing with them later on in the session. Please note that this is very much a case driven session. We do several case studies. We walk you through some difficult things that happened in ... give you a sense of how NIH would handle some of these things. So they are real life examples, and they are issues that have occurred to all of us at one time or another. We are going to try to cover a number of topics directly and indirectly throughout the whole presentation. We will most likely not have time to cover all of the Q and A. I'm expecting that there will be lots of questions. We will do the best that we can. We do have some plans like I said for doing it throughout the presentation, and then we also would encourage you to go to some of the other booths that are around, and all of the NIH Institutes and centers have set up booths and you can get all kinds of great information and do one-on-one sessions there. So let's jump right into it because this is short, and it's 45 minutes, and I really want to make sure we get through everything. So we have a couple of slides just to set the stage and tell you what this is all about. So the first one has to do with some of the things that make projects and grants that NIH funds complex, or they could create pre-award issues, things like grants that involve human subjects research, grants that involve clinical trials research, PIs that have multiple NIH awards, multiple collaborating institutions or PIs on one award, changes that happen prior to award that are unanticipated and other overarching policy changes that NIH or HHS or the federal government can put in place. Next slide, please. So a couple things as we get this started. Our goal and our hope that your takeaway on this is that you're going to get a sense of ... look at and how NIH will help you solve problems, but it's really, really important as you do this and listen to us that you start thinking like a fed. So remember first, NIH is a federal agency. So we have to support federal policy. We have to enforce applicable laws, cost principles, administrative regulations, rules and so forth. We have to support the current president's and all president's initiatives and policies, and most importantly, we are stewards of federal funds. These are taxpayer dollars that NIH puts out in grants, and it's our responsibility to manage them effectively. A couple other things on thinking like a fed. Please remember, NIH is a very large organization. There are 24 funding institutes and centers. You will hear it referred to as ICs, and they are all very different. Some of the ICs have a relatively broad mission. Others, by comparison can be relatively narrow. Larger ICs like the National Cancer Institute where we get lots of funding means we get a lot of flexibility, and there's different things that we can do that smaller ICs might not be able to do because of the level of funding that they have, and not all of the ICs at NIH fund the same grant mechanisms, so it can change the way we answer questions for you as we go through this. Next slide, please. So what is our perspective when we consider challenging complex situations in the pre-award setting? Things that we consider critical in making decisions in tough situations. First, have we listened enough to really understand the issues and the objective of the situation? Many times, we find that the first question that is asked is not actually the question. There is more to it, and when we get the backstory, we realize that there's more to it. What's in the best interest from a scientific and programmatic perspective? How will this impact the scope and aims of the project? Remember, NIH funds research, and that's our primary goal. So we want to make sure that we know what's going to be best from the scientific perspective. What will best serve the investment of the taxpayer in the project? Again, all taxpayer dollars, we want to make sure that those dollars are used wisely. We also want to know, whatever we do, could it create unintended consequences, for example, in protecting human subjects concerns, animal subject concerns, other types of unintended consequences? So we have to look into the future on some of these things that we consider to see what the consequences might be. Next slide, please. So additional considerations for tough situations. We need to make sure if we're going to create a precedent, will it limit our flexibility in the future? So again, it's forward thinking. We don't want to do something that's going to create a problem for the future because we created a precedent. Is it consistent with policies and regulations? That's very important. Do we have the funds to support the proposed arrangements? As I mentioned earlier, some ICs are large. We have more money, and we might have more money to be able to support some of these things. Other ICs may not be. So it's a key consideration, and really, what I tell all of the staff that come into NCI and to NIH, well, you need to think about what would this look like on the front-page of a paper or on the evening news when you make a decision on what you're going to agree to. Next slide. So a couple key things. What's in the best interest of the science? What's in the best interest of the recipient? What's in the best interest of the PIs, and this fourth bullet, which we tell all of our staff, is there an opportunity for a win-win? Is there a way for us to be able to get to yes but keeping all of those other things in mind and not cause a problem. So I think next we're going to go into some case studies. So the types of things we're going to talk about in these 45 minutes through different sort of ways of doing it. We're going to talk about other sources of support. We're going to talk about human subjects research and safety. We're going to talk about some NIH initiatives to enhance clinical trial stewardship and human subjects research, and we're going to talk about some things that happened prior to award that are changes that might change things that might cause things ... complex. So let's get down to business, Sean. Ready? Go.

>> Sean Hines: Very good. So thank you, Crystal. So hello, everyone. So we're going to first start off with probably an interesting case study because for this those ... And this is advanced administrative topic, so we're not going to spend a lot of time talking about what other support is and some of these topics specifically. We're going to jump right into the nitty-gritty, so to speak, of some of these situation. Other support probably for a lot of people if you've been doing grants for a long time seems rather generic. It seems like it's been around forever, a whole bunch of just put the calendar months in and all that kind of stuff. It's become a little bit more complex over the recent past. So the couple points to emphasize here, especially from a pre-award standpoint, is the applicant organizations are responsible for the submission of complete and accurate information in the Just-In-Time. That Just-In-Time documentation is what you provide prior to the competing award being made, your first brand-new award. So this includes other sources of support, and it's important to emphasize here that NIH is relying on the accuracy of the information that you provide as the applicant. That's the information we're going to use to make those funding decisions, and as I alluded to, it's received some interesting focus as of late as many of you may already know. So a lot of clarity has been provided, and what we've done here at the bottom is we've included some references for you in the Grants Policy Statement and also a notice ... a NIH Guide notice that talks about the time and effort commitment, the overlap, other sources of support regardless of whether funds are being provided and also any pending support at the time of the JIT submission. So what we're going to do is, we're going to have a little bit of fun on this. So this is a real-life situation, but first we're going to start off with painting a little bit of a picture for you. So a competing grant comes in with Dr. Dicey, a very interesting, unique name for him, is submitted in June of 2017, so awesome, received a good score, third percentile. It meets the NIH's awarding ICs, so we're making this very generic. So we're going to ... Met one of the ICs funding policies in FY2018, and it was funded as part of that year's January council in 2018. Everything looks fantastic so far, no issues. We're all good, and then a second competing grant from Dr. Dicey is then submitted in October of 2017. That one also receives a decent score ... That one also happened to meet the IC's funding policies. So Dr. Dicey is doing pretty darn well at writing some grants, and also went through that part of the May council in 2018. So far so good. No complaints so far. So we're going to fast forward now a couple years forward. So all of that happened in the pre-award. Grants were made. Everything is looking hunky-dory, no complaints at all, but now we're going to listen in on a call between an NIH program official and the NIH grants management specialist. So here we go.

>> Crystal Wolfrey: Hello, Sean. This is Crystal Wolfrey, the program official, on grant 12345. Dr. Dicey is the principal investigator. You're the grants management specialist, so I wanted to talk to you about something that's come up that we need to address. Hello there, how are you? I hope all is well with you. Well, it's funny that you should ask that question because we may have a situation here. Just this morning I was forwarded a message from our director which included a congressional inquiry on the nature of this grant's research. Specifically, they wanted to know why we are looking into why trees have bark. >> Yeah, no, I've actually heard that's trending in research. It's all over the social media strings and everything too. So what's going on?

>> Crystal Wolfrey: Well, in looking into getting an answer to that question, I was surprised to find out that Dr. Dicey not only has one grant on this topic, but there's another one as well. I'm not the program official on that grant, though it has a slightly different take. It's why do maple trees have bark. Dr. Stewart Little is the program official for that award.

>> Sean Hines: That's interesting. So are you saying there is scientific overlap here? I know the grant you are the program official on is going into year three in the project period. Is the other grant newer?

>> Crystal Wolfrey: Yeah, it was submitted for a later cycle date, so it's going into year two. I think that plus the assignment to another program official is how this got by us.

>> Sean Hines: Okay. Did this not come up in the review of the competing application? As you know, the other support which was submitted as part of the JIT should've included all active and pending grants, including in the statements of overlap. I'm sure the other support included something, right?

>> Crystal Wolfrey: Yeah, I wish that were the case. In fact, not only did the other support not include the grant at the Just-In-Time stage, the other support submitted for both grants at all points competing and noncompeting never reported the existence of the other grant. The problem is that there is obvious overlap here, and it looks like we funded the same basic project twice.

>> Sean Hines: That's not good at all. It sounds like we need to have an immediate conversation with the grant recipient here. Not only do we have an overlap issue, but I think we need to find out how they're evaluating other support at all. That really makes me worried. So I'll contact the recipient right away.

>> Crystal Wolfrey: Great. Thank you so much. Just loop me in on that call, please.

>> Sean Hines: Absolutely. I definitely will. All right. So that's the background. We may have an issue, and now, so we're going to jump ahead, and we're going to now get on that call between the NIH officials, again, the program official, and the grants management specialist along with the grant recipient. We're going to ask our tag team partner here, our special guest Terri, to jump in as well. So here we go. So good afternoon, Ms. Jarosik. Thank you for joining us. I'm the grants management specialist for the two grants with Dr. Dicey as the principal investigator. Joining me is Crystal Wolfrey, the program official for one of Dr. Dicey's grants entitled "Why Trees Have Bark." The other program official Dr. Sertlo could not join us today unfortunately.

>> Terri Jarosik: Hi, how are you. Thanks for contacting us. How can I help you?

>> Sean Hines: Well, we've called this meeting to discuss these two grants with Dr. Dicey. Specifically, it's come to our attention that there are two grants which have significant overlap. Dr. Wolfrey actually noticed this and worked with Dr. Little also to identify the situation. When this occurs, the other support is to report this information. In the case of these grants, none of the other supports submitted for either grant has listed that other grant as pending or active even though the timeline indicates the report should've done so. So pretty much, it's like the other grant never really existed as they were being submitted in. Can you explain y this information was not reported?

>> Terri Jarosik: That's really strange. I'm pretty sure that we had brought this up at least on the noncompeting progress report didn't we?

>> Crystal Wolfrey: Not even close. As Sean mentioned, each grant's other support looks like the other grant does not exist at all. So it's not mentioned on anything.

>> Terri Jarosik: I must have been out of the office or on vacation or something because I never would've let this go by.

>> Sean Hines: Well, Ms. Jarosik, I hate to say you actually approved the progress report that was submitted.

>> Terri Jarosik: Okay, so what do we do now?

>> Crystal Wolfrey: Okay, thank you so much for asking that question because we really do want to try to resolve this. So first, we are going to need an explanation as to what happened in this situation. Based on the read of the proposed aims, there appears to be no doubt that these projects almost completely overlap. So we'd like for you to address that, and point it out to us if that's not correct. We also need you to address why neither one of these grants was included in the other support of the other one.

>> Sean Hines: And I'd like to add to that is we really need to get an understanding from an institutional perspective how you, as the applicant and the recipient organization, are handling your other support evaluations. So I'll definitely need the institutional policies regarding other support review. So this we'll probably need to us by the end of next week.

>> Terri Jarosik: Okay. I'm really surprised that this happened. We really do have things in place to make sure that other support doesn't get through like this, but I'll get right on that and get back to you as quickly as possible.

>> Crystal Wolfrey: Great. Thank you.

>> Sean Hines: Yeah, we appreciate that. Thank you so much for your understanding and working with us. So what happened here? So the recipient organization provided, as a follow-up to our discussion, they provided a statement acknowledging more or less big whoops that there was overlap definitely and there was oversight in the review of the other support. The more recent grant actually, the second one that was funded, had to be relinquished, and so that was obviously a big blow to the funding for that particular organization and for Dr. Dicey specifically.

>> Terri Jarosik: So, Sean, let me ask you a question, was it full 100 percent overlap or was it just one aim?

>> Sean Hines: It was ...

>> Crystal Wolfrey: A full ... Basically full 100 percent overlap.

>> Sean Hines: Yeah. So it was definitely ... It was a lot, and also as was mentioned, the other support review procedures were edited, and as Terri mentioned in this particular case, obviously in her role, was saying that she was surprised to hear that this would've slipped through like that, and that's actually what we received from the applicant as well. There was a big surprise that this would've gotten through to the point of not only one submission but then multiple submissions, and then add in the fact that it never came up even in the annual reports. So additional requirements were put in place at their level regarding the templates and the review process itself. So from the NIH IC, what we ended up doing, and I say we because it was an NCI grant, so revised the award to end the grant, that particular one that was relinquished, and then we also retained the updated policy for that particular institution. So that way we are at least aware that they made some changes on their side, and we can anticipate seeing the different approach moving forward. So what did we learn here? So obviously it's very crucial that all of that information, even if you think it's not as important as others, needs to be completely up to date and accurate. Other support, and the reason why we use this case study, is we have a feeling it's probably a little bit more nonchalant. It may be just one of those things where you get to it at the last second because, especially for the principal investigators on the call, you're very obviously focused in on what's going on with that particular scientific approach, but that's an important item too that needs to make sure that we have fully covered in it, and you're working with your administrative staff on that. So if something is missed on the applicant and recipient side, it's best to address it sooner than later, so please let us know. So if there's something that you submitted to us and you find out maybe even a couple weeks later, a month later, get in touch with us as soon as possible so that way we can at least work with you and rectify that particular situation, and as in this case even though it "got through" the first go around, both grants were actually funded. It was caught after awhile, and that's something that will need to be accounted for. In this case we were able to come to an amicable decision, but this could definitely be more severe with others.

>> Crystal Wolfrey: Okay. Well, I think it's time for a pop quiz. So this ... We're trying a whole bunch of different ways of doing this to keep this engaging. So pop quiz time. Sean? Okay, here is this next study, human subject protection and safety. A competing grant is proposing two studies and is trying to submit Just-In-Time. Study ... approval while study B does not. Both studies are fully described in the application. Study B will not actually begin until later in the project period. What can be done? Please enter your answer A, B, C or D in the chat. We'll give a second to do that, and then we'll go through some of the answers, and I do see questions popping up about that other case. We are going to try to get to questions as much as we can. We've got a lightning round coming up that we'll be able to try to do that.

>> Sean Hines: Yeah, and, Cynthia, you can just let us know what you're seeing in terms of responses.

>> Cynthia Dwyer: All right. I see a lot of C's. They're hoping that it means correct. There is a lot of C's.

>> Crystal Wolfrey: I see a lot of C's.

>> Cynthia Dwyer: There were a few A's and D's thrown in there, but the majority is C's, and they're active. We have a great audience today.

>> Crystal Wolfrey: We do. There's 2,000 people on here.

>> Cynthia Dwyer: We have ... Yes, we've got 2.3 thousand people which is awesome, and they are just ready for all the information they can absorb from you all.

>> Crystal Wolfrey: Great.

>> Sean Hines: Go tell all of your friends about this. We want to see if we can get it up to 3,000.

>> Crystal Wolfrey: No, no, no, no, no, we're good. Sean ... slides and we'll go ahead and jump to what the answers are. Okay, so here is the question again, and actually, the correct answer is D. So we're going to go through each one, and now I see a bunch of D's coming up. We'll see. We're going to go through each answer and why we would not ... how we picked D. So let's go. Next slide, please. So A, what's wrong with answer A? The applicant should just not submit Just-In-Time until both approvals. The award will wait until all is in place. In a situation like this, there's absolutely no reason to wait. Waiting simply delays the award and research that's ready to start. The key here is communicate with the IC what's going on so we can help guide you through those options. So let's go and see what's wrong with answer B, Sean. So the applicant should consider removing the study with the pending IRB, contact the program official to discuss further. The reason that we don't like this answer is, one, dropping a study can dramatically change the application's scope, and that could actually result in the IC questioning the score and the review that the grant got, and if it's a significant enough change in scope, it might have to go back through peer review. So we would not want you to do this option. Now, why option C, which was very, very popular? Send in the JIT with one IRB approval and a statement on the other study. This award can be considered a delayed onset situation and issued with a restriction. Here's the problem with that. Delayed onset is actually a regulatory term, and what it means is that research is anticipated within the period of award, but definite plans are not yet known and cannot be described in the application. If you'll remember the case study in this one, the plans are known, and it was detailed in the application. They just aren't ready to start until a later year. Okay, so answer D, which was ding, ding, ding. The correct answer from our viewpoint. Again, this is delayed start. The plans can be described at the time of the application. There is a human subjects protection plan, and it's described in the application. It's just not ready to start immediately, and it will occur in a later funding period. So in this case, the application provides the plans, like I said, and there's a timeline for when the study is going to begin. So what NIH can do is proceed with an award, we'd issue an award that included a restriction just on that study that that study couldn't start until we had received the IRB approval, and we've received and obtained, and we've filed it and so forth. So delayed start is something that does get confused with delayed onset, but if you have two studies going on or even one study going on that isn't planned to start until a future year, we can issue those awards with restrictions and allow you to do everything else, and then once that study is ready to start, get IRB approval before it's ready to start, okay?

>> Terri Jarosik: Yeah, I just wanted to add a little bit to that because some people ... Some of the ICs with the delayed start, keep in mind, their practice is not to do it unless the delay is for an out year. So if there is a delay within the current year plus we have another IRB, a lot of them will wait until they get full IRB approval before they award.

>> Crystal Wolfrey: That's great, Terri. Thank you. It's good to know. Like we said at the beginning, each IC has different practices and different ways of approaching things. So it's always really, really good. Communicate with your grant specialist that's working on that award so you can find out what their policies and procedures are.

>> Terri Jarosik: Yeah, I've been at three different ICs, and there are definite differences in each one.

>> Crystal Wolfrey: Yeah.

>> Sean Hines: Yeah, and the other thing to that is to reach out, communicate, and find out your options. Just talk through issues. We have a lot of tools in our toolbox for that. So ...

>> Crystal Wolfrey: Absolutely. Communication, communication, communication.

>> Terri Jarosik: Yeah, someone just wrote it's all about talking to the GMS.

>> Crystal Wolfrey: Absolutely. We are the all powerful ... No, I'm just kidding.

>> Sean Hines: Especially with the chiefs.

>> Crystal Wolfrey: We thought it would be helpful to go into a little bit more about more about delayed onset versus delayed start. So we'll do this quickly. Generally speaking, delayed onset falls into three different categories. Usually it could be a single project award, but the investigator has to do pre-clinical work or get FDA approval or something like that before the human subjects research can be fully planned. A lot of the large clinical research networks or consortia fund multiple trials. So some trials are delayed onset based on the results of another trial or something like that, and then there are some award mechanisms that are large center type activities where they'll have pilot project funds that could be developing human subjects work later in that project period. So that would be considered delayed onset. Next slide, please, and I do talk fast. I apologize, and since I have nobody to gauge except for my two partners here, it's hard, but I will try to slow down. When a PI is conducting preclinical studies, we will issue the award indicating that no human subject activities can be initiated until the involvement of human subjects can be fully described. This allows the release of funds, but it also keeps us ... protects us from risk because you can't do the human subjects work, and then once the PI is prepared to begin the research involving human subjects ... The chat is in the middle of my slide ... But we would ask for the full human subjects research protection section, a description of the aims that are going to be done with human subjects. If it's a clinical trial, we'll ask for the full protocol so that that can be reviewed. We will ask for the IRB approval, evidence of FWA if we don't have that already, and education documentation. Next slide, please. So I wanted to talk a little bit why that's different from delayed start. So because the application did not include definite plans for human subjects research, it's up to NIH to review and approve those plans post award. Normally those plans will be reviewed and approved by the study section. So you wouldn't have to send it to us again. Awards must submit a new or revised human subjects section that clearly describes risks, protections, benefits, importance of the knowledge to be gained by the revised, new activities. All of that stuff now needs to be reviewed by NIH in a post award setting, and then the initiation of the trial isn't about just sending us the IRB approval and the human subjects protection. You actually have to send and get our approval of the human subjects research that you're about to do. So that's why delayed onset is very different than delayed start because the review group has not had a chance to review the human subjects section of the application. That would be NIH that does it. Hopefully that ...

>> Terri Jarosik: There was one question that I think we can probably go with now that someone was asking for an example of delayed onset, and I would say, if the first part of your research needs you to conduct a survey or to figure something out ... I'm trying to figure out how to say this, Crystal. If you have to do something before you can actually write the protocol, that would be a delayed onset. We would start giving you funding to develop that first part that is needed in order to know how to write the protocol.

>> Crystal Wolfrey: Yeah, absolutely. That's the perfect example of delayed onset. If you had preclinical work, your investigator has preclinical work he or she has to do before he can develop the human subjects protocol, and like I said, if you have large center grants where an amount of money is awarded for what we call developmental funds for pilot projects, we don't know at the onset what those are going to be until investigators apply for those funds and tell you what the human subjects work might be. So those are good examples of things that are delayed onset versus delayed start, but the key is going back to the regulations. If you could describe the plans fully in the application, that is not delayed onset. If you can't describe the plans because of something that has to happen first, then that would be considered delayed onset, okay? I see we have 99 in chat. So that's one. Look, that's you, right?

>> Sean Hines: That's perfect timing. So again, what we're trying to do is offer as much engagement here as we possibly can with this virtual setting and over 2,000 people. So what we're going to do now is we're going to open it up. Cynthia is actually going to pretty much have the keys to the discussion for the next 5 minutes, and we're going to try to address as many questions as we can in 5 minutes, and then we're going to stop ourselves and continue on, and hopefully if we have enough time at the end, we'll do pretty much the exact same thing and pick it up and run you to the end of the session. So, Cynthia, fire away. Five minutes is started now.

>> Cynthia Dwyer: Okay. "When do you include pending grants on other support? Is it immediately upon submission or when it completes council review?"

>> Sean Hines: Sorry, go ahead. Go.

>> Crystal Wolfrey: This is where it gets complicated. Go ahead.

>> Sean Hines: So this is going back to the other support discussion. So thank you for looping it back to that, Cynthia. So you're going to bring it up based off of the other support submissions at the time of the JIT submission. So anything that you have that's actually been submitted forward should be reported at that particular point because at that stage it's with NIH for consideration. So that's when you want to submit it. Anything like ...

>> Crystal Wolfrey: At the time of submission. Not necessarily waiting for the score or the ...

>> Sean Hines: Right. Yep.

>> Cynthia Dwyer: "Can there be scientific overlap in training grant awards if you're institution is part of a sub-award on one and then main recipient on another?"

>> Crystal Wolfrey: In training grant awards? Go ahead, Sean.

>> Cynthia Dwyer: "Can there be scientific overlap in training grant awards?" Can we rename this to stump the grants management specialist?

>> Crystal Wolfrey: Yes, we could.

>> Sean Hines: So this is one of those that if we were live we would actually ask some follow-up questions on this one. So the best way to describe that is from a training grant standpoint. So I'm just going to use a T32 for an example, an institutional training award. So the T32s all the trainees should be contributing already to some mentor or somebody else's research in that sense. So there would not inherently be overlap in that regard. So if that is a point of concern however, that is something I would highly recommend having a good conversation with your NIH officials, your program staff, and your grant's management staff.

>> Crystal Wolfrey: Yeah, it's really hard to have overlap in training grants. This is why I ask that specifically because you're appointing postdocs and predocs to work on other people's research. So it's not surprising that they may have one or two postdocs working on their research. So the overlap in that scenario is a little unusual.

>> Sean Hines: I will say, just to comment though, is that as soon as if the individual is being appointed to a T32 or a training grant, they should not be receiving support from that research grant for instance. So that is their source of support. It's through that T32.

>> Cynthia Dwyer: Okay. All right. Anne asked ... It just moved. The questions are coming in. You, guys, are moving my chat box. Let's see. All right. Anne, I lost you. All right. "Do key personnel who have no effort such as mentors on K awards, unpaid advisors, et cetera, need to submit other support for Just-In-Time?"

>> Sean Hines: So for ... Right, so these would be for investigators. so for instance as a mentor capacity. That's a great question, actually. I'll have to look that one up. I actually don't know ...

>> Terri Jarosik: Can I take this one?

>> Crystal Wolfrey: Yeah.

[ Chatter ]

>> Crystal Wolfrey: ... because a lot is changing in other support. So you should probably talk about that.

>> Terri Jarosik: So right now, I would say yes because what it is is the program officer is looking at the expertise of the mentor to ensure that you have the proper expertise to mentor that person in this research. So that is generally why they would want the other support submitted for the mentor.

>> Cynthia Dwyer: Okay. Carolina asked, "Do grant management specialists want to receive notifications for changes in effort over 25 percent for investigators that are not listed on the notice of award?"

>> Crystal Wolfrey: No, we do not. That's a great question. I think ... post award session. So that policy only applies to key personnel named in the notice of award. So the principal investigators are always named as key, but everybody else, that would have to be named in a term of award. So we don't want it for everyone. Even though I know everybody is key to your investigator, it's only the people that we designated as key in the award notice.

>> Sean Hines: We should've hooked that one actually and told them that you can't get the answer until tomorrow's post award talk.

>> Cynthia Dwyer: All right, and Christine said, her question has to do with delayed start, "What is the time period for immediate refer to?" She said, "Activities start within the first month or the 6 months or within the first year. What's the time period from either?"

>> Crystal Wolfrey: So that's interesting because I think ... I'll start, and then, Terri, you could do ... because we treat it differently, right?

>> Terri Jarosik: Yup.

>> Crystal Wolfrey: So it's going to start within the first month or two. We would probably hold that award until that was ready to go, and you could get us IRB approval because that's a pretty quick turnaround, and we could hold that award. What I usually advise our staff is if it's going to be 6 months from now that it's better to get an award out so you could get started working on the work on what you can do. Maybe if you have a study ready or if you have other things ready, and then we could do ... we could release the funds if the IRB comes through. So a lot of that answer from our perspective is what is there to do in the grant while you're waiting for that human subjects work to start. So that's a big part of the question. Terri, I think you have a different answer though, don't you?

>> Terri Jarosik: Yeah, so we also have, depending on what time of year it is. So if it's towards the end of the year, absolutely. We're going to go ahead and award it with that one restriction. However, there are several ICs that I know of that will hold that. As long as they'll be able to get that award out by the end of the fiscal year, they will hold it until you get the IRB approval if the work for the other protocol is going to start within that first year. Otherwise, if it's going to start in the next year in any out year, we would award with the one IRB, and then restrict future years until we get the second IRB.

>> Crystal Wolfrey: So again, it's very IC specific. So talk to your grant specialist. We at NCI do about 8,000 a grants a year. I can't have people holding just until the end of September or we would never survive that. I do see that there's a whole lot of questions on other support, and the reason I'm hedging on this is that NIH is going through a massive change in what's going to be reported. Well, they're going to redescribe what's going to be reported in other support and in the NIH Grants Policy Statement that's coming out soon. I think there might even be a session talking about this in the NIH update. So those questions we could answer now, but things are changing, and so I think we should probably wait until those policy changes come out, but if you haven't or you didn't this morning or whenever it is, go to the NIH update because I think they have a big section on the changes that are coming in reported other support. So, Cynthia, do you want to do one more question ...

[ Chatter ]

>> Sean Hines: Yeah, I was going to say let's do one more.

>> Cynthia Dwyer: Okay. Let's see. My goodness, there's so many good ones. "If the subcontract was delayed being executed, are they entitled for a carryforward balance request?"

>> Crystal Wolfrey: Okay, that's a post award question.

>> Cynthia Dwyer: We're not going to cover this. You need to attend ...

>> Crystal Wolfrey: We're covering ... We have a whole section tomorrow on post awards. That's the perfect time for it.

>> Cynthia Dwyer: Yes, tomorrow come back. Okay. Give me another one. Let me choose another one. I'm sorry, there are just so many just really great ones. Let's see. Okay. I'm not sure, this might take more time than you have, but can you speak to the recent change removing the requirement for a single IRB plan at the time of submission?

>> Crystal Wolfrey: Well that change that came out was specifically with regard to COVID studies, right?

>> Cynthia Dwyer: Okay. It says that change was made relatively recently in forms F, but much of the guidance does not yet reflect that change such as the NIH single IRB website, and maybe, I don't know if you want to address this, we have a whole day on Friday as well on changes that are related to human subjects and IRBs and so forth so ...

>> Crystal Wolfrey: I think that would be great because I think that question was perfect for that, and I'm not trying to put it off. There was a notice that came out about COVID research and changing from the single IRB, but I don't remember it off the top of my head. Terri, I don't know if you do or not, but if you don't get an answer to that question, go to a booth or Cynthia, can we save these questions and maybe try ...

>> Cynthia Dwyer: Yes, absolutely. Yes.

>> Crystal Wolfrey: Perfect. We can maybe post an FAQ type thing. That would be great.

>> Cynthia Dwyer: Okay.

>> Sean Hines: All right.

>> Crystal Wolfrey: Good. So let's move on because we're down to 10 minutes. This goes so fast so ...

>> Cynthia Dwyer: Eight minutes. Eight minutes and counting.

>> Crystal Wolfrey: Eight minutes, my goodness.

>> Sean Hines: All right. So we're going to jump into the rest here. So changes prior to award. So as everyone knows, that's been a part of this again in advance, so 9 months is going to happen between the submission application and the NIH making an award. So during those 9 months, a lot of stuff can go on. So we're just going to talk about it. Purely hypothetical here. PI on application is reviewed but not awarded has moved to a non-US organization and wants to take his or her grant with them. So is that even possible? So throw into chat, yes, no? What do you guys think?

>> Cynthia Dwyer: All right. For the most ... Well, I don't know. It's about 50/50. It is all over. Some are saying it depends, and I would say close to 50/50 with a few it depends thrown in.

>> Sean Hines: The NIH answer, it depends. So can a grant transfer? Yes, but it's complicated. So that's the it depends part. So, one, it needs to be permitted by the FOA. So obviously you want to start off with what you applied for in the first place, and, Terri, thank you for that add in. So the grant still needs to be relinquished by the original applicant. The prior approval requirement, so there's change of recipient organization and adding in a foreign component here. So there are a couple of things that are coming into play here. So you need to consider the scope of the originally submitted application, and the last piece of this which is an important one is it has to go through the IC's council for review and approval. So obviously this steps above that. You're talking you're interacting with the grants manager. You're interacting with the program official. There's a lot going on there that you need to make sure that you're covering those bases on. So the above is being considered prior to making competing award, but also all of those steps can also be considered in a post awards standpoint too where you've already had an award made, and now, you're moving in the middle of a project period. So my recommendation there is the sooner the better to have that discussion. So that way, you can start that conversation as soon as possible.

>> Crystal Wolfrey: Yeah, definitely because boards only meet three times a year. So we need to get those to the board as soon as we can.

>> Sean Hines: And so we're going to jump into another situation. Again, these are all real. So institution A has submitted a multi PI application. One of the PIs is located as a sub-award institution. When NIH contacts you to negotiate the award, the contact PI tells the other PI ... tells you that the other PI has left the organization and is now working at an NIH institute. So here's what conversation could sound like. Hello, this is Sean Hine, NIH grants management specialist. I'm calling regarding RO1CA2001. Dr. Finkle is the contact PI on this multi PI grant.

>> Crystal Wolfrey: Great to hear from you. I'm not sure what you're calling about, but I wanted to let you know that we've had a rather big change occur on this grant. Dr. Swanson, one of the grant's PIs recently accepted a position at the NIH.

>> Sean Hines: That is a big change. So I'm glad I randomly reached out.

>> Crystal Wolfrey: Yes, me as well. I was hoping to discuss our options with you. We would really like to keep Dr. Swanson on this grant as a PI. Is that even possible?

>> Sean Hines: Unfortunately, there's a lot of rules in place here when an NIH policy prohibits a federal employee from being a PI on the grant. We do have other options that we probably can kick around though if the plan is to keep Dr. Swanson on the grant.

>> Crystal Wolfrey: Yeah? What would that be? What would be some of those options?

>> Sean Hines: Well, we could consider converting this grant to a cooperative agreement for instance. Dr. Swanson's duties and responsibilities could be specifically identified and then listed as a term in the award. It would have to be something that would have to have all involved. We need to agree to the grant's management, obviously me, program staff and also my chief GMO and of course you as the applicant.

>> Crystal Wolfrey: That's interesting. So would that change the scope of the grant changing it to a cooperative agreement?

>> Sean Hines: Not necessarily. you would need to submit a new PI structure since Dr. Swanson can no longer be the PI. However, the research plan as stated and reviewed could still be pursued here.

>> Crystal Wolfrey: That's cool. So it sounds like he could still be involved just not as the named PI. Could we still pay him?

>> Sean Hines: No. As a federal employee, he would not be allowed to receive support from this grant. So we would need to discuss the impact to the budget on the budget as well. I'd recommend at this point though that we reconvene with the current PI team, and let's set up a time to discuss further with the NIH program official.

>> Crystal Wolfrey: Wow, that's great. Thank you so much for this discussion. It sounds like we do have some options. NIH does have a lot of policies to work with however. It's great to see how some of these same policies can actually work for us.

>> Sean Hines: All right. End of scene. So just a few things on that that came up in that particular one. So there's a lot of options that you can explore, and that's where you should definitely be reaching out to your NIH branch management staff and your program official, and not necessarily immediately think, "Okay, well, too bad. I guess we have no choice." So there's things that we can definitely explore with you depending on your situation.

>> Crystal Wolfrey: New applicant. So, Sean, I've got a question for you. NIH funds thousands of grants every fiscal year. There's numerous awards that go out to applicants that have never received NIH funding before. Is there anything special to NIH that awarding ICs that they consider?

>> Sean Hines: I'm actually pretty glad you asked that, Crystal. There are several things that should be considered.

>> Crystal Wolfrey: Yeah? Well, do tell. I'm sure our audience would love to hear about it.

>> Sean Hines: Well, first off, it is a requirement of an NIH awarding IC to not only consider the grant application but also to evaluate the applicant themselves. If an organization has not previously received any funding, we may not have a solid understanding or history of the applicant's ability to manage a federal fund. So that's a pretty big deal to us.

>> Crystal Wolfrey: Yeah, that makes sense. We do need to be sure we're spending tax dollars well. So what would you consider in evaluating their financial capability?

>> Sean Hines: Well, do you have 30 more minutes for me to sit down and talk?

>> Crystal Wolfrey: I have exactly two.

>> Sean Hines: There are a few things. One, NIH would want to consider the financial stability of the organization specifically by obtaining some financial record. So applicants shouldn't be surprised if we reached out and ask them a little bit more about their money. We would like to obtain audit reports to learn to see if there's any recent finding, and if they did have something, how did they address it. We'd also want to see the organizational structure to see the checks and balances in place. It would be concerning for instance to see that if they had one person pretty much doing all of the stuff, incurring the bills, paying the bills and speaking for the bills. So we'd want to talk to them about that, and then lastly we'd look to obtain necessary policy procedures that are in place to manage the federal funds, a chart of accounts and how they develop that with directs and indirects and so on.

>> Crystal Wolfrey: Wow, NIH is pretty serious about ensuring that applicants are well positioned to be NIH grant award recipients. Could an organization that's new contact NIH to discuss if they have things in place or what else they need to put in place?

>> Sean Hines: Absolutely. There's no other question we like more than this. so applicants should definitely feel free to contact the grants management offices. In some cases the ICs can conduct an on-site assistance review so we can discuss in more detail. Hopefully, we'll be able to travel here again to actually conduct some of those on-site meetings.

>> Crystal Wolfrey: Absolutely, Sean. Great. Thank you, Sean. That was a lot of information.

>> Cynthia Dwyer: And, Sean and Crystal and Terri, you have 1 minute to wrap this up. I'm sorry. We've had such great questions, but our time is almost over, and we need to end promptly.

>> Crystal Wolfrey: Okay. We will race through that. The slide that Sean just put through covered some of that stuff, and we can definitely post that little sort of script that we did if people are interested in that. So just a take-home message, takeaway message, communication is important, lots of solutions. We are a culture of yes, not no, and we would like you to use that reaching out to us in the future, and I think that's it. We're out of time. Slides are up. There's lots of resources and our contact information.

>> Cynthia Dwyer: Thank you.

>> Sean Hines: So much.

>> Cynthia Dwyer: This session is now ending.

>> Crystal Wolfrey: Thank you, guys, so much.

>> Terri Jarosik: Thank you.