Roles, Responsibilities, and Partnerships Throughout the Grant Life Cycle

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Dee Doherty: Thank you, Cynthia. Yes, so I'm Dee Doherty. I'm the Deputy Grants Management Officer, and as of today, I'm the Acting Chief Grants Management Officer for NIDDK. So I will lead you through a conversation, and then Dr. John Connaughton will be our next. John, do you want to introduce yourself?

John Connaughton: Yes, thank you. I'm John Connaughton. I'm the chief of the Scientific Review Branch at the NIDDK. Thank you for joining this conference.

Dee Doherty: Gracie.

Tracy Rankin: Hi, everybody. Great to see the representation flying in the chat. I'm Tracy Rankin. I am a program director within the Division of Kidney, Urologic & Hematologic Diseases within NIDDK.

Dee Doherty: And Natasha.

Natasha Loveless: Hi, I'm Natasha Loveless, and I am a Senior Grants Management Specialist at NIDDK.

Dee Doherty: So this presentation is, Where Do I Turn When I Need Help or Advice From the NIH? So what everyone needs to understand is that we all work together: Program Review, Grants Management. Grants Management talks to review about the funding opportunity announcements. Program actually starts the funding opportunity announcements out. They speak to review. There's a lot of people that are involved in the actual process, and today, we're going to introduce you to each one of those areas so that you can gain an understanding of what each one of them does. So the first area that we're going to explore is the Review Branch. So, John?

John Connaughton: Thank you. So I'm just going to go through some of the roles of the Scientific Review Officer at the NIH. So the Scientific Review Officer, or SRO, recruits reviewers and assigns applications to those reviewers for peer review. We manage the overall execution of grant review meeting as well as managing conflicts of interest during the meeting and actually before the meeting. We prepare summary statements, which is the key definitive outcome of peer review for your application. The face page of that document will have the score and, in some cases, percentile, and we provide that information to the NIH Institutes and Centers. The NIH does split peer review into two domains. One is the Center for Scientific Review that review the bulk of application, investigator initiated R01 grants submitted to the NIH. The ICs, or the Institutes and Centers, like NIDDK, review applications primarily submitted to funding opportunity announcements issued by NIDDK. Okay. So before you submit your application, I think the one thing that I want to stress, and you may have heard earlier, but I'll say it again, is I strongly recommend that you reach out to a program director before you submit or think about submitting an application to the NIH for possible funding. They'll be able to address issues of, "Is my science appropriate for this funding opportunity announcement? Does it fit within the scientific mission of your institute?" And that will really help you avoid wasting a bit of time preparing an application that doesn't quite fit. The Scientific Review Officer, okay, so where are we found? In the bottom of every funding opportunity announcement, there's a Section VII, Agency Contacts. There will be a peer review contact. There will be a scientific contact, i.e., the program director. There'll also be a Grants Management staff person assigned to that forward as well. After you've submitted your application, your Scientific Review Officer will ultimately have applications assigned to him or her for review. This information can be found in the eRA Commons when you log in, and once the application is in, post-submission materials are allowed up to 30 days before the review meeting, and there's NIH policy governing what can and cannot be submitted post-review. Applications are indeed expected to be complete upon submission. So after the review meeting, the SRO will complete the summary statement. Scores will be released generally within 48 hours of the meeting. Summary statements can take 4 to 6 weeks, depending on the workload of the SRO. Prior to getting your summary statement, I suggest that you not contact your program director. They would be a contact after the review meeting. If you contact me as an SRO, your first question is, "Am I going to be funded?" and the SRO will have absolutely no idea. So wait until you get your summary statement. Your program director will be indicated on that document, and they can be very helpful. Reach out to them. Schedule a call and go over your results. Okay. So how are you going to find an SRO? Okay. Well, first of all, you can go to the Center for Scientific Review study sections. It'll be listed there. The CSR has a referral tool for directing your application to various study sections based on the science contained within the application, and study section rosters are, of course, published by the NIH. Do not think about contacting a reviewer that's listed on a standing or special emphasis panel. Applicants cannot contact reviewers. So I think with that, I will turn over the presentation to Dr. Tracy Rankin.

Dee Doherty: So, John .. .

Tracy Rankin: Hi, everybody. Oh.

Dee Doherty: John, there were a couple of questions in the Q&A for you.

John Connaughton: Okay.

Dee Doherty: One of them is, are the additional docs - specifically the multi-PI management plan - is it peer reviewed?

John Connaughton: Yeah, so that is part of the extended review criteria, so that if you have a multi-PI application, the multi-PI leadership plan will be evaluated by the reviewers.

Dee Doherty: Right. And the second question is, what would the reason be for contacting your SRO when your grant is under review?

John Connaughton: So prior to the review meeting, if you're not sure that the application is the best fit for the review panel that's going to evaluate the application, and this would be for R01 investigator-initiated grants submitted to the parent program announcement and reviewed at CSR, you can contact the SRO and discuss whether or not the application is being reviewed by the right committee. For applications that come in for IC review through an IC-issued funding opportunity announcement, your application will be in the right meeting. But that would be another reason, if you have questions about how the applications are being reviewed, you can certainly reach out to the SRO.

Dee Doherty: Thank you.

Tracy Rankin: Okay.

Dee Doherty: You're good to go, Dr. Rankin.

Tracy Rankin: Got it. So, DeRon, did you launch the poll? Now, everybody has had the whole time to think about the answer this question. It's not very hard. But, yeah, please go in and address the question. We'll just give people a few minutes to answer yes or no, and we'll see where folks stand, and then we'll go. Ah. Interesting, so a significant proportion say yes, and that's excellent. But then a not too insignificant portion say no, so hopefully we can provide a little bit more information about what we do here in program, how we fit in the larger scheme of things and how you can find out who your program officers could be with some of the resources that we have available here at NIH. So we can move that slide. Ah! Sorry. Here we go. So program, it is probability the most amorphous role here at NIH in the sense that it's clear Scientific Review Officers. They're going manage the review. You'll hear from Grants Management. They're all about the money and making sure nobody goes to jail and spending the money .. . Program is in this space sort of in between where we can help you before you submit an application, as Dr. Connaughton indicated, in terms of determining the best scientific home here at NIH. We have 27 sift institutes and centers. They cover the breadth of science and disease entities that affect the public across the world. And each one of those institutes has a specific mission. And your science will undoubtedly fit into one of those institutes. And our job here in program is to help you find that best scientific home, to find the best pathway for your particular project. Is it a clinical project? Is it more of a basic science project? Is it really not fitting into any of these easy buckets? Are there special opportunities for my work that are out there that I can consider for applying for support? We can also help with the sticky wickets of navigating the application process. We do attend peer review strictly as observers. And there are subsequent sessions in the NIH Regional Conference here that you're attending that really dive into the nitty-gritties of peer review and what happens during a peer review meeting, so I would encourage you all to attend the mock study section next .. . I think that's tomorrow. But we're there as observers in the study sections where applications assigned to us are reviewed. Now, each program officer at NIH has what we call a portfolio of applications and awards germane to the scientific expertise of that individual. In my case, I have a portfolio of R01s that's focused on urologic aspects of disease in the prostate and bladder, but I also have career development applications and awards in my portfolio, but we've sort of .. . A lot of the portfolios are divided along these lines of science, and we attend study sections where our applications are reviewed, strictly as observers, to listen: listen to the discussion, listen to the entire review of the applications in our domain. Now, as Dr. Connaughton indicated, once you hit submit on an application, you don't call me as a program officer for anything related to the application. That's really .. . I'm just going to redirect you to the Scientific Review Officer. If you have additional materials, or if you have questions about the review process, that's not my domain. However, as soon as your review is completed and you get a score, then absolutely feel free to contact me, reach out to talk about the next steps. These are actually outlined in the summary statement in terms of what happens next after the review, after you receive a score because now it's all going to be about well, what does the score mean? What does this mean in terms of receiving support? Is this something I really have to .. . Is this an application I have to revise and resubmit if I'm going to be competitive for support? So that's going to be the next phase of interaction with program officers. And if you are fortunate enough to get an award, we are going to be friends for the duration of that award, so to speak. You are going to be updating me on the progress every year in the terms of your progress report for how you're going on your project and what progress you're making, what are your findings? And we will certainly stay in touch as the award comes to a close to talk about whether this is something you should renew as a competitive renewal project, or if there are additional opportunities in making sure that the awards close out if you decide not to pursue a renewal or a new award is conducted as it should be, in terms of policy. But we will be monitoring your progress, making sure you're compliant with all the policies that apply to your particular award and also what we really like to do is talk to you about your science and how the project is going and the results you're getting. So I think that brings us to the when. I think I've already touched on this when we were talking about the circle. Before you submit, absolutely call a program officer, make contact with a program officer to talk about your project and the right fit for their particular portfolio and institute. We can also talk about some of these, again, application logistics. Particularly, if you have a big project in mind, there are policies and procedures you need to get through to make sure we accept that application. And then after the summary statement, a large part of my day is spent with individuals after they receive their summary statement to do sort of a postmortem on the review and things they might want to consider in terms of next steps: revise, resubmit, prospects for funding, timeline for such a decision. And I've already touched on what happens during the award. Everything, we hope, goes perfectly, but stuff happens. I find it interesting, natural disasters is here at the top of the list. Those used to be rare. Now, not so. But if such an incident would recall you in the middle of an award period, certainly, program officers can be quite integral to helping you find resources to recover from such an incident, in terms of disruption to your research program. Most recently, COVID was a huge, huge disruption to the research enterprise, and program officers were integral in trying to help awardees and applicants navigate those disruptions. And I think that is it. A brief synopsis of what POs do. I will turn it over -- back over to Dee and her team to talk about what Grants Management is up to.

Dee Doherty: And, Dr. Rankin, we do have several questions in the chat for you. I think we can just kind of summarize some of them, but one of them is, "POs are often very busy and don't have time to chat and don't respond to e-mails."

Tracy Rankin: Oh, yes.

Dee Doherty: "What do we do when we need help prior to submission, but POs are unresponsive?"

Tracy Rankin: Ah! I've actually gotten this question a lot. First, you guys aren't talking to me, so I will put a plug in for my colleagues here in DK and my divisions particularly. Yeah, we've got a lot going on for sure. But bear in mind, everybody has a supervisor.

Dee Doherty: Right.

Tracy Rankin: If you have done due diligence, you have reached out by e-mail, you've left voicemails, you've done all of the steps that we've advised you to take to get in contact with a PO and you're not getting anywhere, sometimes just a quick ping to that person's supervisor. The organizational structure of every institute is on each institute's website. Can often get folks to move. Sometimes it is a matter of timing. I always say the best time to try and reach out to us is when things tend to be a little slower, which is the fall - September, October. The best submission dates, I tell people, are the October and November ones. One, because our budget year closes the end of September, so systems are down. We are not making awards. There's not a whole lot of activity going on in terms of reviewing progress reports and getting awards out, and it's a good time to try and make contact with a program officer. Another good place is at scientific meetings. Please look at who's going to these large scientific meetings. I attend just a variety of meetings relevant to my portfolio. My colleagues do as well. Those are great places to make the face-to-face contact with a program officer. Many societies have sort of a "meet the program officer" session, but do not give up, and again, don't take the unresponsiveness as that we're not interested in your science. Just make sure you can find their supervisor and get them .. . get your e-mail back to the top of the inbox.

Dee Doherty: So there's a couple of other questions, but I think some of this we can come back to, but there's one more I really want to ask you. Is it appropriate to contact several POs to explore the fit of the proposal with the IC admission and strategic plans?

Tracy Rankin: Absolutely. There are some areas that cross mission interests. In my world, a lot of it has to do with hypertension. Hypertension is a complex process. There's some aspects of hypertension regulation are found that are kidney specific we would support. Other aspects would be supported by the Heart, Lung and Blood Institute for instance. And it is absolutely appropriate to reach out to several program officers if the topic is quite broad to gauge their interest and fit. Again, our goal is to find the best scientific home for you, so you want to find a place that is interested in your science but also, once there's an award, that can really work with you to promote your science and ensure that you have scientific continuity going forward.

Dee Doherty: Right. Okay. So we will come back to questions. I don't think Grants Management will take too awful long, so I'm going to go ahead with Grants Management to kick it off. What is Grants Management? We make the award. We manage the grant award after it's been awarded. The Grants Management .. . The Chief Grants Management Officer of each institute is really the only official at NIH that can obligate the funds for an award. So let's talk about .. . There's two different kinds of Grants Management officials. There's the Chief Grants Management Officer, which the chief is the boss of the office. That boss will then delegate authority to the specialists, which the specialists are the people that .. . I mean, they're the ones who do the work. They're the ones who actually get all the documents together. So the Grants Management Officer, the chief, is the authorized personnel that delegates authority to the Grants Management Specialist. That's the first responsibility. Second responsibility is it's the Chief Grants Management Officer that has to ensure and make sure that all business management requirements for each institute is adhered to, so we're like the policy policemen. And I hate to say that, but that's kind of what we are. We assist in the evaluation of applications for administrative content if there is any kind of issues that the Grant Specialists need to actually have a policy interpreted for them. We monitor the Grants Administrator and fiscal aspects. We talk to the budget office a lot. We are involved in decisions when measures need to be taken in order to protect the public interest. We assure compliance with the federal laws and NIH administrative policies and procedures. And then like I said, the Chief Grants Management Officer is the NIH official authorized to obligate the NIH to the expenditure of funds or to change funding amounts, budget, project period dates or other terms and conditions of the grant award. So a lot of people don't understand what the Grants Management Officer is versus the Grants Management Specialist, so there you have. The Grants Management Officer is the boss of the office. We're the bossy ones. We're the ones that tell everybody what to do. And then the specialists will take over with what we want them to do. So I'm going to let Natasha tell you all about her job and what she does and how she helps me to ensure that we do everything right.

Natasha Loveless: Thank you, Dee. So, yes, as a Grants Management Specialist, we have been given authorization to release the field awards. So we are kind of the last people to see your award, and we push it out to you. So we assure that they're compliant with the federal laws and NIH policy, and we're analyzing your grants prior to the awards. We're making sure that everything is okay with your application. If there are anything missing, you will see the e-mail from us to get that information. We prepare the award for release by preparing all the budgets and official file documentation that is needed. So we're going through your budget and making sure that your line items are allowable according to grant policy, and then if there are any cuts, we are making those cuts from your budget. And then, again, anything that is needed in the just-in-time, what have you, we are putting in an official file. We also provide technical assistance, interpret NIH policy and institute procedures. If you have any issues with uploading or just any problems, you can e-mail us, and we will try to help you with that. For the .. . I'm sorry. For the Grants Management Specialist, sorry, when to contact the grant specialist, so just like Dr. Rankin said that the Grants Management Specialist, we also have portfolios, and so therefore, we are .. . We have specific grants, and so we are able to work on your grant. So when your contact, you have questions, we have intimate knowledge about that because for the most part, we're staying with your grant year to year. Sometimes it changes, and we let you know that, but we have that information to let you know. So when to contact us. So pre-award requests, that's our just-in-time, and that's when we ask for your other support, IRB approvals, FMA, what have you, answers to summary statements. A lot of times, you will receive an automated e-mail way ahead of when we contact you, and usually when we contact you, we're giving you more of a detailed request. So it'll be more tailored more to your particular grant. Also, if there's any delays in your paperwork, there's a lot of different deadlines that you have to meet. If there's something going on, just let us know, just e-mail us that this is what's happening, so we can know. And then to discuss financial and grant administration issues, any budget questions. A lot of time when you receive that notice of award and if you start reading through, and you may see cuts or what have you, then you may have questions about your budget, so just e-mail us. If you're adding a foreign component, it's very important that you let us know that ahead of time because a lot of times, those things require State Department clearance, so we really will need that information to help you get in paperwork that needs to continue that work. Questions about the budget or other support, like I said, I really encourage that when you receive your notice of award, to read through the whole thing. There's so much information on there, and things that are specific to your grant, so you'll see a term .. . There might be a special term in there that you need to record or something to send back, but you just want to make sure you go through that, and then you'll be able to see, "Okay, this is what I need to do for this year and the years coming." If there's any clarification or questions about the policy or something that you may be curious about or you disagree with, you can always again e-mail us because we are interpreting that policy to your grants. So another reason to contact Grants Management is prior approvals, and these are approvals that are needed from NIH before you continue a particular action. So a lot of times you can see in the Grants Policy Statement that there's a list of all of the barriers of prior approvals, and you'll need to send that to us. So common ones are change of scope, reducing PI effort by 25 percent or more, going from a single PI to a multi-PI. Also, if you are transferring to a new institution, you really need to know these things ahead of time, so there won't be any delays in your award, and sometimes certain actions may take more time than others. Also, if you have a carryover of unobligated funds from a previous budget period to a subsequent budget period -this doesn't occur for all grants, but some grants, like clinical grants and clinical trials - you may need prior approval before you're able to use those funds. Okay. And I also want to stress that when you are sending us information for the official file that we need that from a signing official. Oftentimes, we are talking to PIs or program is talking to PIs and may e-mail information, and then we might have to turn around and say, "Thank you, but we have to get a concurrence or information from the business official," and the reason why is because we have to put it in the official file. And then lastly, if there are questions that your business office is not sure of, or they have a question, you can always e-mail us, and we will try to answer as best as possible, but if not, we will direct you to the proper person. Thank you, and I'll send it back over to Dee.

Dee Doherty: Thank you, Natasha. So the last few slides on here are just general websites, helpful websites that you can go out, and you can look up things on. There's the coronavirus 2019 information out there, information on electronic submissions, just going through a few of them, "All About Grants" podcast. OER puts out an awful lot of helpful information, who can apply for funding? So you can continue .. . These last few slides are just that. They're just nothing but additional resources. I want to be sure to give us enough time to actually answer some live questions, and then, yes, we talk in federal speak. There's a lot of acronyms out there. NOAs and OPERA and CSR and RPGs, and if you just don't understand exactly what we're talking about, all you need to do is ask us. I started my career out in the grantee institutions, and so I understand that there's .. . We all speak a different language, and so at my institute, a lot of times people pull on my knowledge from the grantee organizations in order to be able to make sure that they're speaking the right language to you. So if you have questions, you can always pick up the phone for one of the NIH officers and ask them the question, ask them, "How do we do something?" So I wanted to give that time back. We do have a lot of questions in the Q&A. We probably won't have a whole lot of time to go back through those, but we can take a look at what was actually recorded, and we can send responses at a later time also, but right now, I'd like to turn it over for questions.

Tracy Rankin: There is a lot going on in the Q&A. I'm trying to type some answers as I go.

Cynthia Dwyer: Hi, this is Cynthia. So there were a couple that were upvoted. As you can tell, I'm still having voice issues, but I've got one for Dr. Connaughton. It said, "How are peer reviewers selected? Is there a specific pool of reviewers, and is there a criteria?" And I know NIH has got a program as they search for new reviewers. Is there anything you can share on that with our audience?

John Connaughton: Yes. So the pool of reviewers would encompass professors, associate professors and assistant professors with appropriate scientific expertise to evaluate the impact of an application. So there are standing study sections that have members that have been appointed for 4 to 6 years, and then there are temp .. . There are members that are appointed to special emphasis panels that are convened to review applications submitted through a specific funding opportunity announcement such as an RFA or a PAR. The SRO in particular will evaluate the science in the application and make the determination of what expertise is needed to review that application. We have a database called Impact 2 that lists essentially everyone that submitted a grant to the NIH is listed in that database. We use information that we've gleaned from attending scientific meetings and conferences and our own knowledge of individual fields. There is .. . Both CSR and NIDDK have a link where you can .. . a new reviewer can apply to participate on a CSR study section, or you can go to the NIDDK review website and upload information about you, your biosketch, and you might be selected for a NIDDK panel or a CSR panel depending on the needs of that panel and the applications being reviewed. I hope that helps.

Dee Doherty: So, Cynthia, can I just jump in one question? One question says, "Is the Grants Management Specialist also a scientist?" Can I just say heck no? We leave the science to the scientists. The Grants Management Specialist and the Grants Management Officer usually are very administrative. Now, I'm sure there are some people that have come from maybe a scientific background that have become specialists, but generally, we leave the science to the scientists. That's the SROs and the POs, and we let them answer those questions. If you ever have a question about the money side of the house, then give us a call. That's us.

Cynthia Dwyer: Great. Thanks. I think we could take one more question if it's a pretty quick response. So I'm going to give this one to Dr. Rankin, and it's really just a clarification, I think, but is it .. . Well, you already answered is it appropriate to contact several POs, but can you give some guidance to our audience about when is the best time to contact you as a program officer. What stage are they in the development of their research?

Tracy Rankin: As early as possible. I like to talk to people at a minimum 12 weeks before they are planning to submit an application. And when I set up a call for pre-application consult or whatever you want to call it, I will ask you for a draft at specific aim, so I get a sense of your project and science, your biosketch and if it's a career development award, I do ask what you had in mind in terms of career development activity. So if it's just an R01, it's those two pieces, so the project should be far along that you've got a draft at a specific aim. Doesn't have to be perfect, pristine, but certainly give us enough information to help you, again, make a determination as to whether it would be in our mission interest at the IC that we're working at, and then the biosketch helps me understand who you are, and the earlier you contact me, the easier for me to give you actionable advice with respect the application and the proposal, certainly 2 weeks before a deadline is really almost impossible for me to provide such advice, so as early as you can.

Cynthia Dwyer: Thank you. Thank you , Dr. Rankin. All right. Well, that is going to wrap up the formal part of the presentation, and so I thank all of our presenters today and all of you for joining us.