America's Seed Fund: NIH's Small Business Program Webinar Transcript

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ADAM SORKIN: All righty, I think things are slowing down so-- and we're one past the hour, so let's go ahead and get started. Good afternoon and welcome everybody. I am Adam Sorkin from NIH SEED, and I'll be your moderator today. A quick bit of housekeeping, please, use the Q&A function to ask questions. We will address them after the presentation, but you can ask them at any time. And slides and recording will be available at our website, seed.nih.gov in about a week or so. And with that, I will introduce our speaker, Stephanie Fertig, Director at NIH Small Business Program, and let her take it away. All yours, Stephanie.

STEPHANIE FERTIG: Excellent. Thank you so much, Adam. And it's great to see everyone virtually here in the number of participants, particularly for this really important webinar on how to navigate the NIH small business grant opportunities. So today we're really going to be looking at a wide-- a lot of specific information around the small business programs, but you can find specific information on our small business program website. Again, we're going to go into a lot of information today, but that website is really an important resource for you to use as you're looking at some of the small business programs And some of these opportunities.

As Adam stated, the recording of this webinar as well as the materials are going to be made available on our small business program website, so that is another great resource that is on that website. So again, since I know some of you may have missed that, this will be available both the recording as well as the materials, the slide deck, will be available on the website about 7 days after this webinar. So definitely bookmark this website as a great place to start. Okay, so with that introduction, I really want to point out that the NIH is actually part of the broader Health and Human Services. And while the NIH is the largest component of Health and Human Services that has an SBIR and STTR program, FDA, CDC, ACL, and ARPA-H all have small business programs and are interested and eager to talk with companies that are developing products and technologies within their mission space. So I do encourage you to look at not just NIH, but these other components of Health and Human Services as well.

Now, really, at NIH, our mission can be summarized as turning discoveries into health. And we're really here to get those great innovations across the United States and get them into the hands of the patients, clinicians, caregivers, and researchers that need them. Now, these are congressionally mandated programs. We have about $1.4 billion of dedicated funding set aside from our extramural research budget. Now, this funding can be broken out in both the SBIR, Small Business Innovation Research, and STTR, Small Business Technology Transfer programs.

And during this webinar, we're going to talk a little bit about the differences between these two programs. But right now, what you should remember is they are two separate programs but they are very similar in scope and mission. One of the big benefits of NIH funding is that we're really working in this early-stage capital space, and we're one of the largest sources in the United States for small businesses. You can see we're in that proof of concept and research and development space there, when often right after a company is formed. This is free money. It's non-dilutive capital. It's not a loan. And many of our awardees are able to leverage the funding to attract partners and investors.

It's really important to note that unlike some of the other agencies that have an SBIR or STTR program, we utilize our program to support technologies that will go out, again, into the marketplace. We're generally not the final purchasers of the products that are developed through our small business programs.

So myth busting-- so one of the great things that I like to do in these webinars is bust some myths. So today, let's talk about this burst myth. And one of the myths that I hear is that it's easier or better for a company to just get investors and avoid all the work and time to apply for an NIH grant. And I really want to bust this myth. What we've found is that many investors really want to see that companies are using non-dilutive funding to de-risk and develop their technology and product before getting additional funding. So again, the small business program can help de-risk your technology and make the company more attractive to investors and strategic partners.

And a number of our companies have done just that. And we have a couple of examples here on this slide. But I want to point out that we have success stories all throughout the country, and you can read those success stories on our website. I picked these three success stories because oftentimes when individuals are thinking about the small business programs within the National Institutes of Health, you're thinking therapeutics and diagnostics. But we do so much more.

We do support for research tools, we certainly do support companies not just on the coasts, but in middle America, all throughout in both rural as well as cities. And finally, we do digital learning, we do digital technologies, digital health. We can support all of that. And one of the great success stories, not on this page, is a bicycle helmet as it helps prevent traumatic brain injury. So we can do both assistive technologies as well as preventive technologies. So again, take a look at the small business success stories, it's a great place to see the wide depth and breadth of things that we support.

So who's eligible? When I talk about small businesses, what are we talking about? Well, the eligibility criteria is set by the Small Business Administration and by the legislation. And so you can see we've bulleted out the small business criteria here. I'm not going to go into it in detail, but I'm just going to say that you have to be a US for-profit business that's considered small, 500 or fewer employees, and that it has individual ownership. And you can see the definition of what individual ownership means. Now, I'll tell you that most of the time when individuals are coming to us, they actually ask us questions around that individual ownership.

So I'd encourage you, if you have questions about whether or not you're considered to have individual ownership, please do go to the link that was popped into the webinar chat specifically on our eligibility criteria. You can find that on our website. And there is a Small Business Administration more detailed document that can help walk through different examples and help you determine whether or not you are considered to have individual ownership.

Now, it's important to note that eligibility is determined at the time of award, and applicants provide that information around eligibility through that funding agreement certification. Now, you'll also see that the work has to be done in the United States, and that's with few exceptions. We do recognize that there might be times where the work cannot be done in the US.

Maybe there's a small patient population. But for the most part, with few exceptions, the work has to be done in the United States. And it's important to note that those exceptions aren't things like it's cheaper to do outside the US or we've always worked with a specific partner. There really has to be a solid barrier where it cannot be done in the US in order for us to consider those exceptions. So I think the work that you're proposing within a small business grant really does need to be done within the United States. Now, these are phased programs, and this is part of the legislation.

These phases aren't clinical trials phases, that's an unfortunate similarity in the nomenclature. Phase I is a feasibility study, Phase II is full research and development. Now, we have a number of ways to enter into the program. We have the standard Phase I and Phase II, where you come, submit a Phase I, do that work, and then submit a Phase II. We also have something called a fast track, which combines the Phase I and Phase II into one proposal. And then we have the Direct-to-Phase II, which allows those companies that have already done the phase I work, maybe with funding outside of the SBIR, STTR program, allows them to go directly into a Phase II. Now, this is SBIR only, so STTRs can't go the Direct-to-Phase II route.

Regardless of how you get to a Phase II, we have a number of specific programs that allow you to bridge that gap between the Phase II and the commercial market partner or investor, because we do recognize that for some of the technologies that we're looking to develop through the small business program, you really do need additional time or money to get that done. And so the Competing Renewal Award, or Phase IIB, and the Commercialization Readiness Pilot, or CRP, can really help bridge those gaps for some companies. It's important to note that only some institutes and centers participate, and there are 24 different institutes and centers at the NIH that are part of the small business programs. Each of them utilizes the program a little bit differently, so it's important to know where you're likely to be assigned when you submit your application so that you can understand what programs and what things might be available.

One of the other big differences that the institutes and centers have is around budget. So we do utilize the SBA's guidelines, and you can see those budgetary guidelines here in the right-hand corner. However, we have a waiver from the Small Business Administration to exceed these budgets for selected topics, and individual institutes and centers do have a list of those topics online, And so I encourage you to take a look at those. And again, reach out if you have questions and talk with an institute or center if you have any questions about their specific program. And really, if you take nothing from the webinar, it's reach out and talk to us. And again, I'm going to say this a couple of times. If you're not sure who to talk to, we'll have contact information for our office, and hopefully, that's going to appear in the chat as well, but we're happy to help guide you to the next person that you should speak with. So here's another myth, it's much harder to get an NIH Fast-Track or Direct-to-Phase II, so don't even bother applying for those.

And I hear this a lot. And so it's important to note that while most new projects are Phase I, we support a lot of Fast-Tracks and Direct-to-Phase IIs. And we find that really, so there's three different paths to enter the program, but oftentimes the success rates are very similar when you're looking across the NIH. It's important to speak with a program officer to determine the best path for your project, if you have any questions or would like to discuss one of these three paths, having a conversation with a program officer can be very helpful.

Now, I talked about the importance of the website. That's where you can find all of our funding opportunities. And in fact, it's front and center on our website. That's how important that is. And you can see it in the Open Funding Opportunities button, and I've got a big green arrow pointing to where you're going to find that on our website. Now, it's important to note that the majority of our funding goes through what we call investigator-initiated grant applications. So what does that mean? That means that you have this great idea, that you and your company have identified a specific problem. And you have a great idea for how to solve that. You have that solution. And you're going to come to us, describe the problem and the solution.

So you are initiating, you've got that investigator-initiated idea. You are coming to us with that idea. So the vast majority of our funding does go through those investigator-initiated grant applications. And we have those standard receipt dates which is September 5th, January 5th, and April 5th. And if one of those receipt dates does fall on a holiday, it moves to the next business day. Now, when I say investigator-initiated grants, that comes in through our general omnibus solicitations. Those are our parent solicitations if you're used to the NIH nomenclature.

These omnibus solicitations are really, if you want to think about it, are open-topic solicitations. Now, we have two sets. We have one for SBIR and STTR. And we have some for clinical trials and non-clinical trials. Regardless, if you want to do SBIR or STTR, clinical trials or not, it's important to really read the program descriptions and research topic sections in the solicitation.

Again, each individual institute and center utilizes the program a little bit differently. And it's so important to understand where you're likely to be assigned and make sure that you're falling within the guidelines of that institute and center. Now, I know I keep saying that, but really, you're coming into the NIH and you're being assigned an institute and center. Now, there are targeted solicitations. There are specific grant solicitations. And you can see an example, and they come in a number of different flavors and different varieties and styles.

But one example I like to point out is the new Notice of Special Interest on Women's Health Research. Now, this is attached to the omnibus solicitation. So you would come and apply through the omnibus solicitation, but reference that Notice of Special Interest in the application. And there's a specific place in the forms to do that. There's also the SBIR contract solicitations. We do a limited number of contract solicitations every year, and there is a current SBIR, NIH, and CDC contract pre-solicitation. Now, we're not going to talk so much about contract solicitations in this presentation. We're going to be focusing on grants and cooperative agreements. But again, if you are interested, that pre-solicitation is out now as well. Now, another example of a specific Notice of Funding Opportunity is the Small Business Transition Grant for New Entrepreneurs.

We did a webinar specifically on this Notice of Funding Opportunity. So I'm not going to go into a lot of detail. But I think it's a good example of how there might be a specific funding opportunity that an individual might be interested in. So this is specifically to foster early career scientists transitioning to entrepreneurship. And it's expected that investigators are going to grow their entrepreneurial skill set while working in small businesses to develop promising technologies or products. I encourage you to take a look at the Small Business Transition Grant website, particularly that webinar. We did a whole hour and a half on that webinar so I really encourage you to take a look for more information and at the FAQs that are available.

And so again, I encourage you to do that. But again, this is a great example of a specific Notice of Funding Opportunity for new entrepreneurs.

But what's also important to note is that not all institutes and centers participate in each of these specific Notice of Funding Opportunities. So it's important to, again, know where you're likely to be assigned, where your research is likely to fit within the NIH and make sure that the institute or center that you're likely to be assigned would participate in the specific Notice of Funding Opportunity. So myth three, and this is a big one. I should apply to a specific program announcement because targeted funding opportunities have their own dedicated funding. Maybe.

Most NIH awards, as I said, are made to applications submitted to the omnibus, and those are the general solicitations. And specific funding opportunities don't necessarily have their own dedicated funding, their own dedicated review. It really depends on the funding opportunity. And so again, sometimes it's okay to come in through the omnibus solicitation if you don't have a specific funding opportunity that really meets what you're trying to do with your specific situation. So in fact, most NIH awards are made through those general omnibus solicitations. So we do often get questions about, well, what if I don't have a specific targeted funding opportunity for me? That's okay. So now you'll see there are specific Notice of Funding Opportunities for SBIR versus STTR.

So what are the big differences? Well, I like to state that the core difference between SBIR and STTR is that the SBIR permits partnering, while the STTR requires a nonprofit research institution partner, such as a university. The differences in policy that you see here on the slide around the work requirement and the principal investigator really stem from that core difference around partnering. But regardless if you do an SBIR or STTR, the award is always made to the small business. Now, one of the differences between our agency and other agencies is that really the scope of work that can be covered within an SBIR and STTR are identical. So it's not that there's a different stage, or it's really about this partnering requirement.

Myth four, and this is a big one. Since SBIR is a bigger program, I have a better chance of getting an SBIR awarded. And you might recall back in those early slides that the SBIR program is larger than the STTR program. But the size of the program doesn't always correlate with the chance of getting awarded. So for example, smaller programs like the STTR or some of the smaller NIH institutes may have far fewer applications. And so sometimes they actually have a higher success rate if you're looking at the number of applications and the number of grants that they award on a given year. So again, it's really important to not look at the size of the program and try to chase that money, but look at what does your company need to do? What are the opportunities for your company? What makes the most sense for your company? And then move forward with that project. Now, one of the other key things, decision points, is clinical trials.

It's really important to note that if you're doing human subjects, you need to look closely at the NIH definition of clinical trials. The NIH has a very broad definition of clinical trials. It's not based on the size of the trial, so one or more human subjects. You can have one human subject and be a clinical trial. Also, you can see, not based on risk. Risk is not mentioned at all in the clinical trial. It's about prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Nothing about risk. So low-risk trials, non-invasive trials, that's all possibly a clinical trial. All of that human subjects research could be a clinical trial. So it's very important to read the definition, utilize the decision tool, and determine if you're going to be a clinical trial.

Now, my project is low-risk and only has a few human subjects, so it's not a clinical trial. We hear this a lot, particularly when we're talking about devices. But again, it's not the same as the FDA's, that definition of NIH clinical trials, and it's not based on risk or the number of subjects. So it's important to know whether or not you are doing a clinical trial because not all NIH institutes accept applications with clinical trials. If you look at those clinical trials required Notice of Funding Opportunities, you will see that not all institutes and centers are on there. So it's so important to talk to a program officer before you apply.

Now, our program does utilize the NIH application and review process, And so we're going to talk about that a little bit, and the first step is submission. Now, you'll see from the time of application to the time of award can take about nine months. And that's a lengthy process, but that's really the time of application to the time where you receive money. But there are specific points along the way that you're going to get feedback. So let's talk about the submission and the review process. So first, you're going to need to use electronic submission. The big takeaway for this slide is there are required registrations. Please, start your registration process early. These are required, and unfortunately, our office cannot help circumvent or get around these required registrations. We can't make it move faster. It's always difficult to hear from new applicants. They've got that great application together, they've got it done, but gosh, there was a problem with the required registrations. One of the sticking points is with eRA Commons, you do need to have a Commons account for the company and all principal investigators. It's so important. So please do make sure that you have all the eRA Commons accounts that are required in order to submit. And this does use two-factor authentication, so you are going to have to use login.gov.

Myth six. So novice applicants to the program are almost never successful at getting awards. And I really do want to dispel this because about a third of our companies receiving SBIR and STTR awards are brand new to the program. We really do encourage new applicants. It's really important to us to support new applicants and those great new ideas, those great innovations that are coming into the program. And we have a number of resources to help you apply. We have application instructions, an annotated form set, sample applications, and there are also state resources through the Small Business Administration FAST program.

And you can find links to all of that online. I recognize that the application instructions are a significant read, however, they have a lot of great information in there and oftentimes can really be used to answer some of the questions that you may have as you're going through the application process. I'd also encourage you to take a look at our frequently asked questions on the website and also looking at those sample applications. Again, I do want to emphasize that there are state resources that you can also take advantage of when you're putting together your application. The Small Business Administration specifically funds groups within states to support new businesses to submit to the SBIR and STTR programs. I want to highlight some recent changes to the programs, although I have to admit these are about a year old now, but I'm going to still count them as recent. First, it's really important to note that the Data Management and Sharing Plan is a new component that is required for all SBIR and STTR applications.

Again, this has been around for about a year now. But it's so important to point out that this is a required element. And we do see a number of applications that do come to us that don't have this component. Now, I really want to emphasize, because we do get questions about this, that you are not required to share. You may retain the rights to data generated during the performance of award for up to 20 years after the award date. And you can certainly state that in the Data Management and Sharing Plan as your sharing plan. That is absolutely acceptable to reference and incorporate those data rights.

It's also important to note that NIH may make plans available, so plans shouldn't contain proprietary information. I encourage you to take a look at the Data Management and Sharing Plan instructions. There are frequently asked questions, again, on the website around the Data Management and Sharing Plan and what's part of an acceptable Data Management and Sharing Plan, including this really important component that you certainly can reference and incorporate the SBIR or STTR data rights within the Data Management and Sharing Plan.

The second component is under Facilities and Resources. You must describe the business environment and resources or how you will obtain them. As well as relevant intellectual property associated with the project. So here are some application tips. Please do build a solid team, in the spirit of the Olympics, this is a team sport, so it's important to build that really important team as you're going for the gold medal. You're trying to get on the podium and get that grant. Talk to people about your innovation. Be prepared to pivot if you're hearing feedback that indicates that you should do so. Read the Notice of Funding Opportunity very carefully. Review successful grant applications. I really want to emphasize that, sometimes it can be helpful to see, wait a minute, this is what a successful grant application looks like, particularly if this is your first one.

And after you've really read the Notice of Funding Opportunity and read the instructions, talk with a program officer if you have any additional questions. Follow those instructions. Make sure you read the review criteria, and we'll be talking a little bit about that later. And write a proposal that addresses those review criteria. Make it easy to read. Edit, proofread. Write for experts and non-experts. And let others read your application. And particularly this last one, get that feedback. Let others review your application. And finally, submit early. Days not hours. Submit early. It's always heartbreaking to hear from individuals who tried to submit, something happened, and unfortunately, they were unable to do so.

The most important piece of advice, though, is to talk to a program officer at least a month before the application deadline. So we have a list of SBIR program officers on the web. If you look at our website, you scroll down, there's a very nice building. Building 1 here at NIH, right under that, is the Institute and Center specific contacts. However, if you're not sure who to contact, you can always email us at SEEDinfo at NIH.gov. Another great resource is to use the research portfolio online reporting tools or report. So if you go to report.NIH.gov, you can go and see a database of the abstracts of all the SBIRs and STTRs that have been funded by NIH previously.

That can help you determine two things. One, what has been funded previously, so you can see who else is out there working in a different area. But two, you can also see specifically what institutes and centers that those different grant applications and grants were assigned. Now, you won't see full applications. Again, it's just the abstract, but it can be a really powerful resource. One of the great parts of the reporter tool is that is this matchmaker function. So you can pop your specific abstract into Matchmaker and find potential program officers, ICs, review panels. You see other individuals that are working in this area. It's a real powerful tool, and I encourage you to take a look at it if you haven't already done so.

Myth 7. And I think I hinted at this already but the myth is that you submit to a specific institute. So you need to choose your institute and to choose your study section. Applications are submitted to the NIH, and then they're assigned a specific institute and study section. You can request a specific institute or study section, but you don't have to. And I'm actually going to dissect this one step further. A study section may have multiple institutes, within that grants from grant applications for multiple institutes within that study section. So it's so important again, to know that when you're assigned an institute and when you're assigned a study section, some individuals think that if they change their institute, they'll change their study section or vice versa, but that's not necessarily the case.

And so again, and we'll talk a little bit about the review process shortly, but it's important to note that you're coming into the NIH and being assigned an institute. So let's talk about peer review, and again, the NIH Center for Scientific Review, it's going to assign and makes an assignment to an institute and a center and review group. So that review group component. So scientific review group is going to evaluate the scientific merit. And that's part of our 2 levels of peer review. So the first level is this peer review scientific review group. Now, the Center for Scientific Review does the vast majority of our reviews. And again, as I pointed out, that study sections, there aren't specific study sections assigned to only one institute. They are assigned around specific topics.

Now, if you look at the Notice of Funding Opportunity, you're going to see that we give you the review criteria. I'd like to say, that's the rubric, you're given the answers to the test, if you will. So this is a really important thing to take a look at in the Notice of Funding Opportunity, take a look at those review criteria. You're going to see scored review criteria and that's the five main scored review criteria. Significance, innovators, innovation, approach and environment.

And those are scored individually and score from 1-9. Then you have additional review criteria that are not scored individually. And you can see those here. And that includes for SBIRs and STTRs phase-specific considerations. And then you have additional review criteria which are not factored in the overall score. And I really want to highlight because I do get this question a lot. Budget and period of support, so how long the grant would be is not part of the scored review criteria. It does not impact the overall impact score. Now, when I talk about a score being from 1-9, 1 is the best, 9 is the worst. And when you do, if you are scored, you will get a score and it is multiplied by 10. So a 1 becomes a 10, a 5 becomes a 50, etc.

Now, each application has 3 assigned reviewers and there are those five review criteria that I said that reviewers score individually. But it's important to note that the overall impact score is determined after discussion and scoring by the scientific review group. So it's not just those 3 reviewers, it's the overall group that provides input and gives that average score that you see at the end. It's also important to know that 50% of the applications are not discussed but all applications receive reviewer comments. Now, it's also really important to note that unlike the standard. NIH R01 or some of the other programs that we have here at the NIH. The focus of the review criteria here is really on that commercialization. So the significance is really about a real problem in the commercialization potential. Innovation is really focused on competitive advantage. So again, read through the specific questions in the Notice of Funding Opportunities associated with each of these scored review criteria. It's really important to read those and write the application with those in mind.

So some common application problems that we see is around lack of significance, lack of innovation or advantage over other technologies or products. Team expertise and lacking in key areas. And this is particularly important if you have, say, a team that's very strong in engineering or strong in developing a product but maybe not so much in the specific area that they're trying to address. So maybe you're developing a great new technology to look at, say, Parkinson's disease or Alzheimer's disease.

You should really think about who on your team knows Parkinson's disease or Alzheimer's disease. It's not enough to just have engineers involved, you should really be thinking about how we are going to get whatever gaps in our expertise that we need. Unfamiliarity with the relevant published work, and that really goes hand in hand with team, your team should be aware of the relevant published work in this space. And then the approach is really important, and you can see that there are a number of common application problems around approach including the failure to consider potential pitfalls and alternatives, that's really important. As well as an unrealistically large amount of work proposed. And so think very carefully about the application.

And again, it's so important to have others read your application. Individuals who haven't been eating, sleeping, or breathing your great project for the past, maybe multiple years in many cases, have others read your application with that fresh set of eyes.

So myth eight, and this is a hard one. My application didn't get discussed or funded the first time, it's a waste of time to try again. And I really want to dispel that myth. Many companies are funded after incorporating the feedback into their resubmission. We do allow for resubmissions. Take that feedback, incorporate it into the resubmission. Read the summary statement very carefully, take a look at your application, see how you can make sure to address the concerns. Contact the program officer if you have questions about that summary statement, and then offer to be a peer reviewer. I always like to say when I'm in person, look to your left, look to your right, that's your peers.

Well, can't quite do that here but peer review is just that. It's peers. You can be a reviewer. And that is often the best way to really understand the review process. And you can contact us at seedinfo@nih.gov if you're not sure which study section might be the best place. But you can also go to the Center for Scientific Review's webpage and see a list of SBIR, STTR study sections. If there's one that fits your specific research experience, you can reach out to the scientific review officer directly with your CV and offer to be a peer reviewer.

If you don't believe me, please believe our successful entrepreneurs. And I have a great quote here from Dr. Carter, who has been part of the SBIR program and has served on study sections and has really been part of the process and seen it being unsuccessful, but then also taken that feedback and been successful in resubmissions.

The next step after getting the summary statement, you get that summary statement, if that summary statement is-- the program officers will review that summary statement, will take that into consideration, and then that goes to the advisory council, the application is then potentially approved for funding and then moves forward through just-in-time and through the due diligence process. Now, it's important to note that as part of that just-in-time process, where we're getting some of that additional information, things like the SBIR, STTR certification form, we do have a new requirement in that pre-award space, in that area that is from the SBIR, STTR Extension Act of 2022.

And that is a required disclosure of foreign affiliations or relationships to foreign countries. So it's important to review that required disclosure. Again, that's going to be part of that just-in-time process and is required for award. And it's important to note that disclosure is required for all owners and covered individuals, including senior personnel. Now, it's important to note that the SBIR, STTR criteria have not changed. Disclosure of foreign affiliations or relationships does not automatically disqualify an applicant. That's not what this is about. This is about disclosure of foreign affiliations and relationships. And again, this is a specific requirement from the SBIR, STTR Extension Act.

There is also now a new foreign risk assessment that is required prior to award. And again, this is also part of that SBIR, STTR Extension Act of 2022. It was put in place last year, but again, I am noting it because it is a change. And this is something that we at NIH are going to be assessing security risks, including cybersecurity practices, patent analysis, employee analysis, foreign ownership, financial ties, and obligations. And again, this is directly from the SBIR, STTR Extension Act of 2022.

NIH may decline to move forward with an award based on security risks, again, as required by the legislation. And so it's really important for applicants to consider if relationships may pose a security risk. Take a look at any relationships that may include foreign entities and make sure that you read through our Foreign Disclosure and Risk Management webpage.

There's more information about this new foreign risk assessment, the foreign disclosures, as well as case studies. And so we will make sure that that's something that you review and are aware of this new requirement. Myth nine. So one of the myths, as you can hear, there's a number of components after the study section that there's a component of not just the study section, but after that, there's the advisory council, there's review by the program officers. But I do often hear a myth that the scientific review group determines if you're going to get funded.

And that's just not true because the NIH staff use the score and summary statement when developing the funding plan. And the advisory council and board has access to the summary statement, but the final funding decision is made by the institutes and center director. And so it's important to note that while the summary statement and while the scientific review group is an important component of determining a funding plan, it is not the only component of a funding plan. So what's to say is that the scientific review group is not making funding decisions. And in fact, if you serve on a scientific review group, you'll find that the funding is not allowed. You can't say we want somebody to get funded because the scientific review group is really there to help, again, provide feedback and input to NIH.

Now, this is a really important myth, that the small business programs only provide money. And I really want to bust this myth because our office, again, the Small Business Education and Entrepreneurial Development Office, provides technical and business assistance, education, partnering and investment opportunities, and commercialization support to our recipients. And so there's a couple of ways that we do this. First, there's technical and business assistance. And it's really important that technical and business assistance programs are something that we have a number of ways that you can really utilize this within your grant.

So the first in the Phase I, we encourage you, this is something that you can request post-award Phase 1's can utilize our technical and business assistance needs assessment program. And that provides a third-party unbiased assessment of areas that are critical for your success in the marketplace. And so that's something that you request post-award. Then, you can use that to better define and make sure you know what your gaps and needs are for the Phase II, where in the application, you can request technical and business assistance funding up to $50,000 to hire vendors.

And there's specific instructions to request funds in an application. So this is a great way to get some of that support beyond outside of the research and development that are part of an NIH SBIR, STTR award. Beyond technical and business assistance, outside of technical and business assistance, we really recognize that many of our innovators are brand new to the SBIR or STTR programs and brand new to entrepreneurship in general. And so we have a number of ways that we support our innovators. We have regulatory and business development consultants on staff.

And we have partnering and investment opportunities to help bridge the gap between the Phase II and that marketplace or partner or investor. Our regulatory and business development consultants actually help mentor companies who then go to these partnering and investment events. And so it's a great way that we can help bridge that gap between our support and the marketplace.

In addition, we have a number of ways that we support entrepreneurs. And again, because we recognize many of you, this may be your first company. And that's great. That's certainly something that we see very often. So we provide an NIH entrepreneurship boot camp that can help early-stage teams, and these are pre-SBIR, sometimes pre-company, but pre-SBIR innovator teams to entrepreneurship, customer discovery, and business model validation.

And this entrepreneurship boot camp is open right now. It's going to be open through the middle of August, so please, do take a look at the Entrepreneurship Bootcamp if you're in that space, in that pre-SBIR space, I encourage you to take a look at the website. We provide support to companies to help them translate their great technologies and really do some of that technology translation, either more on the device side, in the Concept to Clinic, commercializing innovation, or C3I, as well as the I-Corps program at NIH, which is specifically to help people really think about their business model canvas.

And that's for, again, for those individuals who have received NIH funding.

And then finally, we support research and entrepreneurial experiences for individuals from diverse backgrounds through our supplemental program which provides that funding through an administrative supplement. And that's for companies who have received, again, an award to provide those research and entrepreneurial experiences. So I'm going to do the final bonus myth, which is that NIH bureaucrats are unapproachable and I shouldn't bother them. I really hope that we've tried to dispel that myth today. I do try to dispel that myth every time I go out and speak. We are here to help, we're here to provide as much help as we can, and we certainly encourage you to reach out and talk with us.

And so with that, do connect with SEED. There's a number of ways to get in touch with us, not just online. We do have an email, I think I pointed it out a couple of times, SEEDinfo@nih.gov. I encourage you to connect with us on social media. But definitely one of the best things you can do is sign up for our listserv. That really provides NIH and SEED updates, including some of these great programs that I talked about here. So with that, I'm going to close the presentation portion, but we're going to open up the Q&A. And I do see a number of you have put some great questions into the Q&A. We have a number of them, so we're going to try to tackle as many as we can.

Question and Answer Session

ADAM SORKIN: All righty, and it looks like I'm back. Thanks so much. A fantastic presentation, and we do have a lot of great questions, and I will dive right in. So I think on the front end, I am seeing a lot of questions about whether or not specific topics are included in our program. What's the best way for a potential applicant to figure out whether or not their project is a good fit for us, and who should they talk to?

STEPHANIE FERTIG: Great question, and I think this is something that definitely comes up a lot, particularly since a lot of the other agencies are very focused on specific topics and specific topics only. One of the great things about the NIH program is its flexibility. I like to think of that as a core component of our SBIR and STTR program. We're really interested in anything within our mission space. And so what does that mean? That means that we can encompass anything from devices, to diagnostics, to drugs, biologics, assistive technologies, digital health, research tools, and everything in between. I mean, we can really cover a lot within our mission space. The key is that you're trying to address an issue or a problem within the NIH mission space which is very broad. I'd encourage you to take a look at the program descriptions that attach to the general omnibus solicitations.

Now, again, what you're not going to see, or what I would encourage you, don't be looking for a specific topic that exactly hits on what you're doing, because you might not find that. What you're looking for is where might we fit in the NIH community? What institute or center mission space might we fit in? Again, this is where the NIH reporter can become so important. Back to that slide where I was talking about the NIH reporter is that there's this matchmaker function. You can take your abstract and you can pop that into the matchmaker and see what are some similar things, what are some similar topics, and where those might go within the NIH family. Now, that said, as I noted, there are some specific Notice of Funding Opportunities.

I do encourage you to take a look at those Notice of Funding Opportunities so that you can see, is there something that's specific for me, specific for my project? Obviously, if that exists, that's great, and I encourage you to take a look at that, but don't worry if that's not the case. About 75% of what we fund actually, again, comes in through that general omnibus solicitation. So I encourage you to really look at the program descriptions, utilize the NIH reporter, and obviously, you can always email us at SEEDinfo@NIH.gov, and we're happy to take a look at what you're proposing, just a brief paragraph, and we can try to connect you to the right program officer and right program for your project.

ADAM SORKIN: Great. Thanks so much. And following up on this, I do see another question asking if there's somebody available to help determine if a proposal is a good fit for a specific funding opportunity, and the great thing about that is that each of those funding opportunities will have a list of scientific and research contacts in, I believe, Section 7, and towards the end of each of those Notices of Funding Opportunities, they're a great person to reach out to discuss your project and figure out whether or not it's a good fit for that specific opportunity.

STEPHANIE FERTIG: Absolutely, and again, this is where reaching out and talking to program staff is so important, and we really do encourage that, and that is the person on those specific Notice of Funding Opportunities is the right place for you to go and say, "Hey, this is what I'm planning to propose. Is this what you were thinking? Is this part of this Notice of Funding Opportunity?"

ADAM SORKIN: Fantastic. Let's see. Okay, here's an interesting question, if you're currently working on a Phase I project, what is the standard process for preparing a Phase II proposal? What does that look like?

STEPHANIE FERTIG: Oh, that's a great question, and I like that question because I think particularly even in a Phase I, you should be thinking a little bit ahead to what would my Phase II look like? So remembering that for a Fast Track, you actually have to have the full and complete Phase II as part of your Fast Track proposal. So if you're looking at doing a Phase I, as a Fast Track, you're looking at doing both the Phase I and the Phase II into one proposal, but if you're at that point where you're in the middle of a Phase I, and you're thinking ahead to the Phase II, or maybe even thinking about the Direct-to-Phase II, you should be really thinking about that's the further research and development. So that's going to be larger amounts of money, really to get to some kind of inflection point, generally to think about where am I going to go after the Phase II? Is it going to be a partner, is it going to be an investor, is it going to be the marketplace?

You should be thinking about what activities need to happen towards that commercialization. Generally, the Phase II includes a commercialization plan, and that should be part of your Phase II. So that should be part of those considerations. But in general, when people are starting on the process and really looking at that project, of that product development plan, as you're going through your Phase I, generally you have some kind of go, no-go milestone at the end of the Phase I that really determines whether or not you should move forward to the Phase II. And that Phase II should be that further research and development, again, really pointing you to that commercialization point. And you should be thinking about what is that inflection point that really will de-risk my technology enough for the next phase, whether or not that's a program within the NIH, either through the Phase IIB or Commercialization and Readiness pilot, or whether that is something like a partner or investor.

ADAM SORKIN: Great. Thank you. Let's see. Seeing some interesting questions about looking for clarification about the STTR mechanism. We can start simple. Do you have to have the Partnering Research Institute identified before you apply?

STEPHANIE FERTIG: Absolutely.

ADAM SORKIN: Yes. So you will be required to provide a co-signed letter as part of your application indicating that you understand and agree to the work requirements for that specific mechanism. And no, the SBIR does not require a partnership with the university, that is only the STTR mechanism.

STEPHANIE FERTIG: I was just going to say, I do see a question, though, about, can NIH help linking a research institution to the project? And I like to state I'm not a matchmaker in my personal or professional life. So we do not help link companies with research institutions. However, again, this is where the NIH reporter can be so important because you can see who else out there, and it's not just SBIR, STTRs, and that NIH reporter is actually all of the NIH funding.

So you can see who else has been funded in this area and who might I go and reach out and talk with. It's so important to think carefully about who's on your team. Make sure you are all aligned and really think about making and building a good solid team. That team building and having a good solid team around a project is really important, so think carefully about who you bring onto your team. But the NIH reporter can be a really great way of helping connect you with individuals who have been funded by NIH in the past.

ADAM SORKIN: Great. Thank you. Let's see. A couple of interesting questions about review. What can you do if you're concerned about the expertise that is included on your study section or review panel?

STEPHANIE FERTIG: That's a great question, and there's a couple of things that you can do. So there is a specific form that you can submit as part of your application that allows you to suggest specific institutes and centers, it also allows you to suggest specific study sections. You can also indicate individuals that you fear may be in conflict with your application.

So we recognize that this is part of a company. You are in a company, and you may be concerned about competitors or others that are working in your space. Now, it's important to note that you can't say something like if you're, say, working on an imaging technology that everyone in the imaging space is in conflict. Well, that's not going to work, because really we need to have the appropriate expertise to review your application. So everyone in an entire field cannot be in conflict with your application.

But if you know for a fact that there's an individual business that is in direct competition with your business, or there's a specific, say, academic investigator who's working with a business in direct competition, you can name that specific individual or that specific business as potentially being in conflict. So if you do have specific concerns about review, you can always reach out to the Center for Scientific Review.

You are assigned a scientific review officer, and that scientific review officer is the individual who really runs that scientific review. This is, again, a difference between us and, say, the NSF or some other agencies, where the NIH, the program officer, and the scientific review officer are two separate individuals. And so that scientific review officer is the individual that is running that review, and is really pulling together that review panel, and is working to develop the summary statement post-review.

ADAM SORKIN: Great. Let's see, I am seeing a handful of questions about team building, and whether or not your team needs to be complete at the time you apply. What happens if some expertise is maybe to be determined?

STEPHANIE FERTIG: Great question. So you can have some expertise, you know, so first off, I should actually start with, not everybody needs to be an employee, and have a paycheck, and be signed on, and be part of the company at the time of application. We recognize that many of our small businesses are just that, they are small businesses. So there are certainly situations where companies say, 'Hey, we have somebody, and if we get this grant, this person will come on board." So the first step is, you can have someone named, but they might not be part of company yet.

You can indicate that they would come on board, or they would increase the time in the company, if the award is made. The second thing you can do, for some cases is you can say, "Look, we don't have this individual right now, but this is the kind of expertise that we're looking for." I would caution you against that second option, though, because what we can often find in the review meetings, is that the reviewers, they want to see, often, the people who are going to be working on the application. It's okay if that individual is doing maybe a small component of the application, might be less of a concern, but the more important that individual is, the more important it is for you to note who you're going to be working with, and how you're bringing that expertise on board.

So again, I would encourage you to reach out and talk with individuals, see who might come on board, or be able to partner with you, if you receive the award. So again, they don't have to be on board at the time of the application, but they might be somebody who can bring on to the, you know, on board if that grant is made.

ADAM SORKIN: Great. Also, seeing some questions about who can be included on the team. Do you need to be a citizen or permanent resident to work on an SBIR project?

STEPHANIE FERTIG: So you need to work legally within the United States. I think, and this is back to that whole question of US business and the eligibility and I do see a number of specific questions around eligibility. I'm going to point individuals again to the eligibility criteria that's found online, we also stated the eligibility criteria in a briefer form on the slide, but I really want to encourage you to go online and read through the eligibility criteria very carefully. These really need to be US businesses; they need to be businesses based outside of the United States. And really, it's important to make sure that your company is eligible for the SBIR and STTR program.

And again, just a quick reminder, even in the STTR program, even if the principal investigators from the research institution, it always goes to the small business. And it's important to note that when we say small business, we do mean for-profit. So this is for-profit entities. The NIH has a wide variety of opportunities, other opportunities for other kinds of organizations, including not for-profit, not for-profit can certainly partner with or work with a small business. But again, the applicant organization does need to be a for-profit.

ADAM SORKIN: Great. A couple of more questions about a team, is it a myth that we need to have PIs on the team who have been funded by NIH before?

STEPHANIE FERTIG: Yes, that is a myth. I will definitely tackle that myth and I'm going to go one step further. I'm not sure if this question is lingering in the Q&A. So one, we have a number of individuals who are brand new to NIH, they've never received NIH funding. And this is their first time of being a principal investigator and nobody in the team has worked with NIH and that's great. I would encourage you to take a look at the resources that are online. Research grants are a little bit of a different thing. But make sure that you review all the instructions, but it's great to see you and you're absolutely eligible and welcome to come.

And we've seen many of those individuals be successful. The second myth that I often hear is you have to have a PhD in order to be a principal investigator, and that's not true either. It's really important to have the appropriate expertise for the application for the project that you're proposing, so you need to be able to manage and really guide the project that you are proposing within that application. But you don't have to have a PhD. We have a wide variety of individuals who are submitting applications to us, people with bachelor's degrees, with master's degrees, with all sorts of specific professional degrees.

It's more important that you have the right expertise and the right team built together. And so it's not about just a PhD. And I really want to emphasize that we get that question a lot. So I'm sure it's probably buried in there. We do have a number of questions so I wanted to take that one as well.

ADAM SORKIN: Right, and let's see, seeing a couple of questions about applying to other agencies like NSF. Do you want to clarify that NIH and NSF are two distinct agencies, both with their own specific programs so we can't comment specifically on the status of NSF applications or programs. However, would you like to talk a little bit about opportunities to maybe apply to both agencies and how does that work?

STEPHANIE FERTIG: Absolutely. So it's really important to note, and this is why when I'm talking about applying to HHS, really when you have an application pending with Health and Human Services. So when you're applying to say the omnibus solicitation, you're really coming into that solicitation and that application may be assigned to one of the NIH institutes and centers, as well as potentially CDC and FDA if they're on that specific solicitation.

NSF is a different agency, it's not part of HHS. And you can come in to say HHS and NSF as long as you tell us that that's what you're doing. So you can submit the same proposal to each of those two different agencies. And there's a checkbox that you can click and indicate that, "Hey, I've sent this application to this other agency as well." Now, the federal government is not going to pay you twice for the same work.

We do frown on that. So if in the happy occurrence that you potentially are up for consideration for both of those, you'll have to pick one because again, we're not going to pay you twice to do one thing. And it's also important to note that the NSF application and our application, very different applications. So you're going to have to tweak the application, you can't just submit the exact same application to both of us. But the scope of the work can be the same, provided that you let us know. And again, you're not going to accept money for both. We can't give you what we call duplicative funding.

ADAM SORKIN: Great. Thanks so much. And following up on that, also seeing some questions about submitting multiple applications within NIH to multiple mechanisms or different funding opportunities.

STEPHANIE FERTIG: So it is allowed. You can submit more than one application. And in fact, companies have been successful in doing that. A couple of caveats, one, you cannot submit the same application to two different funding opportunities at the same time. So say, and I'm going to pick on the omnibus and the Transition grant because I do see a question about that. So I'm going to do a little bit of-- I'm going to cover a little bit of extra ground here. So say you are potentially able to do the Transition grant and also can submit to the omnibus.

What you cannot do is come September 5th, submit that same grant to the omnibus and the Transition grant because it's the same agency. It's all HHS. And so you can't submit that one grant to both, you can't have a grant that covers the same work under review, two grant applications, same work under review at the same time. That's considered overlap. So that means those would be withdrawn. So however, you can submit two applications on different topics. So say your company has two distinctively different projects and you may be interested in submitting both of those projects to the omnibus. You can do that, and that is absolutely allowed. You can even submit more than two. I would caution you though, and then again, this is not against the policy, but this is important to consider. Many of the companies that we work with are very small, and if you've got an extremely small team, and that team is working on both of those applications, gosh, it's really hard to write a good application. A good application can take a lot of work and a lot of time. And oftentimes, what I would see as a program officer is that if a company was specifically trying to submit two applications, one of them would inevitably be less successful than the other because they didn't have the time and energy to put into that application.

So what I often would encourage small teams to do is focus on one application, submit for an application deadline, and then turn around and start focusing on the next application. Make it so that you're focusing your attention on one application at a time.

Now, again, if you have a slightly larger company, you can really make sure that you have the appropriate resources behind both of those applications and they are distinctively different. That may be just fine. But again, oftentimes we're working with much smaller companies and it can be very, very difficult. Now, I said I was going to cover a little extra ground here and I'm going to stick to that. There was a question about the omnibus versus the Transition Grant.

And you can really say about the omnibus versus any Notice of Funding Opportunity, but let's talk about the Transition Grant. What are the advantages of one Notice of Funding Opportunity versus the omnibus? Notice of Funding Opportunities can have advantages. It's an indication that an institute or center is really interested in a specific topic. And so we do encourage you to take a look at those Notice of Funding Opportunities. Sometimes a Notice of Funding Opportunity can have specific review criteria or specific attachments or requirements that can be advantageous or something that are either advantageous to a small business or can be very helpful for a small business to explain to reviewers a specific aspect of the technology or can be something that an institute or center is interested in making sure that they have in hand on a specific proposal for the review.

For the Transition Grant, if you look at the Transition Grant, you'll see that there are different review questions for those Notice of Funding Opportunity. So there are different considerations that we want the reviewers to think about when they're looking at those grant applications.

The other thing is that there are specific attachments around the mentor. There's a mentor that's required as part of the Transition Grant. And so it's important those additional attachments are going to be required when you submit that Notice of Funding Opportunity. The advantage is, particularly for new entrepreneurs or entrepreneur individuals who are earlier in their entrepreneurial career development, what you're going to see is that really helps-- the review criteria really helps potentially fill in that gap that we sometimes see with some of the new entrepreneurs around the experience and really is tailored for trying to transition new entrepreneurs in the program. So the benefit is that if you look at those review criteria, they're going to be tailored slightly for those new entrepreneurs. And that's true of some funding opportunities is they're going to have specific review criteria.

Again, important to look at the review criteria for a specific Notice of Funding Opportunity or even the omnibus Solicitation. Very important to take a look at those. Those are the questions the reviewers are going to be asking themselves. Don't you want to know the questions for the test before you take the test? Of course, you do. So take a look at those questions. So important.

ADAM SORKIN: Fantastic. So following up on that, seeing a number of questions about timelines. Do earlier applications get earlier feedback? What can you generally expect to hear information about how well your application has fared, and when will you get funded?

STEPHANIE FERTIG: Great question. And that's back to those timelines, and I actually might click back to the timelines because it's helpful. Although by the time I get there, I'll probably have answered the question. But I would state that, remember it's important. So total process from time of application to the time where you actually get, but I stalled just enough. There we go. So from the time you submit to the time you receive funding, it's about, we usually say six to nine months, it's probably closer to nine months right now.

But that first three months or so, a little over three, somewhere three, three and a half months, is the peer review process. So you'll get a summary statement right around the three to four-month mark. And that's pretty consistent. So you'll get that reviewer feedback. You'll have an idea of where you stand at the three to four-month mark. Then it goes through that second level of peer review which is the advisory council. And then due diligence and where the program officers and the NIH staff really take a look at the application and you're providing just-in-time documentation, et cetera. So you'll get an idea after that summary statement is released. You get the score and then the summary statement, you'll have an idea of where you stand. You can reach out to the program officer and see, is this within the zone of consideration? Is this something that a specific institute or center would be interested in supporting? And each institute or center has a little bit of a different ways that they look at and make the funding determinations, the different factors that they utilize to make funding decisions.

Now, there was a question in here about different institutes having different budgets and different budgets that they accept. And you're absolutely right. And so that's another difference between the different institutes and centers. You can find that information in the program descriptions in the omnibus Solicitation. I really strongly encourage you to take a look at those program descriptions in the omnibus Solicitation that talk specifically about generally the kinds of sizes of the projects that they generally allow, as well as if there is a link to the waiver, the different waiver topics and those specific waiver topics and how and what an individual, institute, or center may accept that would allow it to exceed that SBIR and STTR budget guidelines that we received from the Small Business Administration. So I would take a look at those. Now, individual Notices of Funding Opportunities may have different budget guidelines. I encourage you to read the budget guidelines in the Notice of Funding Opportunity very carefully. What you might find is some institutes and centers may go exactly with the SBIR, STTR guidelines, however, for specific funding opportunities may have additional flexibilities.

ADAM SORKIN: Let's see, here's an interesting question. I do see a couple of questions about the structure of the applications and what sections are mandatory. I'll just note each Notice of Funding Opportunity at the front end will link to a detailed application guide that will walk you through the specific requirements for each funding opportunity and let you know how to complete that application and what needs to be included in each section. We also have a link on our website to an annotated form set that can be very helpful navigating that section and considerations for completing all of our forms. So I really encourage you to take a look at those sections and that information when you're putting your applications together.

STEPHANIE FERTIG: I also want to jump in and ask, sorry, Adam. [LAUGHTER] For whatever reason, I thought you were done there. Maybe it cut out briefly for me. But one of the things I would also notice, there was a comment here, is it just okay to have just one PI? I would take a look at those instructions because we do have the options to have more than one PI and we are talking a lot about a team. But it's important to know that when we're talking about a team, it might not be more than one PI, it could be an individual who's on the team, it could be a consultant, it could be there's a variety of different ways that you can build and have people provide input into your specific application.

We do have the opportunity to be what we call, have a multiple PI project that allows for more than one PI. There does have to be one contact PI, that one main point of contact for your application. That individual does have to follow all the principle and all the specific guidelines of a principal investigator in an SBIR or STTR, however, the other individuals on a multi-PI proposal do not. And so I would take a look at that if that makes sense for you and your project. Certainly not required, and something to consider.

ADAM SORKIN: Great. Very helpful. We've got a couple of questions about intellectual property. How do patents play into the process? Do you need to have a patent to apply?

STEPHANIE FERTIG: You don't need to have a patent to apply. And in fact, some technologies, patents aren't how you do barriers to entry. I mean, I think really we're looking now at barriers to entry. How are you going to keep other companies from looking at your technology, doing it themselves, copying it, doing themselves and entering the marketplace? And for many of the technologies that are being developed through the program here, it's with patents. So intellectual property, as I noted, there is this new section where we are asking you to write the relevant intellectual property in the facility section. We consider that a resource, we consider that an important part of what the company may be bringing. You're not required to file a patent, and in fact, providing information in your application is not considered public disclosure.

However, we really do encourage, I'm not an intellectual property patent attorney. I am not. Neither is Adam. [LAUGHTER] Neither of us are. So I would really encourage you, if you have questions about patenting, reach out and talk to a patent attorney. The USPTO which is the US Patent and Trade Office, they have specific resources for small businesses. I'd encourage you to check those out as well. They can be a really important resource in your patent journey. But patents can be very important to a company. They're not required, but they can be very important. Many of our companies do file provision or patents before they come in. So many individuals have started on that patent journey before they come to us. Again, not required, but that's something that many companies decide to do to protect their intellectual property.

ADAM SORKIN: Great. Thank you. That's very helpful. Here's a good question, when reaching out to a program officer about the fit of an application, what kind of information is helpful?

Great question. I love that question, particularly since we do emphasize the importance of reaching out to a program officer. I'd say there's a couple of great tips before you reach out. Each institute and center is a little bit different, and again, you do have that list of small business program managers that's on the website. It's just a great place to start. Each institute or center may have a different way that they like you to reach out, but you can always start by reaching out with a brief description of, hey, this is what I'm planning to propose.

Is this the right institute? Is this the right place to start? Because what we've often found is that sometimes it's really easy to determine the institute or center. So something like if you're working potentially in cancer, for example, it might be very straightforward. Look, there's the National Cancer Institute, I think I belong there. And it could be a very easy and straightforward thing to determine. But, and I'm going to use as my example, neurological disorders can be a little bit trickier. And I'm using that, my previous position was in neurological disorders and stroke. And so one of the things there is that there are some areas that are shared areas of interest between the different individual institutes and centers. And so this is why it's so important to reach out and say, hey, this is the area.

This is what I'm thinking and considering proposing as part of my projects. You don't have to submit a full specific aims, you don't have to do anything like that. It could just be, hey, my first step is, is this the right institute? This is the problem, this is a solution I'm proposing, and this is the kinds of work that I'm planning to propose within the project. Is this within the mission? Is there anything I should know?

And maybe the answer is that, hey, in looking at this work, gosh, this is within our mission, but this might be a clinical trial, you might want to take a look at that and make sure because we don't do clinical trials through our program. We have other ways of supporting those. Then the other thing you might want to consider is that then you may-- this is where reviewing the instructions becomes so important because if you review the instructions and you start looking at it, you can see if there's specific questions, maybe about the budget, maybe about, hey, I see that there's this specific waiver category. Do you believe this would fall under that waiver category?

Maybe it's the, I see that you allow for larger budgets, but I'm not sure if this would be too much. If you have specific questions around the Notice of Funding Opportunity, if you're going under a specific Notice of Funding Opportunity, would this fall within this Notice of Funding Opportunity? Again, those specific questions might be really important, and that's when reaching out to a program officer could be very helpful as well. If you're unclear about a piece-- if you have a specific question about, say, the application process, about some component of your application, that's something that you can certainly reach out and talk to them.

A program officer cannot help you write your application. They can't review the whole application, they can't edit your specific aids, they can't tell you that, oh, you should write it differently, or you should do X, or you should do. What they can do is they can provide some, whether or not it fits within an institute or center, if you've got specific questions, they can help address those. But a program officer is not going to be your, we call it the co-PI. They're not going to help you write your grant application. That's why it's so important to take advantage of some of those state or local resources that you may have. Really take advantage of some of those resources because they can really help you as you're putting together your application.

Because the program officers, that's not within what they can do. And honestly, think about it this way, they can't do it for everyone. And so really, it's important for us to be fair and to provide the same kind of input and feedback to everyone.

ADAM SORKIN: Thank you, very helpful. Let's see, seeing a couple of interesting questions. So can we submit our application to the omnibus and rely on NIH to direct the application to the most applicable institute or center? Absolutely. Our Center for Scientific Review welcomes suggestions and requests through the assignment request form, but ultimately they're going to assign your application to both the institute and center, as well as study sections that most clearly align with the goals of your proposal. So not a requirement to figure out where you need to go, we will take care of that.

STEPHANIE FERTIG: And I will also add that the Center for Scientific Review will assign it to an institute or center, and the institute or center has to then accept that application. So I mean, there is some negotiations here, but I'd also state that you can have-- there's a primary institute or center, but then there's also the potential to have secondary institutes or centers. I always like to say, secondary never hurts. It only helps. [LAUGHTER]

Because oftentimes, you know, sometimes, and it doesn't happen a lot, but there is an opportunity, particularly at the end of the fiscal year, there could be an opportunity for co-funding from another institute or center if they're secondary, or sometimes an institute or center that's secondary may take primary assignment if they're able to fund it when the primary institute or center is not. And so again, important to consider that having secondary institutes and centers, not a bad thing, always helps, never hurts.

ADAM SORKIN: Great. A couple of questions about the Direct-to-Phase II opportunity. What is that appropriate, and what kind of data-- what's the best way to go about figuring about whether that's a good fit for your project?

STEPHANIE FERTIG: Great question. So if you want to think about it, again, there's those three different ways to enter into the program. So there's the standard Phase I, no preliminary data is required, but you should have scientific rationale for what you're planning to propose. For a Fast Track, again, you're not required to have preliminary data but it's expected that a successful application will likely contain preliminary data. So in general, because you really have to have that fully formed Phase II in the Fast Track, in general, you're going to have some preliminary data as you're entering into the Phase I. And then finally, you have a Direct-to-Phase II.

You have to have the feasibility study done, you're going to come in with that preliminary data, you're going to be reviewed alongside individuals who have received their Phase I and are now submitting a Phase II. It basically acts as if you've already received that Phase I. So that's how much preliminary data you need to have. And so you need to think about the Direct-to-Phase II as really skipping the step of doing a Phase I and going direct to that Phase II. It's also important to note that for a Direct-to-Phase II, you are leaving on the table the Phase I funds. You're saying, I don't need those and I want to move directly to the Phase II.

ADAM SORKIN: Great. Thanks so much. And I see we're getting very short in time. So just want to note to everybody that if we haven't gotten to your question, you can still always reach out to us at SEEDinfo@nih.gov with your questions and we will get to them as soon as possible. But I will leave it to Stephanie. Any last questions you'd like to answer or final words you have for our audience?

STEPHANIE FERTIG: I like that you said that. I did see a couple of questions about clinical trials and what to do with clinical trials. Definitely take a look. So first off, if you're doing any kind of human subjects, please do verify, take a look at the clinical trials definition. See if you are, in fact, a clinical trial. Notice of Funding Opportunities will indicate if there are clinical trials not allowed, clinical trials optional, or clinical trials required. And it is just that, not allowed, optional, which means you can have one, but you don't have to, and required, clinical trials only.

If you're doing the clinical trial, you can only come in during the optional and clinical trials required. There are specific forms and specific components that you need to fill out if you're doing a clinical trial. I'd encourage you to take a hard look at the requirements in the Notice of Funding Opportunity. Some institutes and centers only accept clinical trials through specific Notice of Funding Opportunities. Those Notice of Funding Opportunities may have specific requirements associated with that Notice of Funding Opportunity and with the clinical trials. Please, do read those carefully, it is important that you do that. You don't want to put so much time and effort into preparing an application and then have it be returned because it didn't have some important piece of information in it.

And so again, we do really encourage you to read through those Notice of Funding Opportunities very carefully and make sure you have all the components and all the specific attachments that are required as part of that.

ADAM SORKIN: All righty. Well, it looks like that has brought us to 2:30. Our hour and a half has gone by very quickly. So a big thank you to everybody for joining us this afternoon. Thanks so much to our team, Vicki and Laura, behind the scenes writing the webinar, and Suzanne, our captioner. These materials and recordings will be available in about a week at our website, and we look forward to hearing from you all. Thanks so much, everybody.

STEPHANIE FERTIG: Thank you.