America's SEED Fund: Powered by NIH Webinar

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Part 1: Dig Into NIH's SEED Fund

ROB VINSON: Good afternoon, everyone. My name is Rob Vinson. I'm a program manager with the NIH small business office, SEED office. I'm delighted this afternoon to bring to you our guest speaker, Stephanie Fertig, who is the HHS Small Business Program Lead. And her presentation will be about digging into NIH SEED Fund, deeper into the SEED Fund, and then we'll have a chance for Stephanie to give a presentation. We'll have time for questions and answers after that, and immediately following about 15 minutes to take a little break, we'll have an opportunity to speak to other program officers and review officer about the SBIR and STTR program here at NIH. So, without further ado, I'd like to introduce you to Stephanie Fertig.

STEPHANIE FERTIG: Thank you, Rob, and good afternoon, everyone. I see some people are still joining. It's lovely to see so many people join us today, particularly as part of the continuing events of America's SEED Fund Week. Today, we're going to dig a little bit deeper into NIH's SEED fund, and how NIH supports biomedical research at small businesses. In addition, we're going to do some myth busting today about the programs and answer some questions from you. So, let's get started. We're going to go through a lot of information today. And so, I encourage you to visit our website, which has a wealth of information and resources. We're going to be putting some links in the chat.

So, I encourage you to take a quick look at the chat, keep that open, and when you have questions, feel free to ask us questions in that Q&A, and we'll hopefully get to as many of those as possible today. In addition, we've got some upcoming events, and you can always find the upcoming events on our website, the seed.nih.gov. But our upcoming event is a one-on-one event, which is going to be next week when you can schedule time to meet with program staff from NIH as well as the CDC and ACL.

Since I mentioned CDC and ACL, it's important to note that NIH is part of Health and Human Services, and we're not the only ones that have a small business program, CDC, FDA, and ACL all have small business programs, and are interested in having and supporting those projects that

take great innovations and get them into the marketplace. Now, at NIH, our mission can be summarized as turning discoveries into health. And the small business program helps get those great innovations into the hands of the patients, clinicians, caregivers and researchers that need them. These are congressionally mandated programs. And we have about $1.2 billion of dedicated funding that's set aside for small businesses to do that research and development that has that potential for commercialization.

Now, we do that through two programs, the Small Business Innovation Research program, and the Small Business Technology Transfer Program. I'm going to go into the differences of those programs a little bit later. But I'll tell you, the big difference is that while the SBIR program allows for partnering, the STTR requires small businesses to partner with a US research institution. Now, we have one of the largest sources of early-stage capital for life sciences in the United States. And this funding is non-dilutive. So, what does that mean? We don't take a piece of your company.

This is not a loan. And many of our awardees, again, as you can see in our placement here, we're supporting that proof-of-concept, that research and development, it's earlier than some of those investors and partners. And so, we take those great innovations, we de-risk that technology and get you to the point where you can attract partners and investors necessary to take that innovation to market.

So now for the myths, one of my favorite parts. It is easier and better for a company to get investors and avoid all the work and time to apply for an NIH grant. Well, I just have to bust that myth today. Companies that develop their product with non-dilutive small business program money are very attractive to those investors and strategic partners. Remember, investors and strategic partners have a due diligence process too, which can take just as long as the NIH review process.

Now, we support a wide range of disease areas and innovations. And if you want to see some of the small businesses that have done just that, used our funding to de risk-their technologies, and then were able to transition it to investors, partners in the marketplace, I encourage you to go look at our small business success stories. What's great about those success stories, it really

shows how we support research across the United States, as well as in everything from cancer to minority health and health disparities, all sorts of modalities, including everything from diagnostics to therapeutics, drugs, biologics, devices, digital learning, and research tools and everything in between. Now, the small business programs are a phased program. Well, but these phases aren't related to clinical trials phases. That's an unfortunate similarity in the nomenclature. The Phase I is a feasibility study, the Phase II is full research and development. As you can see here, there's a number of ways that companies can come into the program and get their projects supported.

There's the standard Phase I, then you can then do that work in the Phase I, that feasibility study, and then come back in and apply for a Phase II. There's something we call a Fast-Track, which combines the Phase I and Phase II into one application and gets reviewed all together. And then there's an administrative review between that first phase and that second phase. And then finally, there's a Direct to Phase II. Now, that's an option only open to the SBIR program, for those companies that have already done that feasibility study and are ready to move directly to that full research and development.

Regardless of how you get to the Phase II, we recognize that not everybody is ready to go directly to market or even attract a partner or investor. And that's why we have an additional Phase II called Phase IIB, and the commercialization readiness pilot program, or CRP. Now, and you'll see this a lot, there are 24 different Institutes and Centers at the NIH, and not all Institutes and Centers participate in all of the programs that I'm going to be talking about today. For example, not all Institutes and Centers participate in the Phase IIB and the CRP. And that's why it's so important to reach out and talk with a program official well in advance of applying. And in fact, that's one of the great things, we're going to have some of those program officials on later, and they can talk about some of the differences in their programs.

We get a number of questions around the budget as well. And so, I put the budget guidelines from the Small Business Administration on the slide here. However, it's important to note that the NIH and CDC have a waiver from the Small Business Administration to exceed these budgets for specific selected topics. But again, not all Institutes and Centers have their own budget

guidelines that are the same. And so, it's really important, again, if you're thinking about exceeding these budget guidelines, talk to your program officer well in advance.

This is a question I get a lot, another myth, myth number two, it's much harder to get an NIH Fast-Track or Direct to Phase II, so don't even bother applying for those. Well, I can definitely bust that myth. Although most of our new projects are Phase Is, we support many Fast-Tracks and Direct to Phase II, those are both options. And really, it depends on a specific project, what makes the most sense for your application, you should really speak to a program officer. But one of the things we have seen is that regardless of how an application comes to us: Phase I, Fast-Track or Direct to Phase II, we find that the success rate is very similar across these different kinds of mechanisms.

However, again, it's really very project by project dependent, dependent on the specific Institute or Center. So, it's important to reach out. Now, one of the questions you might have as well who's eligible for this program? We get a lot of questions about eligibility. And so, we've briefly spelled out the eligibility criteria on this slide, but there's a lot more information on the website about eligibility, including the Small Business Administration's eligibility guidelines, and there's a full document to help walk you through to determine if you're eligible.

The most questions we get is around individual ownership and you can see the different ways that you can be eligible here, but it's really important to note that regardless of eligibility, that the work has to be done within the United States. There are a few exceptions there, but it's important to note that this is for US companies and we expect that the work will happen in the United States. Now, eligibility is determined at the time of award, not the time of application. And so, we do get, again, a lot of questions about, "Well, we're going to be eligible at the time of award, is that okay?" Yes, eligibility is determined at the time of award. Now, we have a number of funding opportunities that are out there right now. And again, the website is a great place to see what's currently out there with regards to funding opportunities.

The majority of our funding does go to what we call investigator-initiated grant applications. That's where you tell us about a problem that's out there in the community, a problem that's being faced by those patients, clinicians, caregivers, and researchers, and how your innovation

is going to help solve that problem. That said, we do have some specific funding opportunities announcements that are out there, and you can find a list of those on the website, I put a little arrow there, it's on the front page, it's one of the first things you see when you come to our website.

The next receipt date is going to be actually September 6. So, the standard receipt dates are September 5, January 5, and April 5, but when one of those standard receipt dates fall on a holiday, it automatically goes to the next business day. Now, our omnibus solicitations have just been reissued. And we have those up here. The general grant omnibus solicitations, again, that's those investigator- initiated applications are, again, where the majority of our applications come in and where the majority of what we fund, that's how we receive those. It's important to read the program description and research topics selections in those solicitations very, very carefully. They have a wealth of information about, again, those budget guidelines, and what an individual Institute or Center is going to accept and how they utilize the program within their individual Institute and Center to meet their mission.

Again, we have those targeted solicitations, it's important to read those very carefully as not all Institutes and Centers participate in all solicitations, and not all targeted solicitations have specific set asides, or even specific review. And so again, important to read it very carefully, and if you have questions, there's a program contact at the bottom, reach out and ask them, does this fit within this program announcement? We have some specific questions, and then you can ask those questions of that individual.

Finally, we do have an SBIR contract solicitation, we've got the pre-solicitation, was just released yesterday. So, I do encourage you to take a look at that, and we'll be including the link in that chat as well. Now in the contract solicitation, there are specific topics. And again, while the vast majority of what we receive is through that general solicitation, there are some of these specific targeted solicitations as well. Now, that said, a big myth that I do hear, is that I should apply to a specific program announcements because they always have their own targeted funding, and that's actually not true.

As I said, the vast majority of the awards are made to applications submitted to the omnibus solicitation or general solicitations. Less than 10% of the awarded projects are actually to the contract solicitation. And the success rates of the specific funding opportunities and omnibus are very, very similar. So again, just because you don't see a specific program announcement that matches what you're doing doesn't mean that we're not interested. We have that omnibus solicitation there just for you.

Now, you'll see those omnibus solicitations, they were divided into SBIR and STTR. So you might ask, "Well, which one do I go towards?" And that really again depends on the specific project and what you're planning to propose. I always say pick the one that makes the most sense for your company and that project. Now again, you can see there's that partnering requirement really drives the differences between the SBIR and STTR. But regardless, SBIR or STTR, the award is always made to the small business.

In the STTR program, even though there is that nonprofit research institute tuition partner, the award still goes to the small business and that research institution is a self-award. Okay, another myth. Since the SBIR is a bigger program, I have a better chance of getting an SBIR awarded. And I could have really put anything in here. This Institute is larger than that Institute, the budget for this program is larger than the budget for that program. But that's a myth, the size of the program doesn't correlate with the chance of getting awarded. In fact, many smaller programs like the STTR or smaller NIH Institutes may get far fewer applications, and therefore, actually might have a higher success rate.

So again, take a look at what you're planning to propose and connect with what makes the most sense for your application and for your project. And I should also note that some of these success rates can change year after year. And again, it is institute by institute dependent, and again, it just depends on how many applications an individual institute or program receives, and that may vary significantly from year-to-year.

The other thing you may have seen is that there's a question of whether or not you're doing a clinical trial, not all FOAs or Funding Opportunity Announcements, support clinical trials through the Small Business Programs. I put the definition, the NIH definition of a clinical trial

here, and as you can see, it's a pretty broad definition, it might be broader than you think. We really encourage you to use the decision tool that's available online, if you're using human subjects, to make sure to determine whether or not you're doing clinical trial in advance of applying.

It's really important to know whether or not you're doing a clinical trial so that you can put together the appropriate paperwork and submit to the right funding opportunity. Now, this is a big myth that I do here. "My project is low risk, and only has a few human subjects, so it's not a clinical trial." Well, the definition of a clinical trial is not the same as the FDA's and is not based on risk or number of subjects. Again, it's much broader than you may think it is. And this is really important since not all NIH Institutes and Centers accept applications with clinical trials to the small business programs.

So, it's really important to talk to a program officer if you're using human subjects, you're going to be doing human subjects research to make sure that that Institute or Center accepts clinical trials, and make sure that you know whether or not you are doing a clinical trial or not, and what's your best path moving forward. Even if an Institute or Center doesn't accept clinical trials through the small business program, that doesn't mean that they don't support clinical trials with small businesses, they just might be using other programs to get that done.

Well, you think you want to apply, now what? Well, I'm going to walk through the application and review process very quickly, but again, you'll find a lot more information online, and we're going to try to attach a lot of those links in the chat, and they're also going to be in my slides as well. Here's the whole process from submission all the way till funding. You can see it takes quite a bit of time to go all the way through the process, six to nine months. However, companies get feedback three to four months after submission. And so, I'll talk about that today.

But let's start with the first step, submission. Now you're going to submit electronically. Both grants and contracts must be submitted electronically. There are required registrations in order to submit, and I've listed them here. You can find a lot more information online, we'll walk you through exactly what's required with regards to those registrations. Start now. It's so important

to start that registration process early, and I would also say submit early because there are issues that do happen with electronic submission, computers, and it's important to make sure that you submit in enough time to deal with any errors or issues that may come up. We strongly recommend for grants that you use Assist. I've heard nothing but good things about Assist, and so we really do encourage you to utilize Assist when submitting an NIH grant.

We have a whole infographic online on how to apply, and this again has a wealth of resources. There are links to an annotated form set that walks you step by step through what's necessary for each piece of the forms that you need to fill out in order to apply. There's detailed application instructions. And there's also sample applications that are available online. Now, I do get a lot of questions. If you're interested and you know you're going to be assigned to a specific institute or center but you don't see a sample application for that institute or center, don't worry, the sample applications aren't meant to give you exact pieces of information for your specific technology. What they're meant to do is provide you guidance on what an application can look like, what are the different components that are necessary for a Phase I, or a Direct to Phase II, or Phase II, or Fast-Track?

So, you can see the different options that are available online, or from those that are available online, and what should be in that application. You're submitting to the NIH. And so, the application is the same to the NIH for the general omnibus solicitation. Now, it's also important to note individual program announcements may require additional pieces of information. And so that's why again, it's important to read that program announcement very carefully.

Now, another myth, "Novice applicants to the program are almost never successful at getting an award." Well, I'd like to bust that myth. Approximately a fourth of all of our awards go to new investigators, and NIH strongly encourages new applicants, particularly those from underrepresented innovators or from underrepresented parts of the country. Many Institutes and Centers now have-- participate in the Applicant Assistance Program or have their own applicant assistance program, and those programs really help those applicants who have not successfully gone through the NIH process to submit and provides them help through a contractor to submit their grant application for the first, you know, for the first time or in some

cases, you know, help them take an application that they've submitted and make sure that it gets resubmitted appropriately.

So again, I strongly encourage you to take a look at the applicant assistance programs that are available online. The most important piece of advice, though, and the thing I'm really hoping to take away from today, is that you should talk to a program officer at least a month before the application deadline. There's a list of program managers online, it's a great place to start. If you're not sure who you should talk to, we have a RePORT tool, and that tool shows you all of the different projects, the abstracts of all the different projects that NIH has supported, including through the small business program. If you're still not sure who to contact, that's okay, you can contact us. We at the SEED office are more than willing to help you to give us a brief description of what you're planning to propose, a couple of specific aims, we can help point you to the right direction. You can email us at seedinfo@nih.gov.

Now, as I said, we're going to have an event next week, where we're really making it open and trying to connect people with program officers, but you-- even if next week doesn't work or outside of next week or outside of the panel that's coming up later, still, you can always reach out and talk to program staff, reach out by email, ask those questions. That's the most important piece of advice.

All right. Myth number seven, "Applications are submitted to a specific institute. So, I need to choose the Institute and Study Section for my application." Well, I have to bust this myth. And this is something I do hear quite a bit. You're submitting to the NIH and actually you're submitting to the NIH if you're going through the omnibus solicitation, NIH, CDC and FDA. You're then going to be assigned the appropriate institute or center and study section. Now, it's important to note that a study section or a review group has more than one institute's applications in it. Oftentimes, there are multiple institutes have applications within a specific Study Section. So, the Study Section and Institute are not a one-to-one correlation. You can request a specific institute or even a Study Section, but you don't have to, and this is the request, NIH may look at your request and say no, you know, it actually fits better over here with this Institute or with this Study Section.

Well, I'm talking about study sections or peer review groups, let's talk a little bit more in detail. Once you've submitted that application, and that application is looked at by the Science Center for Scientific Review, the Center for Scientific Review, Receipt and Referral assigns it to an Institute and Center, as well as a scientific review group. You hear that go by many names, scientific review group, study section, peer review. But that scientific review group is run by a scientific review officer or SRO. You're going to be hearing from a scientific review officer later. They're a really important part of the process. They take a look at that application and recruit peer reviewers. Those are individuals that are out there in the scientific community with the appropriate expertise to review your application: scientists, clinicians, individuals with small business experience, individuals who, again, really understand science and can best review your application.

At least three reviewers are assigned to each application. and those reviewers use review criteria to score that application. Now, I think it's important to note that that whole process, the whole, from the point it comes in, to when you get a summary statement, a summary of those reviewer comments, that takes about three months. I think this is really critical to note, although it takes a really long time to get through from application to funding can take, it seems like a really long time for a lot of small businesses, six to nine months, you get feedback at the three month mark, you know what the review has indicated about your application and you get an indication of whether or not your application is going to be considered further.

So, what are those review criteria? Well, if you're comfortable and familiar with the NIH process, these review criteria should look similar. The difference is that these are focused more on product development and not hypothesis-driven research. During the preliminary review meeting, and again, so the preliminary-- during the preliminary review, those assigned reviewers are going to take a look at your application and give your application a preliminary score. Approximately 50% of the top applications based on that, the assigned reviewers' preliminary score are discussed. And those discussed applications will receive an overall score. Now, the overall score is an average of the score of the entire review panel, not just those three assigned reviewers.

Regardless of if you were scored or not, you will receive a summary statement, you receive comments from review. It's important to remember that everyone on the panel has to agree not to discuss an application. Any one individual can say, "Hey, this needs to be discussed." So, it's really important to remember that regardless of what happens, discussed or not discussed, you will get those reviewer comments.

This is a myth I hear a lot. "My application didn't get discussed or funded the first time. Therefore, it's a waste of time to try again." And I have to tell you, please don't think that. Many companies are funded after incorporating that feedback, taking that information from that summary statement, changing their application and resubmitting. I really encourage you to read the summary statement very carefully, contact the program officer to discuss your summary statement, program officer, the assigned program officer is in the upper left hand corner of your summary statement, reach out, email. Have a conversation with that individual to better understand what the concerns were within the summary statement, address any questions that you might have.

And then finally, really important piece of advice here, offer to be a reviewer we're looking for good reviewers. Remember, this is a peer review process. You can be a reviewer, if you're not sure how to be a reviewer, you'd like to, you can always reach out to the specific Center for Scientific Review, scientific review officer, give them your CV, but you can also email us at seedinfo@nih.gov for more information.

Okay, if you don't believe me, I put a couple of quotes from some of our successful awardees. And really, again, can't emphasize this enough, take that information, resubmit, you can be successful. Well, you've gone through the peer review process, you've gotten the score, gotten your summary statement, now what? Well, program staff use the review comments to develop a funding plan for presentation to the advisory council and board. Now, it's important to note, and this is another myth I hear, I don't have it as a separate slide, but it's important to note that peer review does not make funding decisions. The director of the Institute or Center makes the final funding decisions.

Those peer review comments are very important to coming up with funding plan, but the peer review doesn't make the funding plan. Once the application is moved forward for funding, the small business needs to provide additional information to grants management and program staff who perform the final due diligence. And again, grant management and program staff, very important points of contact during that process. Oh, it looks like my myth left here. But I will say the Scientific Review Group, i.e., study section determines if you're going to get funded and I just busted that myth, I hope, is that the NIH staff use that to develop that funding plan. Again, they don't make the funding decisions. The final funding decision is made by the Institute or Center director.

Myth 10. "The Small Business Programs only provide money." Well, I definitely want to bust that myth today. The Small business Education and Entrepreneurial Development, or SEED office that I'm part of, provides technical and business assistance, education, investment and partnering opportunities, commercial support. We provide a range of resources to our awardees. So, it's not just funding, although a lot of people do like the funding too. And there's a number of ways that we provide that innovator support. We do it through regulatory and business development consultants. And you can see a wide range of individuals we have as part of our team here.

We provide partnering and investment opportunities, we get you into these partnering and investment opportunities throughout the country, and many virtually now, and give you the opportunity to talk to those investors and partners, again, recognizing that that transition is really important. And finally, there are access to entrepreneurial support programs like I-CORPS, or the C3i program to help many of our entrepreneurs who are brand new to the whole small business process, better understand and get the training and information on how to take that product innovation and get it to market.

We also have technical and business assistance, or we're part of the TABA program. Now TABA is a very specific program within the SBIR and STTR legislation and program. There's two different ways you can take advantage of technical assistance, you can do it either requested in the grant application as TABA funding and that provides funding within the grant to use your own vendors, and you should request that as part of the application to us. Alternatively, we do

have programs that we run centrally, where you get access to consultants or contractors that we fund and you can request access to those individuals. We can provide you with TABA needs assessment, which provides an unbiased assessment of your project and your technology. And then there's also TABA consulting services, which provides unlimited number of awardees support in the specific areas listed here.

As you can see, TABA needs assessment is for Phase I, TABA consulting services is for Phase II. And then again, we have to have a funding that's also available, you can find more information online. And again, this is a great question to ask your program officer when you reach out. We also have the diversity supplement, you can see that here, and that really helps provide an administrative supplement to small businesses to enhance the diversity of the research and development entrepreneurial workforce. And so again, if you're a small business that has an active SBIR, STTR award, I encourage you to take a look at our diversity supplement.

I'm going to end with a bonus myth. "NIH bureaucrats are unapproachable and I should minimize my discussions with them." I hope we busted that myth today, and we're going to work to continue to bust that myth in our panel that's up and coming. The take-home here is we're here to help, and I encourage you to reach out, get connected with our office. And then we have a little bit of time to answer questions here, but don't worry if your question wasn't answered, seedinfo@nih.gov, we're happy to help you. And with that, I'm happy to answer some of these great questions that I see rolling in.

Part 1: Dig Into NIH's SEED Fund – Q&A

ROB VINSON: All right. Well, thank you, Stephanie, for great presentation. You covered a lot of material in a very short period of time. And again, I want to reiterate to the audience that these slides will be available. Please reach out to us. Do not wait and try to answer questions on your own if you're not sure. I did want to reiterate the fact that the submission window opens 30 days prior to the receipt date. So, we strongly suggest you're not waiting until, you know, the day of or a couple of days before the receipt date, because things do happen. And we would greatly appreciate if you could get your applications to us on time, and so we don't have to worry about a late application coming in, and that process will have problem with that. All right. Let's get to a few questions that we've had. Let me see if I can pull up some of the questions.

Okay. One of the questions that have come in this afternoon, do all four organizations within HHS have the same applications, or they each have their different or have their own application?

STEPHANIE FERTIG: That's a great question. So, FDA, CDC, and NIH all use the omnibus solicitation, they are all on the omnibus solicitation, and have that same application format. So they use the same application. ACL has their own funding opportunities and their own ways of accepting applications. And I encourage you to reach out to them directly if you have any questions about their small business program. But FDA, CDC and NIH all use that omnibus solicitation and utilize the same form set.

ROB VINSON: Good, good. Another question that came in, I'm just reading it, basically. We were advised that it's much more difficult to go Direct to Phase II rather than Phase I or Phase II, is this true?

STEPHANIE FERTIG: That's a great question. And I didn't quite touch on this, which is the question of well, how much preliminary data is necessary to getting Phase I, Fast-Track, or Direct to Phase II? So let me answer that now. And again, it really will depend on your specific project, but I will say, a Phase I, you don't-- there's no requirement for preliminary data, you do have to have scientific rationale, a scientific justification for what you're proposing. So you do need to have enough background information to provide that scientific rationale for the Phase I, but there's no preliminary data needed. For a Fast-Track, while there's not a requirement for preliminary data, it's expected that you're going to have preliminary data, and that's because you really need to submit the full application, Phase I and fully formed Phase II, and often that requires at least some preliminary data for the vast majority of projects.

And then finally, for a Direct to Phase II, you need to have the full feasibility study already done. You need a lot of preliminary data, you need a good amount of preliminary data, basically what you would have done in a Phase I, in order to submit that Direct to Phase II. And so because of that, oftentimes, many applicants will end up going to the Phase I because of some of the preliminary data requirements.

ROB VINSON: Good. Thank you, Stephanie. Okay, are SBIR and STTR awards subject to income tax? Are they taxed at a special rate?

STEPHANIE FERTIG: So, I'm not a tax attorney, I would encourage you to reach out to your individual accountants and talk with them specifically about the tax implications of the award. And one of the things that we do often hear from successful awardees, whenever I have a panel of- tell me what you wish you had known, they talked about the accounting. I mean, the accounting is something that you do need to be aware of, it is something you will need to do your own books. There are specific requirements around taking a federal grant funding. And so, it's important to make sure that you have the appropriate accountant, that they understand the grant process, they understand how to work and make sure that they've got all the auditing and everything in place.

And they're doing and following all the rules appropriately. So, there are- when you accept funding from the NIH, there are rules and requirements associated with that funding, and it's so important to make sure that you have the right accountant, and you are making sure that you're following those rules appropriately.

ROB VINSON: Absolutely. Good answer. We had another question. Does software development work all need to be completed within the United States? I can't outsource to a non-US provider?

STEPHANIE FERTIG: So, that's a great question. And I think it's not just software development that we get that question, is basically, do we really need to do all the work in the United States? And the answer is yes, I mean, there are some rare exceptions to that. So, if there is a specific situation where you cannot do the work in the United States, not that it's hard, not that it's expensive, but it just can't be done. And the example that I always like to point out and use is when you have-- so you're trying to do human subjects research, and you've got a clinical population that is just too small in the United States for that clinical trial, there just aren't the patients, it's a rare disease, you may need to have a site outside the United States in order to do the most appropriate clinical trial to look at that diagnostic or that treatment.

But that's a situation where you wouldn't be able to do it in the US. So really, that bar is much higher than for some of our other standard research grant programs. It has to be done in the United States unless you show that it really can't be done in the US. And so again, this is something that I would reach out and talk to your program officer about.

ROB VINSON: Good, thank you. Do I need to be incorporated before I apply for SBIR and STTR funding?

STEPHANIE FERTIG: You do need to have a small business and that small business does need to be registered. And those registrations can take a little bit of time. And again, just to re-emphasize what Rob was saying earlier, it's so important to make sure you start that process early so that you can apply early. We really encourage you to start that registration process. If you haven't started to register, right after this webinar, start the registration process, we really encourage you to start that early.

ROB VINSON: Yeah, especially if you're shooting for September 6th. Here's another good question. You touched on this briefly. However, it's a good question to answer again. What are the stats for first-time applicants who have never received any SBIR, STTR awards being awarded a Direct to Phase II or a Fast-Track?

STEPHANIE FERTIG: That's a great question, and I don't have those exact stats about the Direct to Phase II and the Fast-Track, I will say that for first-time applicants, those can be a little bit more difficult, in part because both of those, the Fast-Track and the Direct to Phase II, do require a full commercialization plan. The Fast-Track can be especially tricky, because you are, again, taking-- you have to have that fully formed Phase I and Phase II. And so that can be a very-- it can be a little bit of a tricky application to write.

The Direct to Phase II is tricky because of the need to have all that preliminary data. If you're a first-time applicant, you might not have that on hand. So again, I don't have the specific stats on that, but I will say it's really important to reach out to a program officer because there are always exceptions to everything, and it's really important to talk about your individual situation with them.

ROB VINSON: Yeah. And I want to piggyback on that reaching out to a program officer. I've always found it helpful if you take a few minutes to review our website, it's going to answer a lot of generic or general questions. And it's going to generate some questions that you might not have even thought of, prior to speaking with the program officer, that will make that conversation much more meaningful. And the program officer will see that, "Hey, you've done your due diligence, you've put your little effort into the process."

The next questions that we have are kind of tied together and it's-- I hope I can phrase it properly, but they'd like to know, when do you get your funding? I guess there's Windows NIH get its funding in the calendar year. And the second part of that I guess is meaning, where does NIH get their dollars? Or when does NIH get their dollars? So, I hope that's clear.

STEPHANIE FERTIG: Yeah. So that's really about the funding schedule. So, our fiscal year ends at the end of September, beginning of the fiscal year is October 1, and that does depend on Congress. You know, the budget gets passed at different times throughout the year. And so that is really dependent on a year-to-year basis, and so it really does vary.

ROB VINSON: Okay. We've got a time for just a few more questions. We've got one here that says, that's asking, does agricultural technology have to qualify for funding? Do agriculture technology have-- has a qualification for funding?

STEPHANIE FERTIG: So, it's, I mean, and again, I think we're less focused on agriculture, our mission is really around health. And I would encourage you to look at other agencies that may-- you know, just again, based on purely that one sentence of agricultural technology, so it's hard with just that to determine what's the best fit for your specific technology. But I would encourage you to look at the USDA, they do have a small business program, and I think it's important to note that just because if you're not a fit for Health and Human Services, that's okay. A number of other agencies have SBIR, and for some of them even an STTR program, take a look at the Small Business Administration's SBIR website, and you can see the different agencies that participate and what they're most interested in.

ROB VINSON: Okay. All right. Can I apply to STTR for Phase I and SBIR for Phase II funding?

STEPHANIE FERTIG: You can. You can come in for the STTR for the Phase I and then switch to the SBIR for Phase II, that's certainly allowable and can work really well for individual projects. I've definitely seen that happen.

ROB VINSON: All right, well, if we didn't get to all your questions, please, you can submit them to us at seedinfo@nih.gov, and we'll be happy to address any questions that we did not get to. I tried to summarize some of the questions that we already talked about, or Stephanie has already answered. And so, we're going to take a quick break. And then we'll come back with your opportunity to speak to program officers and a review officer.

And they'll be readily available and you can see listed on the screen here, the program officers that will be happy to answer any additional questions that you didn't have a chance to talk with Stephanie about. And that's going to be more germane to the specific areas of research that you're applying to or looking to get research dollars from. So, with that, let's take a couple of minutes break and we'll be back shortly.

Part 2: Secrets of a Successful Submission

STEPHANIE FERTIG: All right, it's two o'clock. Thank you, everyone, for staying on. And we're going to have a great panel today. I'm going to let all my panelists start their videos here. I see a couple of faces. There we go. I have to say, because I'm sharing my screen, you guys are all up here and in a little row at the top. So, I just do have to kind of check to make sure I have everyone here. Okay, so thank you all for joining us for Secrets of a Successful Submission. And we're hoping to get some of those tools and tips for successfully navigating the NIH. We have a great panel today. And I see a number of questions from the previous panel that I'm hoping to address and push out to you guys, that I didn't get to.

So, be prepared. Great panel today that's going to provide perspectives from both review and program. So, I'm going to have you all take some time to introduce yourselves. Take that five minutes to introduce yourselves, as well as provide a bit of background, and so I'm going to start- Well, Emily is first on my list, but I'll have each of you introduce yourselves and then we'll have-- going to some questions and then open it up for the broader discussion.

EMILY CAPORELLO: Hi, everyone. It's nice to be with you today. I am Emily Caporello. I lead the small business program at NINDS which is the National Institute of Neurological Disorders and Stroke. My background is in neurophysiology and in startups prior to coming here to NIH. And a little bit about the NINDS small business program, our annual funding is roughly $80 million that is devoted to small businesses through SBIR and STTR awards. We fund technologies that are related to neurology or neuroscience research.

We fund a broad range of modalities of technologies, from therapeutics, to medical, medical devices, diagnostics, assays, other types of research tools and clinical tools, rehabilitation tools, really any products that are going to enhance the neurological community or neuroscience researchers. We also fund types of activities that range from very early-stage drug development, lead identification, device prototyping, all the way through early-stage clinical trials, through our program. And I'm happy to answer questions today as part of this panel. Thank you, Stephanie.

STEPHANIE FERTIG: Great, well, next on-- now that the slide is down, next on the list is Miguel or at least that's who I see next on my screen.

MIGUEL CONTRERAS: Good afternoon, everyone. I am Miguel Contreras, I'm the program coordinator for the Office of Research Infrastructure Program at NIH. I'm going to share with you our website so you can know us a little bit better. What ORIP does is support research resources for the scientific community that involve animal model that most of the time that community need to do studies related to human health and disease. Some of those resources include from the C. elegans, the worms to non-human primate, and in between, we have Drosophila or fruit fly, aquatic model, fish, frogs, salamanders, rodents, pig, and as I mentioned, in the right extreme is non-human primate.

ORIP small business program is slightly different than the other, it's into the center in the sense that we try to align the technology that we are looking forward to our resources. That means, for example, we have a funding opportunity announcement on the street that is called novel tools and devices for animal research facilities, and to support care of animal models. And I'm going to share right away that information we use, so you will have on your hand.

Okay. So, in addition of that, to align that some of the other projects that we accept are preclinical in nature. What ORIP does not support are projects that include human subjects, or those that are related to a single organ or single disease. We consider our office as a trans NIH; therefore, we are not organ or disease-specific. Some of the other limitations that we have is that we do not accept also projects that involve companion or farm animals except pigs. And I'll be happy to answer any question that you may have later on. Thank you.

STEPHANIE FERTIG: Great, and definitely be looking in the chat. We've been putting a number of links in the chat. So, thank you, Miguel, for starting that up for us today. And I know I'm going to try to put in a couple of chats as well. So Toyin, why don't you finish up with the program officers on the panel?

TOYIN AJISAFE: Yeah, Toyin Ajisafe, I'm a program officer at the National Center for Medical Rehabilitation Research, and we are under the National Institute of Child Health and Human Development. I know it's a mouthful, NICHD, so from- moving forward, I'll use NICHD for here in IC. And our mission is to lead research and training to understand human development, improve the reproductive health, enhance the lives of children and adolescents and optimize abilities for all, and the "For all" in that sentence is really important, because often, applicants overlook that phrase and focus on the fact that child health is in the name of the IC.

So, I always want to point out that we fund research across the life course. And that's really important. There are 12 branches at NICHD, not including NCMRR, and I'll explain. The branches, I won't go through all the names, but they range from developmental biology and structural variation to fertility and infertility, pediatric growth and nutrition, and then to NCMRR, which is the National Center for Medical Rehabilitation Research, we function like one of the other 12 branches in NICHD.

So, it really just depends on what the specific problem the applicant is proposing to solve is. We typically don't participate in the U43, which is the cooperative agreements. So, we don't do contracts under the small business mechanisms. Typically, we stick to the traditional research project grants for SBIR. That's about all. We, like many other ICs, we accept one to two years for Phase I applications, and then two to three years for Phase II applications.

STEPHANIE FERTIG: Great. And so, I think we have a number of program officers on the panel, but I want to make sure, and we have a scientific review officer on the panel as well, because the review process is so important. The peer review process is a critical component of the NIH process, and so it's great to have a scientific review officer with us today.

TATIANA COHEN: Hi, everyone, I'm Tatiana Cohen. I am a scientific review officer at the Center for Scientific Review. And I also serve as the reviewer Training Coordinator at CSR. CSR is very unique in contrast to some of these funding Institutes that are with us today, that we don't provide the funding. Instead, we are involved in coordinating the review. In fact, the vast majority of all applications that are reviewed at NIH are reviewed by CSR, about 80% in total, and approximately 95% of all SBIRs.

I wanted to tell you a little bit about the role of the SRO and what exactly it is that we do. So as an SRO, I serve as the designated federal official presiding over the review process of applications. Once the applications are assigned to my study section, I am responsible for the fair and independent review of this application. And I serve as the point of contact for both reviewers and applicants that are involved in the study section.

At the beginning of the process, I review the applications to identify the expertise that is needed. I'm responsible for assembling the review panel. So, I seek out the reviewers who are going to be assigned to these applications, identify conflicts of interest and determine what is and is not a conflict based on NIH conflict of interest policies. I then conduct reviewer training sessions and work with the reviewers to ensure that reviewers follow NIH guidelines with regard to review criteria and the appropriate scoring. Then, on the days of the meeting, I conduct the meeting and work with the Chair of the review panel to ensure that review guidelines are followed. And I also take notes at the meeting that will then serve as the basis of the resume portion of the summary statement that our applicants will receive. After the meeting, I then ensure that the scores are accurate and the critiques are clearly written, and then release the scores, and then release the summary statements. And at that point, my role as the point of contact is finished for that review sample.

STEPHANIE FERTIG: Great, and I think it's really important to have the scientific reviewer, review officers as well as the program officers, we're all part of a team here that, you know, if as an application is being considered, this is the team of people that are a part of that whole process. So, it's a great opportunity. And I see based on the questions that we're getting; you all are planning to utilize this opportunity. But I'm going to use this opportunity to slip in a couple of my own questions before we move to your questions.

So first, I'm going to ask you all, when should applicants approach you and what do you wish that they knew? What do you wish, you know, what is maybe even the one mistake that you see the most that you wish people didn't make, or what's the one thing you wish that they knew when they were approaching you? And again, when should they approach you? And I got a question in the chat. I'm going to segue this off of a question in the chat where somebody said, "Wait a minute, I have to wait until 30 days before to approach somebody?" I don't think that-- that's not what we're saying you can- So when should people approach you? And anybody jump in, or I'll start calling on you, but anyone jump in.

TOYIN AJISAFE: I can go first. I think as early as possible, with a caveat. And it's really important, as you start thinking, or as applicants, potential applicants, start thinking about what they would like to propose, it's really important to get in touch with a program officer, but it's also very helpful when that either a page synopsis of what they're thinking, because often, the program officer needs to make a determination in terms of aligning with the strategic mission of their institute or their branch.

And so having some meat that gives them the ability to do that is quite helpful. I understand that at times, potential applicants are brand new to the NIH, and they may not have a specific aims page, but again, just a synopsis, I think that helps the program officer make that determination, because sometimes they may have to connect you with a different program officer who has a portfolio that's better aligned. So, giving them enough meat to work with is quite helpful.

STEPHANIE FERTIG: Anyone else? I mean, from a scientific review officer's perspective, when should an applicant contact you and what are some things that you wish that they knew?

TATIANA COHEN: Sure. I would add that, so applicants can actually contact us at any time if they have general questions about NIH review. So, what they really should not be contacting us about is specific programmatic questions, those would really go to the program officers, but if they have questions about study sections or just need a person to contact, and certainly asking questions about different study sections, the kinds of applications that they review, and the kinds of experts that we recruit on the study section panel.

Now, once the application is actually assigned to the study section, that will be a good time for applicants to reach out if they have questions about the study section. They might have, again, general questions, you know, regarding when the meeting will take place, when to expect scores and summary statements release, and things like that, general questions.

Applicants may not ask us confidential questions about the meeting, or about the assignments of the applications. That is privileged information that we cannot disclose. However, any kind of general question about the study section is always welcome. Applicants also can reach out to us when they are thinking about the type of study sections that they wish to apply into. Now, one thing that I'd like to point out is that it is not necessary to indicate the study section ahead of time. A lot of people feel like they want to do, that they should do that, and you certainly have the right and the ability to do that, but your applications will get assigned to the study section that best fits the scientific expertise, regardless of whether one is indicated or not. And then finally, at the end of the process, if there are questions regarding whom to contact, right at the time when scores are released or before the summary statement is released, that it would be acceptable to contact the SRO at this point.

What I would say is, it is useful actually to wait until the summary statement is released. A lot of times, applicants will see the scores released and they immediately make some judgment about whether or not they believe that that application will get funded at that point, and that is something that would be good to wait. It'd be good to wait for the summary statement to be released, and then contact the program officer to determine what the next steps ought to be. The most important thing that applicants should know, there's-- I do have quite a few that I'd like to point out. The most important thing in my mind is that you should understand that the application and review process is confidential. And so, we can maybe allude to that a little later

as well but it's really important to understand the rules involving conflict of interest and the rules involving confidentiality to be able to understand the kind of information that could be included in the application, so that you provide the reviewers with enough information to deduce whether your applications have the merit that they sought.

STEPHANIE FERTIG: Great. I saw Miguel, you were going to jump in?

MIGUEL CONTRERAS: Yes. Before I answer the question, I would like to indicate that I really wish that they know that we have limitations. So, I'm going to share in the chat an article that actually describes what really we can do and we cannot do. Okay. Now, with regard to the actual question, approaching to us, the program officer rarely is the better. With regard to again, what I wish they knew, I will point to three elements. And sorry, Toyin, I will-- and that will be even in what you said.

One, first, they need to be aware of the funding opportunity announcement that they will associate to the application that they are thinking to send to us. So, knowing the funding opportunity announcement is vital because that is what will guide all the application. And along those lines as you go through the funding opportunity announcement, prepare a question list, so you are prepared when you come into the meeting with the program officer. And that also includes questions related to budget.

The second point or thing that I wish they knew is they need to do a little bit of homework and identify the Institute, Center office that will fit better the research topic or the proposal. Okay, in this way, they will really find the right home for the project. And how you can do that, well, you can visit any one of the 27 Institutes or Centers' website. Also, I'm going to share right away, there is a document associated with the omnibus solicitation that also describes the topics of interest for all NIH institutes and centers.

And finally, as Toyin mentioned, I wish that, if possible, prepare what is called a specific aim page, where you describe basically a background or abstract of your project, you include the aims, and at the same time a brief summary of what will be the outcome of the project. And this is important because then the program officer will be prepared to or have in mind what is the topic of interest to be discussed. And along those lines, also, there is a really nice resource

on the internet that I'm going to share right away, because it's a nice summary how you can address the writing of the specific aim page. Thank you.

STEPHANIE FERTIG: Those are great links, Miguel, and particularly, you know, the- I know, we've posted some of those HHS program descriptions, and it's important to note that those program descriptions also cover CDC and FDA as well as the institutes and centers within NIH. So, you can really get a good broad breadth of the different kinds of things that we support. So, Emily?

EMILY CAPORELLO: Yeah, I completely concur with everything that my colleagues have said, it's great advice. The only thing I will add is, it is absolutely to your advantage as an applicant once you, you know, have sent in your aims page, you have a call on the books with your program officer to talk about your application. It is to your advantage to at that time, kind of read through everything you can about the program so that when you have that call with us, we're able to really dive into those specifics about your application. I think, you know, it's hard, you basically get one shot to have a call with the program officer based on how busy it is before you apply.

And so, if you can have as much background information that you've already read through or have specific questions, that will really help the richness of the conversation and the support we're able to provide to you at that time. We're of course happy to explain the basics to you, but if you are able to review what SBIR and STTR are, some of the FAQs, we can just have a more in-depth conversation and I think you're going to end up feeling like you have a lot stronger guidance for actually sending in that application.

There are wonderful websites. Some Miguel is putting in the chat, I'm sure Stephanie pointed to the SEED website that really lay out this information. Some programs like ours will send a resource guide to potential applicants when they're first emailing with you that has links that we highly encourage you to review. And again, reviewing these things in advance will really help that conversation be productive and in-depth.

STEPHANIE FERTIG: Great, I mean, this is all some-- we've gotten some great tips from everyone here. And I'm going to follow up with one other question before we kind of get to

some of these questions, as I said, that are coming in, in the chat, and I encourage you to use question and answer, it's a little bit easier to make sure that I can snag your question. But one of the questions I have, so I mentioned in my presentation about resubmission. So, what's the one most important tip or piece of advice you can provide to somebody who may need to resubmit?

EMILY CAPORELLO: I'll jump in. The first thing I would say is do consider resubmission. I think all too often, we see really promising applications, and it's very frustrating, you've worked very, very hard on this application. It is an onerous application, it is long, it took a lot of work. And when you receive feedback that isn't entirely positive, it can be really frustrating. I think one thing I would want people to know is the program is competitive, and I think it is probably the most likely thing that you will need to resubmit at least once, I think that is probably the average that things typically get funded after being resubmitted at least one time.

Of course, it can happen on the first time, sometimes you get really lucky but resubmission is part of the process. And I think it's really important that you, you know, take those reviewer comments, and really look at that and really look at how you can address them in your application. You know, it's easy to say, oh, they just didn't understand, they didn't read it, it can certainly feel that way.

But part of the role of the investigator in writing the application is that burden to explain everything as clearly as possible and help reviewers understand what you're trying to do. So, I would consider resubmitting, don't give up, it's part of the process, and then really take those comments, and really think about how you can best address them to be successful in a resubmission.

TOYIN AJISAFE: Yeah, I would echo the same comments I have here. It's a long game. And so, one has to have the patience, to Emily's point, sometimes review comments can be annoying and frustrating. Reviewers miss things sometimes. And so, PIs or applicants are upset, "Well, I had it in multiple places, how could they miss it?" Honestly, one just has to have the patience to move beyond those things and address the comments and resubmit. That's the winning

strategy. So, it's really important. And I think it's also important to understand which critiques one can address and how to best address them.

For example, a critique regarding a publication record, while one may not be able to change that in the next year or in the next few months, but maybe there's an opportunity to bring in a collaborator who makes up, who's trying things that area, so versus a critique on innovation. So, understanding, and part of this is also brainstorming, talking to pull them off, but understanding the different critiques and trying to read between the lines to strategize and respond appropriately.

MIGUEL CONTRERAS: I will go next. I think the single most important that I suggest to our applicants is that you need to read the summary statement very carefully, or whether you need to avoid what we call the adrenaline rush, usually you see your score, you're disappointed and the adrenaline take over. So, I suggest then you read the summary statement, put it aside, take a walk, open your mind, come back, read it again, and then start to think about all those critique that you have on your hands.

And the point here is that you really need to be able to come up with the answer if you are really able respond to all those critiques. Because when you resubmit, the study review group is going to look to the responsiveness for your submission. And the second point after that is, again, reach out to your program officer, sit in a meeting and discuss. Present your point of view, ask what are the option, and ask the question at a time that you need to ask. And one of those question is, for example, how you can use wisely the extra page because you are going to have only one extra page to respond to all those critiques when you submit your application. Thank you.

TATIANA COHEN: Yeah, I would also like to add that from the SRO's perspective that for the resubmission, there is actually no guarantee that the same three reviewers who reviewed the first submission will be there for the response in the resubmission. And that is something really important to think about because we sometimes see applicants look for specific things that some one reviewer pointed out and try to respond to that one reviewer, and rather than focusing on the big picture, so the things that really need to be addressed, like significance and

impact can sometimes be missed in the resubmission, because of this excess focus on what one reviewer had said. So that is really the biggest and the most critical part of the resubmission, and in fact, any application. We train the reviewers to focus on significance and impact. In other words, the importance of the problem, and what kind of sustained effect that the proposal will have in the field.

And if those are the critical issues that were the problem in the initial submission that remain unaddressed despite the fact that the applicants meticulously went through every single comment that other reviewers have said, and, you know, added details or revised text, but left those two problems glaring, then it's not likely that that application will do well the second time around.

STEPHANIE FERTIG: That's a really good point, and I just want to emphasize the importance of reaching out and talking to that program officer that's on the summary statement and about that summary statement. Program officers, and I know when I was a program officer, we see a lot of summary statements. I mean, we get really good at looking at the summary statement. And it's the resume and summary of discussion, I mean, that is such a critical component, and the scientific review officers really make sure that summary statement is, you know, a good summary and includes that information.

So, take a look at that and reach out to your program officer. So, I'm going to start with the questions. And because there was actually a specific question about resubmission, and so the question was, do the reviewers of the resubmission receive the summary statement and reviews of the original submission? Do they have to do something to make sure that that happens? So, what do the reviewers of the resubmission get?

TATIANA COHEN: Absolutely, yeah. So, the reviewers definitely see the summary statement of the initial submission. They go through, and they identify what the issues were. And then they look at the submission that is in hand, and they look at that introduction page. So that one page that outlines exactly what was done in response to previous submission serves for them as the key to look at specific issues that were addressed. Sometimes it can be apparent in the resubmission what exactly was revised in response, sometimes it is less apparent. So that

introduction page is really important. And then the reviewers will continue through the review process to evaluate the application, again, focusing on significance and impact.

STEPHANIE FERTIG: Great. So, one of the things that I heard several of you discuss was about that idea of research partners. And so, the question was, are more research partners helpful to success, is one strong research partner sufficient? So, what do you want to-- you know, I'm interested in what your all thoughts are on research partners or building teams in the SBIR and STTR.

MIGUEL CONTRERAS: I can start. From our point of view, you need to show that you have the right expertise to carry forward the proposed research that you're putting in your application. So, it doesn't matter the number of collaborators or advisor, what matters is, when you assemble your team, they have to cover all grounds to show that you have the expertise in-house or to [INAUDIBLE] to show that you are able to carry forward the project that you're proposing.

STEPHANIE FERTIG: And I would also add a big- one of the myths that we do hear, is that you need to have a PhD, but that's not actually true. I'm seeing a lot of head shaking here, but with what Miguel said, you need to have the appropriate expertise on the application.

TATIANA COHEN: If I could also just add very quickly, so another thing to think about is the overall organization of the multi-PI plan, expertise is very important, but it's also important to ensure that that expertise is non-overlapping. If the MPI plan lacks structure, if there's a lot of redundancy in the plan, that is something that reviewers will pick up on.

STEPHANIE FERTIG: And I think it's really important, this is something that's a little unique to NIH, we do allow for multiple principal investigators. We allow for multi-PI. And a quick important note, for that multi-PI, only the contact PI has to meet the eligibility requirements for, say, in the SBIR, there's that requirement that the PI for an SBIR has to be majority, at least 51% with the company. But the good news with the multi-PI is only the contact PI has to meet that 51% requirement, the other PI does not. And it does give you the opportunity to bring on other expertise if appropriate for the project.

So, I have an interesting question here, and it's the well, who tells you if you qualify for a Phase I, Fast-Track, Direct to Phase II? So, I'm going to throw that out there. When you're hearing from an applicant as a program officer, what do you say with regards to your options?

EMILY CAPORELLO: Yeah, I can take that. I think this is a great point of conversation that you should have with your program officer because there is no hard and fast scope of what a proof-of-concept study is or what a feasibility study is, or what continuing R&D is, what substantial preliminary evidence you need for a Phase II. The program officers that are working in your space, the one that's going to be a best fit for your project will have the best sense of what's appropriate in terms of the mechanisms for your project.

I can say for what we see at NINDS, typically if for instance a therapeutic has not yet shown preclinical efficacy, we're often looking at doing a Phase I, but not always. Same thing when we're kind of past that preclinical efficacy. At that point, usually we're looking at maybe a Phase II, but not always. There are so many things that depend that it's really a customized conversation about your project with a program officer that knows the space best.

So yeah, and then for Fast-Tracks, there are going to be some things you really want to think about for that mechanism, you're really going to want to think about the fact that you are proposing a full plan Phase I and Phase II. And so, if your project is such that your Phase I results are really going to inform what you're supposed to be doing in Phase II, that may not be the appropriate mechanism, because you can't change what you're proposing in Phase II.

It's really an ideal mechanism if the path forward to commercialization is very clear that you need to show success at a gate, you know, after a year along the way without proof-of-concept, you can show that you have clearly and quantitatively met success criteria at the end of the Phase I to simply further go on that path, then that Fast-Track mechanism might be right for you. So those are all really good conversations to have with your program officer about your specific project.

STEPHANIE FERTIG: Anyone want to add anything?

MIGUEL CONTRERAS: Yeah, I will add if the project is related to equipment or instrument, most of the time when applicant approach us, they say, well, I already have a prototype because I

have these pieces in my lab that in the overall, they kind of achieve the proof of principle. However, that set of elements that have been not assembled in that kind of actual prototype doesn't from our point of view reach the point of to have already accomplished Phase I or proof of principle. So, we really recommend that they propose the first aim actually to bring all those pieces together and propose an actual prototype.

The second point, I would like to highlight with regard to what Emily mentioned related to when you can decide if a Fast-Track is the right application for you is, you need to consider the state of development of your commercialization plan. If you really have the plan in mind, you know, you know what will be your business model, you know how you are going to deal with customers, you know what is going to be your community that is going to buy your device, your product or use your drug, then you may consider the Fast-Track approach.

STEPHANIE FERTIG: Great, so this is- and I'm seeing a number of questions come into the chat, and I just want to state that as we're going forward, if we don't get to your question, don't worry, I encourage you to reach out to our office, seedinfo@nih.gov, we'll pass it to the appropriate individual, we'll make sure that we get your question to the right place. We are getting some questions about, well, how do you make sure the right review expertise is in these panels. And I do want to make sure to address this because I know I do hear some questions about this when I'm out and about and talking with applicants. So, can you talk a little bit about how do SROs make sure that the right expert, you know, you've got the right people reviewing the right application?

TATIANA COHEN: Sure. So, most SROs have backgrounds that actually match the study section that they are in charge of. And SROs, we go through, we have databases at our disposal that we can use to identify the expertise that is needed for the applications. Once the applications are received, we go through the applications very carefully, we identify the expertise that is necessary to assemble the panel and then recruit the expertise that's needed using those databases. And the reviewers that we assemble generally have experience with NIH review and have experience with the types of disciplines that we see in the applications. So this is something that SROs are trained to do, and we train our reviewers to recognize how to evaluate the applications using NIH guidelines.

STEPHANIE FERTIG: And I think that's really important since SBIR applications can really be very broad. And I do see a question here and I'm going to use my prerogative to kind of jump in, but then also all of you, I encourage you to jump in as well. Because there was a question about, look, it looks like you're mostly doing biomedical research, but do you do other things, medical devices, other technologies? And so, I'm going to use one example that I think Emily knows very well, but I encourage you all to again, kind of jump in on this point.

We fund such a variety of different technologies and different things. And so, one of our success stories if you go online is a bicycle helmet. And you might go, "Well, bicycle helmet, why is NIH interested in a bicycle helmet? Well, that bicycle helmet helps prevent traumatic brain injury. And so, you know, we're interested in digital health, prevention, all sorts of interesting technologies. And the Center for Scientific Review brings together the right expertise for those projects. And this is one of the reasons why our study sections, they're ad hoc study sections, they are brought together based on those applications that are received so that we can make sure the right expertise is there. But I know, Miguel, I'm sure you have thoughts because you all certainly support a wide range of technologies that people might not be thinking about with regards to small business, too.

MIGUEL CONTRERAS: Certainly, and we had really few successes story. We were able to support from the beginning to then end the final product that was a digital PCR, that was one of the first digital PCR brought to the market. And the success story is that that small company was acquired by a big pharma. And along those line, we have high interest in devices to improve, as I mentioned before, based on the funding opportunity announcement that we have, we are looking for devices to major extensive factor in different, the varying settings, that goes from air quality to pathogens, to vibration, et cetera, etcetera. So indeed, it is not just that kind of technology is more broad.

STEPHANIE FERTIG: So, there's- and we're going to start getting to the lightning round of questions soon to try to make sure we cream in a couple of extra ones. So, the first question I want to make sure we get to is, how does someone become a reviewer?

TATIANA COHEN: Maybe that is something that I can tackle. So, it is-- that is a really great question. So, we have several methods by which somebody can become a reviewer the first of which is reach out to the scientific review officer. We, the Center for Scientific Review has a website, a really great website where you can actually visit and review individual study sections. You can see all the SROs who are listed, and feel free to reach out to that SRO. You can provide them with your CV or bio sketch. You know, tell us a little bit about yourself and, you know, we can keep you in mind for invitations.

Now, if you have already become an applicant, if you've already submitted an application, so then you actually get entered into the database that I referred to earlier. And so, we can actually draw upon our applicants' pool to identify the expertise that's needed, and then we will reach out to you. We will invite you to upcoming study sections, like, you know when they are and see if you are available during that time.

There's also on the CSR website, if you go to the section called Reviewers, there is a whole writeup on how one can become a reviewer for a CSR, not just for SBIRs, but for any type of application, but in particular for SBIRs, you can use those resources to identify who to contact and how to reach out. And I'll actually, I'll post a link to that as well in a short--

STEPHANIE FERTIG: Perfect, because I'm seeing some questions about that and I want to make sure since we did strongly encourage people to become, or at least I did, to reach out and offer to be a reviewer. That's great. So, here's one, I have several projects, can I submit five applications to NIH at once? How many applications can I submit, you know, per round? I'm not going to answer that one. I'm going to make you all answer it

TOYIN AJISAFE: There's no limit on the number of projects, as long as they're distinct projects, you can submit multiple applications per council round.

STEPHANIE FERTIG: But what do you recommend?

TOYIN AJISAFE: Now, what I recommend is a different story. One has to think about bandwidth. Obviously, you want to put your best foot forward. So, being realistic and thinking about quality, how many different applications can one reasonably submit with good quality and with good odds? I'll recommend looking at one bandwidth and deciding based on that.

TATIANA COHEN: Maybe I can add a little bit from the study section point of view. So sometimes applicants do submit multiple applications. And if the applications are similar enough, they can end up in the same study section, and there is absolutely nothing wrong with that. There is nothing that prevents reviewers, you know, reviewers will not look at it and think, you know, why there are so many applications. The one thing to keep in mind is that NIH prevents the submission of identical applications.

So, if the applications have a lot of substantial overlap between any two or more applications, those applications will have to be withdrawn. So, in that case, division of receipt and referral will end up contacting the applicants to find out, you know, why there is an overlap, and, you know, if there is something that they wish to keep versus another one. But aside from that, there is no limit, the applicants have to demonstrate, I agree with what Toyin said, that they have the ability to perform all of the portions of those applications if they were to be funded.

STEPHANIE FERTIG: So, I know we're coming to the end of our time today, but one of the things that is coming up and I'm sure, you know, there is a number of questions we're not going to get to today, so what's the best way for someone to reach out to a program officer? How can someone reach out to a program officer? If someone heard you today and really wanted to schedule some time with you, how should they proceed? What should they do?

EMILY CAPORELLO: Email is the best way for us anyway, I will say for me. I would just caution, it is, especially when we're coming at, say the September 5th deadline and we are getting lots of inquiries, it can- sometimes, the inbox gets backed up, and so please be patient. Feel free to ping us. We do appreciate, as I appreciate getting the pings if I haven't responded in a couple days. Again, please be ready with a description of your projects because we want to make sure before we schedule the call with you that you're talking to the right person. My guidance is going to be very, very different than my colleagues at NIH or Toyin's guidance, right? So, we want to make sure you're talking to the right person before we get on the phone and tell you what you should be doing, that could vary very much.

Also, please be aware, especially as we approach those deadlines, because there are a lot of applicants and we do encourage those applicant calls, we would like to talk with every applicant

before they apply, but that means our calendars get filled up very quickly. So, for instance, right now, I'm scheduling calls out in the beginning to middle of August at the moment, and that just gets worse and worse as we get closer to the submission date. So, another reason to reach out early. For us, please reach out via email. I will put my email in the chat. You can also always just email if you have specific questions.

For instance, I know in the beginning there was some really specific questions about the HEAL funding opportunity that we may not get to before the end of the session. You can ask those specific questions to me in email and I can reply to you in email, and then you'll get an answer a lot quicker than setting up a call. So please take advantage of that opportunity as well.

MIGUEL CONTRERAS: I will mention I'll second Emily, email is the best way. Phone call sometime take a while to check the voicemail. In our case, we are less busy. We are not as big as NINDS, but also if it's possible, when you try to reach out to program officer, it would be good if you already indicate what is your availability so we can match to our calendar and right away send a response.

TOYIN AJISAFE: I took the liberty to pull an excerpt from an email I received today. And for those who are maybe thinking, well, how do I even start that conversation? It reads, "My colleagues and I are considering a Fast-Track SBIR application to NICHD. Having never submitted a grant to NICHD, we thought it might be wise to share an early sketch of a proposal with you to see if NICHD would be interested. Please see attached draft of specific aims. If it's in the ballpark for consideration, we would find it very helpful to have a 30-minute call to discuss how best to shape the proposal so it's more acceptable and in alignment with NICHD." Done. So that-- something like that would be a good way to broker and initiate that conversation.

STEPHANIE FERTIG: And I think what's great about that example that you provided was there is a brief description of what you're planning to propose. So, you can look and see, "Well, is this NICHD or not?" And before you think, wow, how hard is it to determine which Institute or Center, it can be a little tricky. So particularly, and I'm going to pick on the neurosciences for a minute, there's a number of Institutes and Centers that do neuroscience. And I know for

example, Alzheimer's disease research, is that neuroscience or aging? So sometimes you can fall between Institutes and Centers. And so having that overview is really, really important.

Things like rehabilitation research actually fall under child health. I mean, you'd be contacting Toyin for that, and that might not be the first institute you think of. So, it's really important to provide that brief description and then have some questions like we discussed, here are some things that I'm-- here's the purpose of the call. Here's why I want to talk with you, and does this fit within your institute? And if it does, I've got a couple of questions, and I want to make sure those get addressed. So, when reaching out to a scientific review officer, what should somebody-- you know, should it just be an email help? What's the best way that someone can contact you?

TATIANA COHEN: Yeah, definitely the best way to contact us is email. We do sometimes end up being on the phone and so, you know, making a phone call in the middle of that is not always ideal, or maybe away, definitely an email is the best option. Again, just keep in mind about the kinds of information that you are looking for when contacting the SRO. We can provide information about the study section, about, you know, the expertise that's needed, general review guidelines, but we can't really provide information about whether or not your application would be suitable for a particular program or even a particular study section, because that kind of information is really evaluated during the time of submission.

So scientific review officers cannot guarantee that an application would necessarily go into a particular study section. And as I said, you know, other times to contact us would be during the actual process once the application is in the study section.

STEPHANIE FERTIG: And I think it's important to note, there was a question in the chat and I want to make sure to get to this. So, when you go to the website that has all of those different small business program contacts, there are two columns. There's a scientific research contact and one around financial obligations. So, you're going to want to connect with the program officers, the one that- that middle scientific research contact. The other one is associated with the grants management part of the program and who to contact for grants management issues.

So again, if you're first starting out, it's that scientific program contact, that's a great person to start with, and particularly in the small business program, they'd be able to talk with you about any of the specifics around their program. And particularly again, I encourage people to reach out when you're talking about clinical, if you're doing anything clinical, or if you plan to go above the budget or anything like that, those are the kinds of times when it would be really important to reach out and make sure that you fit within the mission and how that specific Institute utilizes the program.

So, I think we are actually a little bit over what we thought we were going to do. I'm not surprised, and we have a huge number of questions still that need to be addressed. So, what I'm going to do now is the last lightning round question, the one thing you want to leave all of the participants with today, last big piece of advice, and I'm going to say it a little slower and give everybody an extra moment to think about it. The most important piece of advice, the thing you really wish people would take away from the panel today. And I'll let you guys volunteer, to whomever wants to go first.

MIGUEL CONTRERAS: I can start. Sorry, go ahead.

TOYIN AJISAFE: Go for it, Miguel.

MIGUEL CONTRERAS: No, no, please.

TOYIN AJISAFE: Okay. Yeah, no, I was going to say.. . I think understanding this can mitigate frustration, understanding that NIH funds research. And so, you know, the technology development, device development, ultimately there has to be an angle with research in the approach. So, I think sometimes potential applicants are frustrated because they think there's a high focus on the research. But by-- it's inherent in NIH's mission to be able to commercialize a technology with the claim that it benefits or improves health, there has to be some research that gets you to that point.

So, I think it's important and this is where it's critical that if the PI or the small business doesn't have the primary expertise or they don't have a statistician or a biostatistician in house, for example, that they reach out to make sure they add one to the team. It's very doable. It's about

building your team, but understand that research is very much part and parcel of what NIH funds.

EMILY CAPORELLO: Mine would be, I feel like we do pretty well at talking to people before they apply, but it's after they apply and get their summary statement, especially if the summary statement and the score isn't as high as they wanted that we don't have those touchpoints. And so, I would want to get the message out to you that if you're in that situation where you didn't get funded, your score wasn't high enough to be funded, to please consider resubmitting, please reach out to your program officer, ask to talk with them about the summary statement and the reviewer comments, and figure out a path forward for that project and what their recommendation is.

I feel sad when people kind of just give up on the process because it didn't work out the first time because I think there's a lot of wonderful science and technology out there that's kind of getting dropped, and we'd really like to work with you and give some guidance and figure out how we can bring that forward.

MIGUEL CONTRERAS: I agree with my colleagues. I think the single thing that I would like to reinforce is that the program officer, we are here to help. So again, I put in the chat the link, we have our limitation, sometimes we are busy, but the overall process is long and sometimes we are busy. So, keep trying until you can reach us because that is the starting point for a successful submission.

TATIANA COHEN: Yeah. I agree with everything that everyone has said. I want to add that I think it's really important for the application to be written clearly and to have impact. So, one of the key issues that sometimes happens is that if the application is not written in a way that the assigned reviewers and even the rest of the panel can understand exactly what is being proposed, what was done before and what will be done as part of the award process, that's what causes the issues and the problems.

Sometimes applicants think that it's a lack of expertise of the reviewers, but if the reviewers are confused about what is being proposed, one person will read it one way and the other people will read it a different way. So, it's really important to be clear, concise, make good use of the

space of the research plan, and really when resubmitting really take into heed what it is that the reviewers have said, again, focusing on the impact and significance.

STEPHANIE FERTIG: And with that, I want to thank all of my panelists today. Great words of advice, great information. Thank you for staying on even a little bit longer to answer some of those last questions and provide those last bits of tools and tips. We really appreciate all of your comments. Thanks to everyone who stayed on and stayed with us for these two hours. As was indicated, we will be- this was recorded, we're going to be posting this on our website. The slides will also be available as well as all those links that we put in the chat. So, thank you everyone. Thank you, panelists, and everyone have a wonderful day.