Digging Deeper Into Small Business Programs and Policies (SBIR-STTR)

>> Stephanie Fertig: Thank you for joining us today. We're going to talk about the small business programs and policies. My name is Stephanie Fertig, and I'm the HHS Small Business Program Lead, part of the SEED, Small business Education and Entrepreneurial Development office.

>> Robert Vinson: And I'm Robert Vinson, I'm Program Manager at the National Institutes of Health. And I'm going to start our presentation today. I want to start off by talking about our website, which is probably the most important slide that we're going to have today, because it's going to contain all the information that Stephanie and I are going to talk about. And it's real important, because it's going to contain not only the topics for today, but also frequently asked information. It's also going to have all of our contact information of our program staff in the various institutes, and this is where you can reach out and talk to those individuals about the area of research that is of concern to you.

>> Robert Vinson: The NIH mission, as you can see here, is to seek fundamental knowledge about the nature and behavior of living systems, and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. In a nutshell, the Small Business Program helps NIH accelerate discoveries from bench to bedside.

>> Robert Vinson: The SBIR Program is a congressionally mandated program; two programs, actually. It's the Small Business Innovation Research Program and the Small Business Technology Program. The SBIR Program is approximately -- or it is 3.2 percent of our R and D budget, and 0.45 percent for the STTR budget. The SBIR Program was started in 1982, and the STTR Program followed in 1992, as its beginning.

>> Robert Vinson: What's important concerning this particular slide of budget allocations is the fact that you can see that our largest institute is the Cancer Institute, all the way around to the National Library of Medicine, which is the smallest. We have multiple institutes; each uses a different program to meet the specific mission. It's important to contact us in advance of these applications, or prior to submitting an application, and you don't want to get caught up in just looking at the largest budget or largest institute for funding. You want to submit your application based on your area of research, and these areas go from therapeutics all the way to diagnostics to research tools. And most importantly, as you can see here, our budget for fiscal year '20 was a little more than $1.2 billion, which is an awful lot of money that's very important to provide that type of research for our biomedical and life science research concerns.

>> Robert Vinson: Some of the benefits of receiving NIH funding is the fact that, one, this is non-diluted capital, in a sense. This is not a loan. You do not have to repay it, whether you go on to Phase II, or your research in the Phase I was not successful. The other important thing is that the intellectual property and data rights remain with you. We also have something that is very attractive to other investors or investors and partners down the line is that you can leverage your award or your funding to obtain angel investors, or venture capital, or to set up strategic partners after your Phase II award.

>> Robert Vinson: This slide is talking about our application and review process. The application process starts with your idea of research and goes all the way around to the grantee conducts the research, or actually, you start your project shortly after you obtain your funding. The process does take anywhere between six to nine months, and it's important that you understand that you will receive feedback from the institute that you applied to, as far as where you are in the process, or as far as whether or not you need to carry on as far as receiving the summary statement with any critiques about your application.

>> Robert Vinson: This process, the application process and the review process, really starts with the eligibility of your company. As you can see here, the organization needs to be for-profit, less than 500 employees including any affiliates. All of the work must be done within the United States, except that there are very, very .0 -- 0.1 percent, I should say, exceptions to that rule, that the work must be done in the United States. Then we go into individual ownership must be greater than 50 percent. Also, we go into the fact that it must be more than 50 percent owned by multiple venture capital companies, hedge funds or private equity firms. And this is something that's only going to be applied to our SBIR awards, but it's certainly something that is determined at the time of award as far as the eligibility is concerned.

>> Robert Vinson: All right, we're showing this slide again because it's the next step in the submission process. Once you've submitted the application and once you have the small business, you've talked about the concerns, eligibility concerns have been met, you're going to actually submit the application electronically. And this is where you submitted the application, and we've got several submission dates, and we've got several ways that you can actually submit that application. And I'll talk about that in just a second.

>> Robert Vinson: Again, we talk about the website and where you can find funding to determine whether or not, or what area you'd like to submit your application to, or what institute you'd like to submit your application. And this is where you want to reach out and talk to a program official prior to. You can see that we've got three receipt dates, the next one is January 5th. Also the one after that is April 5th, and then September 5th. We also have the Application Assistance Program, which actually helps you with the process of submitting the application. And we also have another program that's called the ASSIST Program, which we'll talk about a little further on. And it's important to understand that our website, again, has a wealth of information. It can walk you through the process from beginning to the end, and this information is there and can provide that assistance to you.

>> Robert Vinson: All right, I want to mention the fact that our agency has done an extremely good job of including or being inclusive to women-owned small business, and also social and economically disadvantaged businesses. And essentially, we want to make sure that both of these communities must have at least 51 percent ownership in the application and the award itself, and again, it still must be a small business or primarily small industry in accordance to the SBA size standards. We want to make sure that this information is only used for tracking purposes. It does not give any benefit or extra credit for being in these communities, but it's strictly for tracking purposes and to help us determine and do a much better job, as far as making awards.

>> Robert Vinson: From this point we're going to have Stephanie Fertig continue on with the remainder of the slide deck. And I'm going to stop at this particular point. Thank you.

>> Stephanie Fertig: Thank you so much, Rob. And I just want to emphasize that we're interested in the self-identification of women in small businesses and socially and economically disadvantage businesses, because that helps us with our tracking purposes. And while it's not required, we really do encourage you to self-identify, if it's appropriate.

>> Stephanie Fertig: So as Rob was saying, we have a number of different funding opportunities. Now the NIH, and actually HHS as a whole, tends to be very investigator-initiated. The majority of our applications and the grants that we fund come in through the general omnibus solicitations, and you can see them on the slide here. It's really important that you read the program descriptions and research topic section very, very carefully. There's a wealth of information in that document, including what an individual institute or center might be interested in, the budget guidelines that they allow, and any other features of their program that you should be aware of. Now there are targeted solicitations, but please keep in mind not all of those solicitations have a separate set-aside or peer review; it's important to read a solicitation very carefully, and then if you have questions, contact the program officer that's listed at the bottom of the solicitation. You can provide them information by email; a brief description of what you're planning to propose, and ask questions about whether or not you fit within that application -- that solicitation, or if your application might fit better with another program.

>> Stephanie Fertig: We also do have contract solicitations -- not all institutes and centers participate in the contract solicitation, so again, it's important to read the contract solicitation carefully and make sure that what you're proposing fits into one of the topic areas.

>> Stephanie Fertig: Now one of the big questions that we get is, what is the difference between the SBIR and STTR programs? Now those two programs are distinctive programs, as Rob was saying. But the real difference between the two is that the SBIR permits partnering, while the STTR requires partnering with a nonprofit research institute or university. At the end of the day, though, it's important to note that the award is always made to the small business, regardless if it's an SBIR or STTR grant. Now all the differences between SBIR and STTR really fall out of that big, over-arching difference in partnering requirement. And I'm not going to walk through everything you see here, but again, it's important if you have questions and aren't sure if SBIR or STTR is right for you, reaching out to ask the program officer and walk through what your options are is a really great first step.

>> Stephanie Fertig: I'm going to spend a little bit of time walking through the next slide on the different phases of the program. And this is where there are some significant differences between the SBIR and STTR program, and some of the other grant mechanisms that NIH offers. The SBIR and STTR programs are phased programs. The Phase I is a feasibility study, Phase II is full research and development. And that hopefully leads to the commercial market, or an inflection point where you get support from an investor or partner to take your innovation the rest of the way. So now I get a lot of questions about what's a feasibility study, versus full research and development, and I always tell people, one person's feasibility study is another person's further research and development. We really don't have hard and fast definitions for feasibility versus full research and development, so really, it's the feasibility study necessary to de-risk your innovation, so that you can do the full research and development.

>> Stephanie Fertig: Now we have a number of different ways that you can get supported. You can go through a Phase I and then a Phase II, and keep in mind the Phase I and Phase II here has nothing to do with clinical trial phases; it's an unfortunate similarity in nomenclature. The Phase I and Phase II is how it's designated in the law, the SBIR, STTR law, so it's a Phase I SBIR and STTR, and a Phase II SBIR and STTR. So you can do them as separate applications. You can also do them as a combined application, something we call a "fast track," and that takes the Phase I and Phase II application, puts them into one proposal with clear, quantitative go, no-go milestones that are reviewed by the program staff prior to the initiation of Phase II.

>> Stephanie Fertig: So the fast track application is a good fit for those projects where it's very, very clear what's going to happen in the Phase I and the Phase II, prior to the Phase I even being started. And you have a full commercialization plan already in place for that Phase II portion. We also have something called a "Direct to Phase II, and that's for those companies that have already done enough of the de-risking feasibility work that they can jump, because they have a lot of preliminary data, directly into the Phase II portion. Now that's for the SBIR Program only. Regardless how you get to the Phase II, we recognize that biomedical research often takes longer and requires more money to get to that inflection point for the market, and that's why we have a number of additional programs, a competing renewal of the Phase II -- we call it Phase IIB -- and the Commercialization Readiness pilot program, or CRP, that helps support that additional work. But it's important to note that only some NIH institutes and centers participle in those, so again, make sure to contact your program officer if you have any questions.

>> Stephanie Fertig: Now another big question that I get is around the budgets. In fact, I get a lot of questions around the budgets. So it's important to note that you can see the SBA guidelines here for both the Phase I and the Phase II. However, as I noted before, different institutes and centers have their own budgetary guidelines, and what they allow with regards to the number of years for both the Phase I and the Phase II. In addition, NIH has a waiver that allows us to exceed these guidelines, and that allows those institutes and centers to be more flexible than you might think, so it's important to -- and I keep saying this, and I'm hoping if you take nothing else from this talk, you'll reach out and talk to your program official in advance. And you can find that contact information on our website, under the Engage and Connect button.

>> Stephanie Fertig: One of the other big questions we get is around clinical trials, and it's important, particularly for small businesses, to realize what is and is not a clinical trial, per the NIH definition. So if you go to the Program Announcements, you'll see some of our omnibus solicitations have clinical trials, and some of them don't allow clinical trials. And the definition of what a clinical trial is is broader than you think it is. It's not the same definition as the FDA. So it's important that you go to the Clinical Trials policy website you see here if you're doing human subjects research, and make sure that you're not actually a clinical trial. If you are a clinical trial, it's extra important that you reach out to the program officer, because not all institutes and centers allow clinical trials in their Small Business Program, and they may have other ways to support your clinical trials research.

>> Stephanie Fertig: So you found your solicitation, and now you have to submit electronically. The big difference, the big thing that a lot of our small businesses need to do that they might not be aware of are the required registrations; companies need to be registered before they can apply, and those registrations can take time. So I really encourage you, if this is your first time applying, get those registrations in order. They're not necessarily difficult to do, but there can be time between each step, and the steps are in series. So again, it's important to start that process early and make sure you have all the registrations in place while in advance. I'd also encourage you all to use the ASSIST and submit through the ASSIST system. We've heard a lot of positive things about ASSIST, and I really encourage you to consider utilizing that to help develop your application.

>> Stephanie Fertig: Now what's great is, we have a number of resources on our website, including the Annotated Form set. There's a lot of questions people have about what goes in what part of the application, and that Annotated Form set can be really helpful if you get to a box, and you're not quite sure what to put in it. I keep mentioning this, but the most important piece of advice we have to give is to talk to a program officer at least a month before the application deadline. We are here to help you as I noted, and I've pointed out on this slide exactly where to find all those program contacts. There's an SBIR-STTR program contact at each of the individual institutes and centers across NIH, CDC and the FDA who can help guide you through the process if you have questions.

>> Stephanie Fertig: If you're not which institute or center is right for you and right for your project, that's okay; there's a couple of ways that you can determine what's the best fit. So one, again, is to look at those program descriptions that I had talked about previously. Another way is to look at the reporter tool, or the report tool that you see here, that has a list of all the different grants that have been supported by the different institutes and centers over the last couple of years, and so that'll help you to determine, hey, where is this kind of research likely to be assigned? But if you're still not sure, that's okay. You can either click on the link that you see here, specifically to go through our website to contact us, or email us at SBIR@od.nih.gov, and we'll help guide you to the right institute.

>> Stephanie Fertig: So now we get to the review process. Now once your application is submitted, it'll be assigned to not only an institute, but at the Center for Scientific Review where most of our SBIRs and STTRs are reviewed, it'll be assigned a study section. Now this is very similar to the NIH review process, and the criteria that are utilized for other great mechanisms. But it's important to note that the SBIR-STTR applications tend to go to study sections that are specifically focused on the SBIR-STTR applications, and that STTR-SBIR application program.

>> Stephanie Fertig: So the review criteria -- as you can see, it's again similar to the NIH standard review criteria that you may know and love -- Significance, Innovators, Innovation, Approach and Environment. The difference is that the focus is on product development here, and not hypothesis-driven research. So the significance talks about, is this a real problem? What's the commercial potential? What are you trying to solve? A little bit on the customers -- for innovation, is it new or is it improved? How does this relate to what is currently in the marketplace? The investigators -- we're looking at the PI and the team; not all small businesses are going to have a ton of publications. Maybe the team has patents or experience bringing something to the commercial market -- that's just as valuable in an SBIR and STTR application. The approach, again -- important that it be a clear, rational research design, for Phase I clearly show feasibility, and again have those quantitative go, no-go criteria at the end of the Phase I -- you really want to show that you're moving things through the product development process. And then environment -- can you do what you're proposing? Now there are those additional review criteria, you can see them here. And again, that's standard for most grants at NIH, but it's also true of SBIRs and STTRs. You can find out more information about our review process at the Center for Scientific Review, including a listing of the different SBIR-STTR study sections.

>> Stephanie Fertig: It's important that you realize you probably, or may likely have to, resubmit. And that's okay. Our funding rate is usually in the twenties or somewhere in there; it does fluctuate year to year. But it's important to know that you may not get a great score the first time. That's okay -- don't be discouraged. I have a great success story here of one of our successful awardees who's on our Success Stories website, and she talks about how it was really a journey for her, and how the feedback from the reviewers made her proposal stronger, and she was able to take those, learn from them, and then was successful. So I encourage you to be prepared to resubmit after you get your summary statement. Reach out to the program officer, have a discussion about how best to proceed. Again, the program officer is there to help you.

>> Stephanie Fertig: Now it's not just about money. We are part of the Small Business Education and Entrepreneurial Development, or SEED. And really, what SEED is trying to do is support the entire NIH innovator community, both at academic innovation, small business, and then providing innovator support. And we're trying to bring all those together to develop relationships, and again, try to bring those great innovations and get them to the marketplace in the hands of those patients, clinicians, caregivers and researchers.

>> Stephanie Fertig: Our awardees can take advantage of some of that technical and entrepreneurial training. Many of our awardees and applicants, this is their first company, they've never done this before. That's why we're here to help support them. We have a number of educational and entrepreneurial training opportunities: NIH I-Corps, NIH C3I for medical devices. We do have a specific NIH SBIR-STTR diversity supplement to help, again increase diversity in the entrepreneurial workforce. And we also have our technical and business assistance programs that allow awardees and companies to get some of that technical and business assistance that's really necessary again, on the business side of things; it's not just about the science, it's getting the business to the right place, too.

>> Stephanie Fertig: Since we have so many companies that are brand new to this, we provide in-house strategy and commercialization experts as well, from a regulatory specialist to entrepreneurs in residence to intellectual property, to even an investor in residence. These individuals help pitch-coach our companies, which we then support going to different partnering opportunities and investor showcase opportunities that are all across the country, although right now they're all virtual, similar to this. But really, helping those companies get out in front of investors and partners, again, once they've hit that inflection point to help take them the rest of the way. And we help pitch-coach them to make sure that they have the highest chance of success.

>> Stephanie Fertig: So with that, we're going to end today, but I encourage you to get connected with us. Come to the different panels that are at this conference. We'd love to see you at the different panels, and the Let's Talk About It that we have going on, on the last day. But even if you don't reach out to us at this conference, we encourage you to reach out to us via the website, email, Twitter, and read our success stories, and encourage you to come and apply. Thank you so much.