The NIH Seed Fund (SBIR/STTR) is Open for Business Webinar Transcript

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STEPHANIE FERTIG: We're going to share a lot of information today. And really, if in the future you want the most updated information or have any questions or need specific guidance, you can go to our website seed.nih.gov. It's a wealth of information, and that's where these slides are going to appear. And so I really encourage you to reach out and take a look at the website as you move forward and think about NIH funding.

Now the mission of NIH really can be summarized as turning discoveries into health and the small business programs help us achieve that mission by going and taking those great innovations and getting them into the hands of the patients, clinicians, caregivers, and researchers that need them. Now these are congressionally mandated programs, and they're one of the largest sources of early-stage capital in light in, in the United States for Life Sciences, about $1.4 billion of dedicated funding for small businesses. Now there are two programs, and we tend to use them kind of together as a group that are part of the America seed fund. The SBIR the Small Business Innovation Research Program and the STTR, the Small Business Technology transfer program. And I'm going to talk a little bit about the differences between these two programs because they are two distinctive programs, but both of them allow for small businesses to engage in research and development with the potential for commercialization.

Now the big difference between these two programs can really be summarized in the partnering requirement. For SBIR, we allow partnering, but the STTR requires a nonprofit research institution partner, such as a university, as part of the grant.

Now there are a number of other differences that stem from this partnering requirement. One is the work requirement. How much work that is being proposed can be outsourced, and the principal investigator, what is the employment requirements of the principal investigator? But regardless of whether it's an SBIR or an STTR, the award is always made to the small business and the nonprofit research institution partner is considered subaltern.

Now the benefits of NIH funding is that seed funding is non- dilutive capital. Which means that awardees can really leverage that to attract investors and partners. So if you want to think about where the NIH funding is located, it's really in that early stage proof of concept. Research and development before then it gets transitioned to an investor or partner or in some cases, the marketplace and a number of our companies have successfully done that. And if you go to our website, you'll see some of our small business success stories, which are located across the country and in multiple different modalities. What you'll see is that not only do we support and fund, therapeutics diagnostics we also support research tools, therapeutic devices. There's a wide variety of things on the website. There's even a bicycle helmet to help prevent traumatic brain injury. All of these things were supported with NIH small business funding and were able to use and leverage that funding to take their great idea to the marketplace.

So the first step is finding funding opportunities and applying. Now the majority of our funding goes to what we call investigator-initiated grant applications. So what does that mean? That means you see a problem out there that is being faced by the community by clinicians, by patients, by caregivers, by researchers and you have a solution and so you come to us indicating the problem and proposing that great solution. And then what needs to be done in order to make that solution a reality.

Our standard receipt dates for these investigator-initiated grant applications are September 5th, January 5th and April 5th, and you can find a link to all of our open funding opportunities right there on our website. Now we have again those open funding opportunities - the general grant omnibus solicitations. Those are our parent solicitations. There are open topic solicitations and they come in a couple of different varieties. One is clinical trials not allowed. And then there's clinical trials required. And they come as SBIRS and STTRS. So you can see there are four of those open topic omnibus solicitations. Now included in those omnibus solicitations are program descriptions and research topics. I encourage you to research those very carefully. There are 24 different institutes and centers here at the NIH that participate in the SBIR and STTR programs, and each of them utilize the program a little bit differently.
So it's important to read the program descriptions carefully to see whether or not an institute or center accepts clinical trials and what kind of budget guidelines they may have.

It's important to note that when we're looking and talking about clinical trials, and again program announcements do indicate whether or not they allow clinical trials or clinical trials optional, it's important to know whether or not your human subjects research is considered a clinical trial. Please read the NIH definition of a clinical trial very carefully. NIH's definition of clinical trial is different from the FDA and so we do encourage you to really read the definition of clinical trial, make sure that you are not considered an NIH clinical trial if you're coming in under a funding opportunity that doesn't allow clinical trials or make sure that if you are doing a clinical trial, those institutes and centers do accept clinical trials through the small business program.

So I'd encourage you reach out and talk to us and you're going to hear this several times in the presentation. Reach out and talk to us in advance of applying, but particularly if you're doing a clinical trial. Note that clinical trials are defined differently. The definition is a very much broader than you might anticipate. So again, so important to reach out and check that before you apply.

We also have targeted solicitations again for both clinical trials and for non-clinical trials and you can see those specific grants locations. As I noted, there's a direct link on our website. You'll see that there's a number of different kinds of funding opportunities. Sometimes there's notices of special interest, like the Women's Health research that are attached to those open topics, solicitations that indicate areas of special interest to the NIH. In addition, there are specific funding opportunities that may have a separate review criteria or may have specific targeted areas, and if you look the example that I put here. The small business transition grant for new entrepreneurs, that's a specific funding opportunity where we're targeting and focusing on bringing new entrepreneurs into the small business program. Individuals who might not have as much entrepreneurial experience, but again, have that great idea and are ready to be part of the small business and get some funding to hopefully see their project turn into a reality. And finally, we do occasionally put out contract solicitations throughout the year.

So as I'm talking about the program, let's talk a little bit about the structure, because one of the other things that you'll see in those notice of funding opportunities is they talk about different phases. Now these phases are not phases for a clinical trial. That's an unfortunate similarity in in the nomenclature, the Phase I program is more of a feasibility study, and the Phase II is full research and development. Now we have 3 different ways to come into the small business program. A standard Phase I where then you complete the work and then can submit a Phase II application. A Fast Track which combines the Phase I and Phase II into one proposal and the Direct to Phase II.

That's for those applicants who really have completed the work using other funds have really completed enough work for the feasibility that they don't need to go to the Phase I and they can jump directly to a Phase II. Regardless of how you get to that Phase II, whether it's a standard Phase II, Fast Track or a direct to Phase II.

We have a number of different programs that are available to help bridge the gap between that Phase II and the commercial market partner or investor. The Phase IIB and the Commercialization Readiness Pilot or CRP are both potential options for recipients. But again it's not all institutes and centers utilize these mechanisms and it's important to reach out and talk with the program officer well in advance of application.

In addition to the different Phases, there is flexibility for entering the program.
We have some flexibility with regards to the budget guidelines as well. Now I have the budget guidelines up here and you can see in the bottom left hand corner of the slide for both the Phase I and a Phase II and these are SBA budget guidelines $314,363 and $2,095,748 for a Phase I and II, respectively. Now these are set by the Small Business Administration on a yearly basis. So, if you were at a presentation, maybe last year or you might notice these budget numbers have changed. But the NIH and CDC and ARPA-H all have waivers that allow us some flexibility with regards to these budgets from the Small Business Administration. What does that mean?

That means that we do have the flexibility to make some awards for specific topic areas over these specific budget guidelines. So, put another way, we may be able to fund a larger project, and so it's important if you're planning or looking at the potential larger project to reach out and talk with us again well in advance and you're going to hear that a lot in this presentation, the importance of reaching out and talking to program staff before you apply.

Now there's a number of resources that are available online because we do recognize that preparing an application is a significant expenditure of time and can seem daunting. We have application instructions, annotated form set, sample applications, and a link to state resources through the small business programs FAST program. For each of these, the application instructions do walk you through the application indicating what's required for each section. The annotated form set helps show you section by section what should be in the application. The sample applications are very popular. They help people really see what an assembled application looks like, and then the state resources each. Almost all the states.
I believe they're missing one right now, but almost all the states do have organizations funded through the small business program that mission is to help small businesses apply to the SBIR and STTR programs. You can find all that information on the how to apply page under prepare your application. I encourage you to take a look at that. It also shows a timeline and kind of step by step through the process and what to expect as you're going through the application process.

But the most important piece of advice, and the most important resource is that program officer conversation and talking to us, or sending an e-mail with specific questions. It's important to ask those questions because we can make sure that you're looking at the right program, that you don't submit something incorrectly, which would mean that your application wouldn't be able to be processed or moved forward. It's so important to talk to a program officer at least a month before the application deadline. And you can find a list of program managers at our website seed.nih.gov and you can see I always say look for the very nice picture of NIH and you can find the Small Business Research areas and you can see there's a link to specific SBIR/STTR contacts.

Now, if you're not sure who to contact, you can utilize NIH Reporter. So that's https://reporter.nih.gov/ and you can e-mail us directly here at the Seed Office at SEEDINFO@nih.gov with a brief description of what you're hoping planning to propose. And we can connect you with the appropriate individual within NIH. With NIH Reporter, it's a fantastic tool where you can see all of the projects that have been funded by the NIH, you get an abstract, so the abstracts are made public from our funded grant applications. You can see an abstract as well as what institute or center they were assigned to. A really simple way of doing that is to go to this matchmaker tool here that I highlighted it. You go to matchmaker, put in your specific aims or abstract and it will indicate what other projects that have been funded previously. Or where available where they were assigned to, so you can see not only what was also supported previously by the NIH, but you can see where that went. What study section? And what institutes or centers it was assigned to? Now here at the NIH, we do utilize a peer review process and that's done through the Center for Scientific Review. We have five main score criteria significance, investigators, innovation, approach and environment. Now, for those of you who have done RO1s or other NIH grant applications, these five categories may look very familiar and they are. They are those standard 5 review criteria. However, what's important to note is those five review criteria are tailored to the small business programs. Again, to that mission of the research and development that is necessary to move something to commercialization. For significance you have a real problem or commercial potential. Investigators, you have an investigator and team. For innovation we want to see competitive advantage. What's innovative about the product or the service that you're proposing? The approach has to be a reasonable rational research design and the environment is appropriate facilities and resources. Now, similar to other NIH applications, each application has at least three assigned reviewers and it does go through the peer review process. That means that about 50% of applications are not discussed, but it's important to note that all applications do receive reviewer comments, regardless if it's been discussed during the review meeting or not.

Now the overall impact store is determined after discussion and scoring by the Scientific review group. It's important to note that if you look at the notice of funding opportunity, there are specific questions within the Notice a funding opportunity under Section 5 and I like to say that's the rubric. That's the CHEAT SHEET for what is going to be discussed in review. Look at those questions very carefully when you're putting together your application. Think am I addressing the questions that the reviewers are going to be asking themselves. It's really important to take a look at those, particularly if this is your first SBIR or STTR proposal. It is also important to note, budget is not factored into the score, but it is something that the reviewers can comment on. One of the big takeaways I want to point out is that this is a very competitive process. It's important for you to realize that you should be prepared to resubmit. Resubmission is a part of the process at NIH. We anticipate that the majority of our applications will have to go through resubmission. It's important to take a look at those reviewer comments. Read them carefully. Revise and resubmit.

I also encourage you to talk to a program officer if you have any questions after you've reviewed the comments, talk to them about what's in the summary statement and what might be the next best steps. Program officers can help you as you figure out what are your options. Once you've received your summary statement, you can find your program officer in the upper left-hand corner of your summary statement or on the era Commons. On your era Commons account, you'll see the assigned program officer.

Now, once you've been successful and received your SBIR or STTR, it's important to note that there are other opportunities and other resources that are available to you once you become a recipient. For example, we do have technical and business assistance programs and for Phase I we have the TABA needs assessment program, which provides third party unbiased assessment of the areas that are critical for success in the marketplace for your specific project now. This is requested after you receive an award, so for Phase Is that have received an SBIR or STTR, they can request assessment at no cost. Now, if you're a more experienced investigator or entrepreneur you can request TABA funding in the application and receive $6500 to hire vendors for technical and business assistance. If you receive technical and business assistance funding in your application, you cannot get a needs assessment, but we find that the vast majority of Phase I do not ask for that funding in their application and they can receive that needs assessment. It's strongly encouraged to get that needs assessment because that can help you determine what to ask for in your Phase II because in the Phase II you can ask for up to $50,000 to hire vendors for technical and business assistance. The needs assessment can help identify those areas that you might want to focus on in the Phase II and figure out what vendors or who you know what areas you want to focus on and hire a vendor for that Phase II grant. In addition to technical and business assistance, we do have other product development support. For Phase I, we do have I-Corps at NIH. And that's again, if you haven't been through the have I-Corps program, it really helps you figure out the marketplace and do customer discovery associated with that project to better hone and focus the project and determine to make sure that you've got a really good idea of all the different business components necessary to move forward. Similarly, there is the Concept to Clinic: Commercializing Innovation (C3i) Program and that is a pre-SBIR and STTR medical device innovator award, but I believe you do need to have an NIH grant. And again, not all institutes and centers participate in the C3i. It's important to take a look at their website and then reach out if you have any questions. And finally, for all SBIR/STTR awards, we do provide innovator consulting services in different areas such as business, intellectual property, pitch review, reimbursement and regulatory support. And so that gives you some consulting and help because we recognize that many of our innovators, this is their 1st company and they may be inexperienced entrepreneurs, even if they're experienced investigators. We're here to help, provide not just funding, but these other resources to help you become successful and move your project to the marketplace. So with that, I'm going to conclude and open up for some questions. But again, please do connect with us we are online. You can e-mail us with any questions and then again, we're also available on LinkedIn. And I'd encourage you to subscribe to our NIH entrepreneurship newsletter for the most updated information about different programs and projects that we might have. So with that, I see there are a number of questions. I'm going to turn it over to Adam, and Adam let's see if we can address some of these questions.

ADAM SORKIN: Great. Thanks so much for that great presentation, Stephanie and yeah, happy to get into it. I do you see a couple odds and ends just as a reminder as this has come up couple times, we should have materials available within the next 7 business days or so at seed.nih.gov at our events page and should be sending out a notification once those become available. You can always send questions to seedinfo@nih.gov if we don't get to your questions today. So we do have a number of good questions already and please put anything you'd like to ask into the Q&A box. I do see a couple hands raised, but please do use that Q&A function.

And the first question I see is the way I read the small business transition grant is it appears geared only towards younger research scientists who want to start a company, that is the PI must have a deep background in academia research. Is that correct?

And I'd be happy to kick things off if you'd like. That's actually not exactly the case for that transition mechanism. The only real hard eligibility requirement we have here that's different than a regular SBIR and STTR award is that the seeker can't have had a prior research grant like nor a series of grants or equivalents. And while this does mean that many of the applicants we do see are newer academic investigators, it's really available to any new PI that wants to enter that biotechnology entrepreneurship space who doesn't have a lot of experience and can benefit from entrepreneurial training as well as strong mentoring from experienced entrepreneur. So it's really open to sort of a wider swath of new entrepreneurs than you might expect.

Let's see, we've got a question, they're coming in pretty good. Now a question about resubmission. Resubmitting refers to future application windows, correct? There is not an opportunity to resubmit for this same intake cycle. Stephanie, do you want to talk about resubmission a little bit?

STEPHANIE FERTIG: Absolutely because resubmission really is a part of the process here at NIH and you're absolutely correct. Resubmitting here refers to future application windows it's not for the same cycle, so when someone submits an application, it gets assigned to a peer review group. One of the myths that we hear about the peer review system, by the way, is that it is somehow connected to your assignment of the NIH Institute or Center. So we hear a lot about, well, if I change my institute or center, that will change my review group or vice versa. And that's not actually the case. The Center for Scientific Review does the peer review of the SBIR and STTR applications and if they assign it to a peer review group and that peer review group has applications for multiple institutes or centers within the same peer review group. Resubmitting, in this case, means that you're submitting to the to the next receipt date or even receipt dates after that, and it goes through the peer review process again, and so that it basically goes through the process that the peer review process. It's important to note that when you resubmit, the peer reviewers look at your application as it's written then, so you're not guaranteed to get a better score when you resubmit. They're really looking at the application that is in front of them, and if they have new questions or new issues that they want to bring up, they can do that. It's important, but they will also look back and see what the other prior issues were. They do have access to the summary statements. They will look at both and so it's important to make sure you address the questions that were raised in the prior review so that you can make sure that your application is putting its best foot forward.

ADAM SORKIN: Great, thanks so much. Looks like we've had a couple questions about the about eligibility and the application entity. Would you like to talk a little bit more about eligibility requirements and where our applicants might find more information about figuring out whether or not they're eligible for the program?

STEPHANIE FERTIG: Absolutely. And eligibility, we get a lot of questions about eligibility, I will say we do have a section on our website specifically devoted to eligibility. Now the eligibility criteria for the SBIR and STTR programs are set by the Small Business Administration and they have a fantastic section on their website associated to eligibility as well. In addition on our website, you'll see that there is an eligibility document that helps address the many of the questions we receive around eligibility. Now you have to be a for profit entity you cannot be not for profit. It does have to be a for profit entity. It has to be a small business defined as within the United States, so it has to be a US, small business owned and operated by less than 500 people and it does need to have independent individual, owned by individuals and independently operated. Now, one of the questions we get a lot is around VC ownership and if VCs are not considered, venture capital is not considered an individual in this case. So it has to be 51%, you know over 50% owned by individuals and independently operated for the SBIR program. There are some instances where we can allow for a majority of venture capital or hedge fund or equity ownership, but no one VC or hedge fund or equity owner can be a majority owner and it has to continue to be independently operated. the CEO or Presidents or other individuals need to be the ones who are operating the business. So if you find yourself in that situation, I would really encourage you to read the eligibility criteria very carefully and reach out if you have any questions or if you're not sure where to find that eligibility criteria, we can point that out to you. Another important component is that the work does need to be done in the United States. There are some rare situations where we do allow some work to be done outside the US, but the majority of the cases really, it needs to be done in the US unless it absolutely cannot be done in the United States. So it has to be done outside the US for some reason and an example of that is say if you are doing a clinical trial, it's on a small population and that population doesn't exist in the US you might in that case ask to do some work outside the US, but the bar is pretty high there, so that's another really important component to keep in mind. Adam, what am I forgetting?

ADAM SORKIN: I think that was a very thorough answer. Yeah, a lot of great information on our website about all of these topics, including links to some specific SBA developed guidance material that can also be very helpful. All right, here's an interesting question about the differences between SBIR and STTR. Are there any benefits to applying for SBIR or if you qualify for an STTR, do you want to talk a little bit about the two programs and maybe how they might change over the course of a multi-phase project?

STEPHANIE FERTIG: Absolutely. And I love that and I'm actually going to go back to the slide that talks about SBIR STTR while I'm talking because I think it's important to reference that in the slide deck. And again, the differences between the SBIR and STTR, the scope of work is the same the budget sizes are the same, it's really about whether or not you have that nonprofit research institution partner and how much work that nonprofit research institution partner is going to do? In addition, one or the other could be really driven by whether or not you're employed primarily by the research institution partner or by the small business. But some projects could do either and so the question is, which one do you choose? And that really depends a lot on what you're proposing usually we find that people tend to drift towards one or the other as they're starting that first Phase I and it again may depend very heavily on the project. Now the good news that I want to provide here and I think this is what Adam was getting at is say you come in for an STTR for your Phase I. Well, you can come in for the Phase II and do the SBIR for that Phase II, you're not locked into the STTR program throughout all the phases. Of the SBIR/STTR similarly can be vice versa. So you could come in for the for Phase I as an SBIR and then switch to the STTR for the Phase II, although we see that a little less frequently, I think a lot of the times people may come in with the university partner initially if they're transitioning that technology out of the university setting and then move towards the SBIR as they go further along. So it's really important to note that there is an opportunity here as you're trying to decide which one of these two programs may work best for you and for your specific project that there is, there is some overlap for some individuals, again based on where you might be employed so I will also say and that the STTR program if you look online, you'll see has a smaller set aside than the SBIR. However, we get fewer applications to the STTR program, so some years it's a little bit better to be an STTR. Some years it's little bit better to be an SBIR, so I would caution you against trying to chase the money between the SBIR and STTR program. And actually, I'd say that's true across the board at the institutes and centers as well. Some of the larger institutes and centers may actually be some of them are more competitive institutes or centers because we get a lot more applications in those research areas. Versus other institutes or centers may have fewer applications assigned to them and so they may have better success rate. So I'd say don't be afraid of looking at some of those smaller programs and don't be afraid of the STTR program just because it has a smaller set aside.

ADAM SORKIN: Great. Thanks so much, Stephanie and here's a good opportunity to address an important question and give you a little bit of a break. We do have a question, can we work with an NIH team officer to determine which specific solicitation is most appropriate to apply for?

The answer to that question is yes, we absolutely encourage you to work with a program officer and discuss your project well in advance of submitting an application. Reach out at least a month in advance to discuss that one of the ways you can do that is by going to our website seed.nih.gov. We have a list of small business program managers for each of our participating institutes and centers, as well as the centers, institutes and offices at CDC and FDA as well as ARPA-H. They will be happy to hear from you and set up a discussion. If you're really not sure where you should end up or who you should speak to you can always reach out to us at seedinfo@nih.gov with a brief overview of the project you're interested in submitting, and we are happy to point you in the right direction and make some suggestions about who you should speak to.

Let's see, okay, here's an interesting question. For SBIR Phase I proposal, can you partner with caregivers directly to gain access to potential subjects or patients, and I might post that to you a little bit more broadly- do you want to talk a little bit about who you can include on your team when submitting or putting together a project?

STEPHANIE FERTIG: Yeah, I would say, you know the importance of putting together the right team is one of the things that we really do try to emphasize. And if you look, if you're going back to those review criteria, one of the things that you do see is investigators, the investigator and team, as well as the environment, the different facilities and resources that are available to you, as you're putting together that project. Now, no one can know everything, and I'm sure you're hopefully seeing that between both Adam and myself as we're both taking different questions. No one individual can know everything, and that includes about your project. One of the potential pitfalls that we will often see is individuals will be very strong in one area, such as engineering or they'll really know one aspect of their technology, but they will lack expertise in maybe the disease area or some other aspect of the technology. And you can really see that in the application and the reviewers will pick up on that.

Building a solid team is so important, and that may include caregivers that may include other expertise or individuals that have worked with caregivers that can provide that expertise and that guidance. And that as you're putting together your application to make sure that not only are you on the right path, but you're really aware of the potential pitfalls and potential risks of the project moving forward.

So some of our best projects have been individuals who may be a little earlier in their career, but they put together a solid team event of individuals who can help guide them and provide their expertise to the project. One last thing I would state is these individuals don't have to work for your company. They can work with your company.

They could be consultants. They can be key individuals, they can work as sub awards. There's different ways that they can work with you in order to provide that guidance and feedback. They don't need to be full employees of the company in order to be considered part of your team.

ADAM SORKIN: Great. Thanks so much, Stephanie. Let's see to apply for Phase I, do we need to have preliminary data?

STEPHANIE FERTIG: You do not need preliminary data and I'm going to use this as a launching off point, and I know I'm doing this with several these questions. I'm trying to address maybe a couple questions at a time, so I hope that's okay. But what we see here is there's three different ways to enter, right? There's the Phase I, the Fast Track and the Direct to Phase II. The preliminary data requirements are a little bit different for each of those. So for a Phase I you do not have to have preliminary data, but you should have solid scientific rationale for the application that you're proposing. For a Fast Track, you also don't need to have preliminary data. However, it is expected that a successful Fast Track will have some preliminary data in hand. So that's what makes a Fast Track a more competitive, Fast Track in the process. And then finally, for a Direct to Phase II, because we anticipate that you're going to have completed the Phase I already using other funds, you need a good amount of preliminary data, you need solid preliminary data. You essentially need to put in -hey, here's the Phase I already done and ready to go. And so that's why we should be able to move directly to that Phase II. And it's important to note, I should also point out that the Direct to Phase II is only available for the SBIR. I didn't point that out earlier, but I want to point that out now as well.

ADAM SORKIN: Thanks so much. I am seeing a couple hands raised. Please do use that Q&A function to submit your question and don't raise hands. We're not going to be able to get to you through video. Let's see, interesting question that we do get a lot, can different parts of the same project apply for clinical trial required and clinical trial not allowed funding?

And the answer to that question is absolutely yes. So if you want to submit a proposal to a clinical trial required notice of funding opportunity only if the specific project that you're proposing is a clinical trial in Phase II, you only would need to use a clinical trial required opportunity for that Phase II project. So you can submit a clinical trial, not allowed proposal in Phase I and then switch to the trial required in Phase II. So it's just that specific proposal and your future, your future plans don't figure in to that decision.

STEPHANIE FERTIG: There is one about environment that I think is important and it talks about how do you justify environment as a small business who might have just started. I think it's a great question because we do get that question a lot and we recognize that. So first off, when we're talking about eligibility, eligibility is determined at the time of award, so it's not at the time of application at the time of award, and that includes the employment requirements as well. So you can say if I get this application I will then transition to being majority with the company, but you don't have to do that at the time of application, because we do recognize that it can take 6 to 9 months from the time of application to when you would receive your funds. Additionally, we recognize that not all small businesses may have access to all the lab facilities that they need for the proposed project. And what you can do is it's important to note how you would get that lab space is by having a potential letter that indicates that that you have identified a location and that you are ready to sign the lease the second that you can get those funds. That you can indicate what would be available to you as part of that and there are a number of different ways individuals can get access to that different laboratory or in different locations, often through incubators or other state or local resources. You could have access to space and again provided that you're able to show that this space would be available to you, if you receive the award, be able to clearly describe that space and where the work would take place, that's definitely an option. Also, this is why the STTR is so attractive for some people is that they can really utilize and partner with an academic research institution in order to do and have a location for some of that work. So that's an opportunity for some to get access to some research space or for different facilities, as well.

ADAM SORKIN: And here's a related question. Is there a requirement for patented IP for eligibility for funding? Do you want to talk a little bit about how IP figures into this?

STEPHANIE FERTIG: I that's a great question because we do get that question a lot is do we have to have a patent in order to apply? So, I first say is that not everything can, you know, not everything falls into patenting. Some software tools and we do support software tools and we do support all sorts of different services where maybe getting a patent might not be the most appropriate way to go there. Or that's just not how it's done in the marketplace, so on. You certainly don't need a patent in order to apply. I'm not a patent attorney. And Adam here is not a patent attorney, so I encourage you to reach out and talk with someone prior to applying many of our applicants do at least have a provisional patent or have started that filing process, have started talking with an appropriate IP expert in order to determine how best to move forward. An application is not considered public presentation of your idea. However, it's important to note that if you are funded, your abstract will be made publicly available as well, your title and your company name. And so it's important to note that and not put proprietary information in the wrong sections of the application, but intellectual property is really important and we don't. There is the Bayh-Dole act that does provide protections for a small business and your intellectual property. There's also data exclusivity as part of the SBIR and STTR program for up to 20 years. And so, it's important that there are a number of different protections associated with the SBIR/STTR program. But no, you don't have to have the IP all filed in wrapped up with a bow. You can be doing that as part of the SBIR/STTR, while that's going on. The other last thing I'm going to state is that as part of the SBIR/STTR program, you can ask for us to pay for the intellectual property filing, but you do get a 7% fee. As part of the application, you can request and receive IP for a7% fee. That fee is profit for the company and you can use that for a variety of things, including supporting your intellectual property. So, protections and getting patents and working with attorneys to do that. That could be part of that 7% fee. Definitely take a look at that and you'll see more information about the 7% fee in the application instructions.

ADAM SORKIN: Great. And here is a very common question. When should we expect to hear back about decisions? When will we be able to resubmit if we're unsuccessful? Do you want to take the opportunity to talk a little bit more about what that application decision timeline looks like?

STEPHANIE FERTIG: Absolutely so when you submit your application, and I recognize and I think Adam and I recognize that there's a journey just to get to the submission of the application. There's a lot of work that happens to get there and then once you've submitted the application again, as I stated, it goes through two levels of peer review. So the first level of peer review is that it does get assigned to a study section that is with external peer reviewers. Those peer reviewers will review the application and provide a score and a summary statement. Or if it's not discussed, you'll indicate not discussed and get a summary statement. That summary statement will include the reviewer comments. That summary statement that process takes approximately three to four months, I would say it's closer to three. It's pretty rapid on the NIH review timeline, so it'll be closer to three months, but three, three to three to four months for you to receive that summary statement. Now at that point, you know your score and you know what the reviewer comments are. Most institutes and centers consider applications within a specific score range. Getting a score of not discussed while it is not impossible to receive funding is highly unlikely, and so at that point that would be a great indication at that three to four months whether or not you are likely to be funded or whether you're going to be under consideration if you receive a score and you're not sure if you're going to be under consideration. That's a great time to reach out to the program officer and ask- Hey, if my project is under consideration, or should I start thinking about revising and resubmitting. So you'll get some feedback at that three to four month mark if you're under consideration, it can then move to the Advisory Council, that's the second level of review and then move forward for the administrative review. Review by grants management staff as well as go through the foreign risk assessment process. I should point out, I think it's important to note that the foreign risk assessment process is a new requirement put in under the last reauthorization of the program in 2022, I would encourage you to read the Foreign Risk Management section of our website very carefully. Take a look at the foreign risk assessment process. If you are under consideration, if you get to a certain point in the process you may be asked to submit a foreign disclosure form and undergo foreign risk assessment. Please make sure you read that very, very carefully on the requirements and what gets assessed as well as what will need to be submitted so that you can make sure to manage any potential foreign risks prior to the application process. It's so important that you take a good look at that. We have a number of case studies on the website as well to help you as you're taking a look at what this may mean for your project prior to submission, so do encourage that as well. But again, that initial piece of feedback will happen three to four months, but I figured I'd slip in a little piece about the foreign risk process there as well.

ADAM SORKIN: Great. Thanks so much. Here's an interesting question, but where can we find historical data about the number of applications by Institute in past cycles? So, there are a couple of great resources to find information about the program if that's of interest to you. You can read general information about past awards at our website seed.nih.gov in the portfolio heading if you're interested.

For more detailed information use the reporter.nih.gov link that Stephanie included, where you can look up prior awards and learn about the kinds of awards we've funded, specifically the NIH data book, which is linked, there has a lot of great information including application rates, success rates, what have you. So, it's a great resource for general information about the program. Let's see.

STEPHANIE FERTIG: I am going to jump in and maybe go out of order and apologies Adam.

ADAM SORKIN: Please. Nope.

STEPHANIE FERTIG: Who is doing a great job keeping all of your questions straight, so please do keep them coming. We did see a question about how and who can be a reviewer, and one of the big tips that I do tell people is if you have the opportunity, it's always great to be a reviewer. Nothing teaches you the review process faster than being a peer reviewer. You can request to be a peer reviewer, so you can say, hey, I'm happy to be a peer reviewer. You can do that by sending an e-mail with your CV to seedinfo@nih.gov and we're happy to pass that along to the Center for Scientific Review.

ADAM SORKIN: You know, thank you. I'm seeing a couple questions about how to approach certain parts about of the application, whether that's what kind of data to include or what kind of costs to include, and one resource for a number of you who are asking these questions might find helpful is that on our website if you do go to the how to apply portion of our page there's a handy infographic there the prepare your application page includes, among many, many great resources, sample applications from a handful of institutes and centers. So that's a great resource you can find to see what kinds of proposals have been very successful and well received by reviewers in the past and how they've approached these specific problems. And of course, these are always things that you can discuss with the program officer when reaching out to you to get more information about our programs and discuss potential applications.

STEPHANIE FERTIG: And I would also state because there was a question in here about if we offer any pre award workshops or specific programs and I would encourage you to reach out to state and local resources, but one great place to start is the Small Business Administration's FAST program. So, if you go to our website and you go to that that prepare your application section and I'm doing it in real time but you will see a list of those FAST awardees and what are those organizations within each of the individual states. And again, they offer a whole wide variety of different resources, programs, presentations and support for small businesses who are looking to apply and not just to the NIH, but to other agencies as well. So obviously we're big fans of the NIH small business programs, but the NSF, the DoD, NASA, all of these different agencies have a small business program. And these FAST awardees can help you take a look and see what programs may be applicable to you and then help you through that process? And so again, I'd encourage you to reach out to state or local resources as well. Even if you're not affiliated with the university, that's okay many of them help those nonaffiliated small businesses, particularly those who may be brand new to the program.

ADAM SORKIN: And since she raised the issue, I will take the opportunity to bring it up. We did get a question about whether or not a company awarded Phase I funding from NSF was eligible to apply for Phase II at NIH, and the answer to that question is yes, we can accept a Phase II proposal from any Phase I awardee from any participating federal program. There are a handful of special considerations that you do need to address when applying, so do be sure to very clearly read the FAQs and instructions that address this in the How to Apply section of application guide. Always a great idea, if you're in this situation to reach out to us and to a program officer to discuss the smoothest path forward to do that, but absolutely welcome Phase II applications that were funded in Phase I from other agencies. Let's see.

STEPHANIE FERTIG: There was a question about talking to someone before submitting an application and I am just going to jump because this is such an important and critical takeaway.

ADAM SORKIN: Please.

STEPHANIE FERTIG: I'm hoping that if you take nothing from our presentation today, if you take nothing from this Q&A, the most important piece of advice is on the slide here, which is talking to that program officer. So where can you find the program officers that are specific to the small business programs? First you can find them on our website seed.nih.gov/aboutseed/contact-us/hh-small-business-program-managers or you can go to that seed.nih.gov go to about the middle of the website. You will see the Institute specific SBIR and STTR contacts. You can click on that. You will see a list of all the SBIR/STTR contacts for each individual institute or center. They are all there. Now, but again, if you're not sure you can use NIH reporter to see which institute or center you're likely to be assigned to. That will help guide you to that program contact, but you can always e-mail us seedinfo@nih.gov with a brief description of what you're hoping to in planning to propose, and we'll connect you with the right individual or a couple, sometimes people fall between a potential number of different institutes. They could be assigned to a number of different institutes depending upon what's in their application. We provide some of those options. I would tell you if you're not sure, so say you're working in an area and you're looking at the different list of institutes or centers and you're thinking I could be two of these, I don't know which one e-mail both, put them both on the e-mail. As it turns out, we're a pretty small community. We do know each other. We don't get upset if we see both names on there. And speaking from experience as a program officer, it was perfectly fine if I saw my colleague also noted there and someone asked, hey, I'm not sure which institute can you tell me which one is likely to be the right one and will help you know. We may even talk amongst ourselves will help provide that guidance to you. So, the program officers do help determine, you know, will help you figure out who you should continue to have that conversation with.

It's important to note though, at the end of the day, it is up to the Center for Scientific Review and the institutes or centers, if they want to accept the proposal as it's submitted. So, we can provide guidance based on the information that you provide. But the final determination of assignment and whether or not it's going to be able to move forward and whether it meets the requirements in the notice of funding opportunity, that's all going to be determined after you've applied based on the full application and unfortunately NIH staff cannot review your full application before you apply. We just don't have the bandwidth to do that. So, it's important though, this is why reaching out and talking to someone and asking some of those questions and getting some of that information from a program office or if you have any specific questions you want to bring up- Hey, is this a clinical trial or? Hey, I'm not sure if this is a clinical trial as it’s only a low-risk human subject study. That still might mean the clinical trial definition, so you might want to reach out and have that conversation in advance.

ADAM SORKIN: Here's a very important question. Are there rules or NDAs that prevent reviewers from utilizing IP in SBIR and STTR proposals?

STEPHANIE FERTIG: Confidentiality is a very serious thing here at the NIH and confidentiality, and the confidentiality of the review process is paramount. It is something that NIH strives to enforce. We do require individuals to sign, conflict of interest they are not a full non-disclosure, but there is confidentiality and that that is a component and part of the agreement. Now I will tell you this, we do get one of the questions I'm going to go off of this slightly. One of the questions we do often get is around conflicts of interest and whether or not small businesses and who's going to be reviewing my proposal? And what if there's a conflict of interest there?

There is the ability as part of the application to indicate if there are any specific conflicts of interest. So, for example, if you know that there's another company that is your direct competitor you can indicate that they would be a potential conflict of interest. They're a direct competitor. That said, please do not put as a conflict of interest, and I'm just going to make this up, all imaging experts, because then we won't have the expertise to review your imaging focused SBIR or STTR proposal. So really, it's important to target if there's a specific individual that is in clear conflict or if there is a specific organization that is in conflict, you can indicate that individual.

Make sure you don't indicate people who you'd like to review your proposal. That will automatically put them in conflict. So, asking for this individual person to review your application that will put that individual person in conflict with your application, guaranteeing that they will not review your application. So do make sure that that what you can indicate this is the kind of expertise that I think is required and necessary to review your application, you can also indicate what institutes or centers you think would be interested. You can indicate more than one. It's okay to have more than one institute or center. You'll have one primary, but it's okay to have a couple secondary institutes or centers, no harm in that. And potentially they might pick it up if the first institute or center, your assigned institute or center is unable to fund the application. But if it's a good solid application other institutes or center may indicate interest. Finally, I would state there is a place to indicate your study section. And in that form you can indicate which review study section you think it should be assigned to. But I definitely tell people if you're not sure, just leave it blank. It's okay. The Center for Scientific Review they do this for a living. They will make sure that you're assigned to the appropriate studies section based on what's proposed so you can get the right expertise to review.

ADAM SORKIN: Right. And just adding to that, you know, if you have concerns about any of these issues after your application is received and referred to study sections and institutes and centers, you will have a scientific review officer who's a great point of contact that can help you sort through any confidentiality concerns? Any reviewer concerns and things like that. Just making sure you get you know the best, most appropriate review. And I think you've answered one of our most recent questions as well. Let's see. Questions look like they're slowing down a little bit. Do you see anything else in the Q&A that you'd like to address.

STEPHANIE FERTIG: I did see a couple of questions around and targeted on individuals who may be a little bit earlier in their career and what they should do and what they should be thinking about. I think that's a great opportunity again to talk about our transition award and points and actually, Adam is the point of contact for that program. So, I'd encourage you, if you do have questions, read through that notice of funding opportunity. And then happy to if you have questions, reach out to seedinfo@nih.gov. You can see it here the small business transition grant for new entrepreneurs. It's a great place to start if you have a question.

ADAM SORKIN: Here's an interesting question. How can we find the appropriate viewer roster for my area of interest? So, the NIH Center for Scientific Review does publish the rosters for the SBIR and STTR review meetings each cycle, so you can go to their website and review the small business special emphasis panels and they will have recent rosters. That doesn't necessarily mean that that will be the roster that's guaranteed for the next cycle, but it should give you a good idea of who is typically on those panels at least in recent cycles.

STEPHANIE FERTIG: Great. And I see there's a question that came in again about where to go if you want to find specific points of contact. So, I'm going to scroll back to this slide. I can pretty much leave this slide up at the end of the day, it has the list of individuals. You can find that on our website the institute specific SBIR/STTR contacts. But you can also always reach out to seedinfo@nih.gov. We will connect you to the appropriate points of contact for your specific research area. And I see the question about a presentation for later viewing. And as we indicated on the top of the hour and we always get a couple questions about this, and I love that because from my perspective it means that it was a helpful presentation we will be putting this on our website in approximately 7 to 10 business days. The recording and the slide deck will be made available so please do be looking for it there on the event section. We do try to post these because we recognize that individuals may have had partial conflicts or full conflicts, last minute conflicts and were unable to attend.

ADAM SORKIN: Okay. Let's see. Well looks like the questions are winding down, Stephanie. Anything you'd like to get to, any last words you have for our audience before we wrap things up?

STEPHANIE FERTIG: I would just encourage you as to read the notice of funding opportunities very carefully. Even the open topics solicitation. Read those program descriptions. Read the notice of funding opportunities very carefully. Read through the those the peer review section. Read that Section 5. Read the information that's under each of those individual categories, as well as the additional review criteria. That rubric has the information that the reviewers are going to be looking for.

Utilize the resources both online as well as your state and local resources, and finally reach out and talk to a program officer well in advance of the application. That's really important to do that. If you have any questions and just to make sure that what you're planning to propose is in the right program announcement and fits with what they anticipate.

ADAM SORKIN: Great. Well, thank you so much everybody to joining us today. Thank you to Katie and Kara for helping us keep things moving on the back end. If we didn't get to your question today, you can always reach out to us at seedinfo@nih.gov. We're very happy to address your questions offline. And with that, I will wrap things up as we just discussed, lookout for materials online in 7 to 10 business days and thanks so much. We're excited to hear from you.

STEPHANIE FERTIG: Thank you, Adam. Thanks everyone.