NIH SEED Small Business 101 America's Seed Fund is Back - Powered by HHS

June 9 2026, 1:30pm ET

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Sorkin, Adam
Alrighty. Well, thanks so much for joining us today. I am Adam Sorkin. The small business policy manager here at NIH seed. A little bit of housekeeping before we get started, we ask that you please do use the Q&A function to ask any questions you might have during the presentation. We will address everything at the end of the presentation today.

We do ask that you please disable any AI agents in note takers as NH policy does not allow for them. Materials, including slides and recording should be available to everybody who's registered by e-mail in about seven days after today's event. And with that I think we can get started.

Fertig, Stephanie
Great. Thanks, Adam. So hello, everyone. Great to see so many people have joined us today. My name is Stephanie Fertig and I'm the director of the NIH Small Business Program here within the office of Extramural Research and I'm pleased to talk to you all today about how America's Seed Fund is back and some of the opportunities that we have to support small businesses through Health and Human Services.

We're going to talk about a number of different things today. We're not going to go into maybe all the details and all the little different components that make up the program. We're really going to be focusing on some changes and so I encourage you to take a look as I'm going through my slides today for those stars that designates changes to the program since we've recently been reauthorized and we're back in action. However, you can find information at our website, seed.nih.gov. That has a lot of specific information, particularly as we're going through it today. If you miss something or have some specific questions, you can find information there as well.

We really do utilize the Small Business Programs here at HHS. Now, today I'm going to be focusing very heavily on the National Institutes of Health, but the Food and Drug Administration, as well as the Centers for Disease Control and Prevention, also are signed on to the some of the solicitations that we're going to be talking about today. There are two other components within HHS that have an SBIR and or an STTR program: the Small Business Program at the Administration for Community Living, specifically the National Institute on Disability Independent Living and Rehabilitation Research (NIDLER), and the Advanced Research Projects Agency for Health or ARPA-H. But I'm not going to go through these two today in detail. But I will say ARPA-H is having their own webinar and proposer's day coming up shortly on the 11th, so I encourage you to take a look if you may be interested and take a look at their information and see if that might be something that you might want to look at as well.

All right. With that, I really do want to focus on the National Institutes of Health and our mission today. Our mission is turning discoveries into health and we really utilize the small business programs to take those great innovations and get them into the hands of the patients, clinicians, caregivers and researchers that need them, to help us meet that overarching mission.

Now these are congressionally mandated programs, recently reauthorized, and they are some of the largest sources of early-stage capital for life sciences in the United States. It's about $1.4 billion specifically for small businesses. We call this America's seed fund, but really it's two specific programs. The Small Business Innovation research, or SBIR program and the small business technology transfer or STTR program. They're very similar in scope, but there's one big difference. The SBIR *allows for* partnering while the STTR *requires* partnering between a small business and a nonprofit research institution. There are some specific policy differences between the two. I'm not going to be going into them in detail, but regardless of which program you may go into and and want to be part of, in both of these situations, the money is always going to a small business.So the small business is really the center of both of these programs.

What are the benefits? Well, really we're here at the early seed stage. We're supporting those brand-new innovations and supporting companies before they may be getting those additional funding or partners. This is non-dilutive capital. It's not a loan and we can help those companies de risk their technologies and attract investors or partners to be able to take their technology to the marketplace. So we really fit in this early seed funding space.

That's great, but who's eligible? Well, the eligibility criteria is one of the things that hasn't changed: you still have to be a for profit U.S. business, a small business that means 500 or fewer employees including affiliates and have individual ownership. Now the individual

ownership, that's often something where we get a number of questions around that. You can see some of the bullets that define individual ownership here. But the Small Business Administration that sets the eligibility criteria, they've got a great eligibility guide. I encourage you if you have questions about eligibility, take a look at that guide. It is a wealth of information.

Now one change and this was always true, that the work must be done in the United States. But an important change is that now NIH only allows for unfunded international collaborations or foreign components. So we no longer allow for foreign sub awards or subcontracts to be a funded part of the SBIR or STTR grant.

So these are phased programs. These are not clinical trials phases. It's an unfortunate similarity in the nomenclature. We have phase one, which is feasibility, and phase two, which is full research and development. Now there are a number of ways to enter the program. You can enter doing a phase one. We call it a more standard path. You get a phase one if you're successful with that phase one, you can then apply for a phase two. We also have something called a Fast-Track which combines the phase one and phase two into one application. It basically eliminates the need to come back in and go through our review process between the phase one and phase two. It undergoes an administrative review and finally there's something called a Direct to Phase Two. It allows those companies that have already done the feasibility work for a phase one to go directly to a phase two.

Now you'll see there's a star there, and that's because one of the changes in the most recent reauthorization is that now you can have either an SBIR or an STTR and take advantage of the Direct to Phase Two. So it's now open for both programs.

Regardless of how you get to the phase two, we recognize that there's often a gap between that phase two and the commercial market, or even a partner or investor. That's why we have the two programs that you see here, the Commercialization Readiness Pilot Program (CRP) and the Phase 2B Strategic Breakthrough. Now the Phase 2B Strategic Breakthrough is another new program and we're going to get into the differences between those two and provide a little bit of extra detail, a little bit later in the presentation.

NIH has a very flexible small business program compared to some of the other agencies. One of the flexibilities we have is around the budget. We do have the Small Business Administration budget guidelines you see here on the slide. However, we do have the ability to award larger grants for some selected topics, and so again, we're going to talk a little bit later

about budget and where you can find information on some of our solicitations. But there is some flexibility there for some specific topics.

Now the majority of our funding does go to what we call investigator initiated grant applications. What does that mean? Well, generally NIH is not the final purchasers of the products that we develop, but that are developed through the small business programs. We really look to the community to identify those difficult problems that are out there being faced by again clinicians, patients, researchers, caregivers and give us their great ideas to solve those problems. That's those investigator initiated grant applications. Come to us with those problems and with those great solutions.

We have 3 standard receipt dates a year, September 5, January 5, and April 5. And this September, which is the first receipt date coming up, you'll see that we're right up against Labor Day when a receipt date falls on a weekend or a holiday, it goes to the next business day. So you all have until September 8th to submit those great applications.

Now you can find a link to our funding opportunities directly on our website, but I will tell you they are now open and they are our parent notices of funding opportunities. So again, these are open topic solicitations. These are our parent Notices of Funding Opportunity, or NOFOs. We have a parent SBIR and parent STTR.

This year we have the small business funding considerations and contacts Web page. So for those who have been around a while, maybe you were looking for specifically the program descriptions page. Well, that's the brand new funding considerations and contacts page. So check out that page. You'll see the Institutes and Centers that are part of these different NOFOs. You can get an idea of some of their funding considerations as well as get those extremely important contacts.

One of the big takeaways I'd like everyone to take away from today is to reach out and talk with us. Reach out and talk with the different institutes and centers that might be interested well in advance of your application. The Notice of Funding Opportunity has a lot of great information and I encourage you all to read them thoroughly. It's important to see and make sure that you're applying to a Notice of Funding Opportunity or applying to the right Notice of Funding Opportunity and you're following all the requirements within it. You can see they have the participating Institutes and Centers, those due dates, the purposes and objective, budget guidance, review criteria. And again, it's important to get those contacts. So it gives you an idea of the different components that you might need as you're preparing your application.

One of the big differences you might have noticed is instead of having two separate Notices of Funding Opportunity, one for clinical trials required and one for clinical trials not allowed, we've combined them into one. We've reduced the number of Notices of Funding Opportunity, so now we have a clinical trials optional and that's pretty exciting. It simplifies things, but it's important to note that not all participating Institutes and Centers accept clinical trials. So it's important to look at the Notice of Funding Opportunity in Section 1. Under the applications not responsive to this NOFO, see the Institute or Centers. If you're likely going to be assigned to one because your project is in their mission, check to see that they accept clinical trials. If not, reach out and talk to them ahead of time. Consider if you are doing human subjects research, are you really a clinical trial?

You can also look more generally at those small business funding considerations in context, but always follow the Notice of Funding Opportunity. Now if you're doing any human subjects research, make sure you read through the NIH definition of clinical trials very carefully.
It may be broader than you think. It's important to note that we've seen throughout the years a number of small businesses who thought they weren't doing a clinical trial, but come to find out, per the NIH definition, they are. And so it's important to read that definition. Use the decision tool that's available online and see am I a clinical trial? Is that how I need to identify and submit?

Some other significant funding opportunity changes that you might want to be aware of is that we now require a regulatory plan attachment and this is required for those phase one and Phase 2 SBIR and STTRs that propose a clinical trial. So again, very important to know, if you're a clinical trial or not. In addition, all Phase 2B strategic breakthroughs and CRPS also have to have this regulatory plan attachment.

The good news is you're no longer required to submit a data management sharing plan. We're not accepting those for SBIRs or STTRS anymore. So that's no longer a requirement, no longer have to worry about that attachment.

Now, I did promise to talk a little bit about the Phase 2B Strategic Breakthrough and the Commercialization Readiness Pilot Program or CRP. Now the CRP has always been its own Notice of Funding Opportunity. But the Phase 2B Strategic Breakthrough is new.
We're no longer allowing for Phase 2Bs through the standard parent. Those second phase. twos all have to come in through the Phase 2B Strategic Breakthrough. The big thing to note for the Phase 2B strategic breakthrough is that it does require 1 to 1 matching funding. I encourage you to read through the Notice of Funding Opportunity very carefully if you're looking at doing a Phase 2B Strategic Breakthrough. Not all Institutes and Centers participate in the CRP or the

Phase 2B Strategic Breakthrough. All applicants to these two funding opportunities must have been awarded an NIH phase two SBIR or STTR in order to be eligible.

So you've got your notice of funding opportunities you're ready to get started. Well, you're going to be submitting electronically. In order to submit, you need to make sure that you have the required registrations. Every receipt date we hear from individuals who did not realize that they needed these required registrations and they do take time. If you do not have these required registrations in hand start getting them right now. That should be your first step after this webinar. We encourage people to submit using the ASSIST system, although you can submit using grants.gov, but we do encourage you to utilize ASSIST. It has some features that make the submission a little bit easier.

One big change is the common forms for the biographical sketch. This is required. Now what this means is that all senior and key personnel must have an orchid ID and link that to their ERA comments personal profile. So it's really important that any senior or key personnel that you plan to have on your application have that ERA Commons profile and have that linked to an orchid ID.

Another important change is that we are not no longer offering late submissions for SBIR or STTR. There is no late submissions, so yes, you have until September 8th because of the holiday. But please don't wait that long. Submit early just in case something isn't quite right or there's an issue with the submission, you want to have time to be able to make the fix and get your application in.

We have a number of application resources to help you prepare your application. We have an annotated form set. We have application instructions, sample applications which are very popular and there also might be state resources and you can check out some of those state resources. The Small Business Administration supports some specific state resources. We do have those online. So again, take advantage of all the state and local resources as well as the resources on our website.

So first NIH as a whole (and this includes the SBIR and STTR program) limits principal investigators to six applications per calendar year and limits the use of AI and writing applications. Please do make sure you take a look at that Notice to make sure that you understand or aware of the policies there. In addition, as part of the reauthorization, small businesses also have a limit. They are now limited to 9 applications or proposals per fiscal year. So PIs are limited to six applications per calendar year and in addition, small businesses are limited to 9 SBIR or STTR applications or proposals per fiscal year.

Now the SBR and STTR programs do support research and development, but we find that many of our recipients need more than research and development. They need some help with commercialization as well and one of the changes in the legislation provided a little bit more flexibility with regards to technical and business assistance funding. Now companies can ask in their application for technical and business assistance funding to help address some of the product development needs that they may have with regards to that specific project for a phase one, you can ask for $6500. For a phase two, you can ask for up to 50,000.

One of the big changes is that now, while yes, you can still utilize this funding to get a vendor or consultant to help you in this area, you can also support new and existing staff sub awards. There's a lot more flexibility with the individuals that you can support utilizing this technical and business assistance funding. I again encourage you to check out our website and see what is and what is not allowed using this money.

And finally, I would be remiss if I didn't remind everyone about the SBIR/STTR fee.
You can ask for a reasonable fee of up to 7% of the total cost, and you can utilize that for commercialization activities. And so that is often a way that small businesses will support some of the things that they need beyond the research and development.

I mentioned this before, but I'm going to mention it again. The most important piece of advice is to talk to a program officer at least a month before the application deadline. You can find points of contact on that small business funding consideration and contacts page, and I encourage you to take a look. It has a lot of information in there, not just the points of contact, but again, it does have some of those funding considerations, including if there is specific information around the kinds of projects or if there's larger budgets for specific scientific areas that Institute or Center might be interested in supporting. If you're not sure who to contact, you can look at NIH REPORTER. That is where we post all the different projects that we have supported previously and where they were assigned, which Institute or Center. You can also e-mail us directly at seedinfo@nih.gov and we can assist in connecting you to the right individual or individuals for your project.

Now I hinted at this a little bit with the funding considerations, but let's talk about once you submit your application, what happens? Well, we utilize a peer review process here at the National Institutes of Health. And so we have that peer review and then there is a funding decision process as well. And I've laid it all out here for you to see.

One of the big questions I always get asked is how long does it take from the time of submission to funding and it takes about 10 months. However, you do get information from the peer review process about three to four months from application, so you'll get feedback within three to four months of your submission.

Now let's talk about that peer review process.The Center for Scientific Review now conducts all reviews of SBIR and STTR. Historically, they've conducted the vast majority, but they are now conducting all peer review of SBIR and STTR applications. There are 5 review criteria significance investigators, innovation, approach and environment. If you've come to the NIH for funding in the past, those might look very similar. But unlike some of other programs, these are really focused on product development and commercialization. If you look at the Notice of Funding Opportunity, you can see the specific questions in Section 5 that we ask our reviewers to consider when reviewing a application and so it's important to take a look at those specific questions. They are the CHEAT SHEET. Make sure you're answering those questions in your application. While each application is assigned several reviewers, if an application is discussed and overall impact score is given only after discussion by the Scientific review group and it's the overall review group that weighs in to that score. Now, not all applications are discussed, but all applications receive reviewer comments - and those reviewer comments are very, very valuable. So I would make sure that you review them carefully. It can be extremely important as you're looking in and determining what you might need to improve in your application moving forward.

One of the changes that has occurred at NIH is that we're no longer utilizing a pay line. Scores and reviewer comments are considered, but they're considered along with other factors such as strategic plans or budgets. And again, I do encourage you to take a look at the small business funding considerations and contacts page. They have specific information that for SBIR and STTR programs. We are a very competitive program. Please be prepared to resubmit - most applicants don't get it on the first try, and that's OK. Resubmission is part of our process. Be prepared to take a look at your application, take that reviewer feedback and resubmit if needed.

Part of the process if you go, if you think back to that process, we do ask you for just in time documentation and one of the things that we review as part of that just in time documentation is foreign disclosure and risk assessment and now this is required as part of the legislation and HHS is required to assess all SBIR and STTR applications for foreign security risks prior to award. Companies have to provide a required disclosures of foreign affiliations or relationships to foreign countries form, and you do one per application as part of that, just in time documentation process. You provide one form, but it encompasses the entire project, so all the

owners, covered individuals, the company itself. It is one form for the whole project.
NIH cannot make an award if a foreign risk is identified in any of the denial categories that are listed in the SBIR and STTR legislation. We do have a specific Notice that details that as and it's also on our foreign disclosure and risk management web page. You can take a look there to see some of those categories of denial. If a small business does have a foreign risk that's identified, they can take a look address that foreign risk and resubmit at the next receipt date. It is not an eligibility issue. You can certainly take a look and again make sure that you that you've addressed that when you resubmit. Now, small businesses are responsible for monitoring those relationships with foreign countries of concern. And so I do encourage you to again take a look at our website. You'll see the process there, the denial categories and most importantly, case studies. We found that those case studies are very helpful as people are trying to understand the process and what might be considered a foreign security risk. I encourage everyone to take a look at that website, read it carefully.

And so with that, I'm going to encourage you to connect with us again. If you have any questions after this webinar, seedinfo@nih.gov, you can go to our website, seed.nih.gov, and make sure you take a look at the National Institutes of Health, LinkedIn and Twitter.

A Q&A session followed.