

Navigating America's Seed Fund at NIH – August 2023

Adam Sorkin: I am Adam Sorkin, Small Business Policy Manager for the NIH Small Business Education and Entrepreneurial Development Office, known as SEED. I am very excited to welcome all of you to our webinar today, "Navigating America's Seed Fund at NIH." A little bit of housekeeping before we get started: The recording for this webinar will be available in approximately 7 days at seed.nih.gov on our Events page and slides and transcripts will be available at the same time. Also, please use the Q and A function to submit questions during the presentation. We will address those after the presentation concludes. And with that, I am excited to introduce Stephanie Fertig, Director, NIH Small Business Program, who will take it away.

Stephanie Fertig: Thanks so much, Adam, and thank you, everyone, for joining us today as we discuss how best to navigate America's Seed Fund here at NIH. Now, we're going to be talking about a number of different topics today, and we're going to be going through a large amount of information. I really encourage you to go to our Small Business Program Website, seed.nih.gov. It has a wealth of information, including information about this event and upcoming events as well in the future. Today, I'm going to be focused on NIH, but I really want to point out that NIH is not the only component of Health and Human Services with a small business program. FDA, CDC, and ACL all have small business programs and are interested in funding great innovations through their small business programs. So, I would encourage you to take a look at their mission areas, as well. FDA and CDC are on our general omnibus solicitations, which were just released, so I encourage you to take a look at those. Take a look at their missions and see if that might be a good fit for your technology, as well. So, the NIH mission really can be summarized as turning discoveries into health, and the small business programs help take those great innovations that are across the United States and help them get into the hands of the patients, clinicians, caregivers, and researchers that need them. These are congressionally mandated programs.

You'll hear us talk about them as America's Seed Fund, but they're also known as the SBIR and STTR programs. That's the Small Business Innovation Research and Small Business Technology Transfer programs. Now, these together are about \$1.3 billion specifically dedicated to supporting small businesses. And this is a, again, congressionally mandated set-aside specifically for small businesses. This is one of the largest sources of early-stage capital for life sciences in the United States, and really, these provide small businesses the ability to take their innovations and derisk their technologies and allow awardees to leverage funding to attract investors and partners.

One of the unique features of the NIH program compared to other agencies is that we tend not to be the final purchasers of our technology. So really, again, we're here to provide non-dilutive capital. It's not a loan. You don't have to pay it back. We're here to provide that capital so that you can, again, derisk your technology, do that feasibility study, do that further research and development to then take that innovation to market or attract the investors and partners necessary to take that product to the marketplace and get it into the hands of the individuals that need it. One of the things I'm going to be doing today is a little myth busting, so myth number one, and this is a myth I hear a lot, that it's just easier and better for a company to get investors and avoid all the time and work for an NIH grant.

And I really want to bust that myth because many of our companies have developed their product with non-dilutive funding that is very attractive to investors and strategic partners. And in fact, we have a number of examples of that on our small business website where you can go and look at our Small Business Success Stories, and I have a couple of examples here because I like to illustrate the depth and kind of wide breadth of different technologies that we can support, everything from drug development, which, I'm sure you might say, "Yes, obviously drug development," but also diagnostics, research tools, digital technologies, digital health, a wide range of different modalities.

We have 24 different institutes and centers. Those 24 different institutes and centers that participate in the program, yes, there is the National Cancer Institute, Allergy, and Infectious Diseases, but there's also some of our smaller institutes, the National Library of Medicine, Minority Health, and Health Disparities. So, we have a wide range of different institutes and

centers that support technologies within their mission space. So, let's talk a little bit about the small business programs. These are phased programs. Now, these are not related to clinical trials' phases. That's an unfortunate similarity in the nomenclature. Phase I is a feasibility study. Phase II is full research and development. Now, we don't really define feasibility and full research and development. We do get a lot of questions about what counts as feasibility, what counts as full research and development.

I would say one person's feasibility study is another person's full research and development, so really you should see the feasibility study as the feasibility study necessary to do that full research and development. We offer the standard phase I and phase II. We also offer something called a Fast-Track, where you take the phase I application and the phase II application. You put it into one proposal, and it gets reviewed together as one package, and that's a Fast-Track. We also participate in the Direct to Phase II. It's only for the SBIR, but the Direct to Phase II allows those companies that have already done feasibility to go directly to the phase II. Now, regardless of how you get to that full research and development, we do recognize that there might be a gap between the phase II and the commercial market, partner, or investor. And that's where we have some additional programs, an additional phase II, a competing renewal or the Commercialization Readiness Pilot, or CRP. It's important to note that only some institutes and centers participate in those additional programs, and this leads me to, if you take nothing else from this webinar, please contact a program officer well in advance of applying. And we'll have a little bit of information on where you can find that, who to contact on our website, and it is on our website, but please contact us in advance. Another big question I get is around the budget sizes.

You can see the Small Business Administration Budget Guidelines here in the corner, but we do have, both NIH and CDC, have a waiver from the Small Business Administration to exceed these budgets for certain topics, and we do have those posted on the web as well. And so again, even if you may need additional funding and additional time because that is the nature of some biomedical research, we'd encourage you to take a look at these programs because we do have some of that flexibility. So, this is another myth that I do here, "It's much harder to get an NIH Fast-Track or Direct to Phase II, so don't even bother applying for those." And I really want to

bust that myth. Although most of our new projects are phase I, we support many Fast-Tracks and Direct to Phase IIs. It's really important to speak to a program officer and see what makes the most sense for your project. Really, it is based on the project, the preliminary data that you have and what makes the most sense for what you're trying to propose. So, who's eligible? Well, I've put the eligibility criteria here. In general, the most questions that we receive is around individual ownership. And I'm not going to walk through all of these specifically, but I will state that if you need additional information about eligibility, that is available on our website, including a Small Business Administration document that helps walk you through how they did make a determination around eligibility and provides some examples.

So, I would encourage you to take a look at our website for a deeper dive around eligibility, but in short, it really is supposed to be for a for-profit US business that is small with individual ownership. And the work needs to be done within the United States. There are some exceptions, but in general the work needs to be done in the United States. Now, this eligibility is determined at the time of award. We do not determine eligibility prior to submission at the application. So, we're really looking at the time of award, are you eligible? The majority of our funding does go through what we call investigator- initiated grant applications. So, you can look at our solicitations. You can find those front and center on our website. We do have three standard receipt dates. The next receipt date is September 5th, but if you're worried, you're going to miss September 5th, don't worry. January 5th is right around the corner. And then we have another one in April 5th. So, the good news is, we have multiple opportunities through the general solicitations for you to submit. A little bit more about a deeper dive into some of our open funding opportunities, yes, we do have the General Grant Omnibus Solicitations. And I'd encourage you to read through the program descriptions and research topics within the solicitation.

It's very important that you do that because that gives you an idea of what the focus and the specifics for each of the individual institutes and centers because each institute and center really does utilize this small business program in different ways to meet their specific mission and research needs. We have two sets. We have Clinical Trials Not Allowed as well as Clinical Trials Required, and we have one for SBIR and STTR. In addition to these general, open

solicitations, we do have targeted solicitations. We have the specific grant solicitations. You can, again, find them at that on our website as well as the contract solicitation. That presolicitation is currently out. We do expect the full solicitation to be released shortly. It's extremely important that you read the notices of funding opportunities very carefully. Not all institutes and centers participate in specific notices of funding opportunity, and not all targeted solicitations have specifics set aside or review. Now, this is a big myth that I often hear, "I should apply to specific program announcements because targeted funding opportunities have their own dedicated funding, or I have a higher probability of getting money if I come in through a targeted funding opportunity." Well, most NIH awards are actually made to the general omnibus solicitations. If you don't see a specific funding opportunity, that's okay. I still encourage you to look at the general omnibus solicitations. Really only about 8 percent of our awarded projects are contracts.

The vast majority, usually more than 75 percent, of our grant awards are made to the omnibus solicitations, and so it's really important to look at that as an option as well and not just look at targeted funding opportunities. Now, you saw in there that there was an option to do either SBIR or STTR. Let's talk about some of the critical differences there. The SBIR, really the big difference that divides the two is that the SBIR allows for partnering while the STTR requires a nonprofit research institution partner. All the differences that you see here kind of flow out from that difference in the partnering requirement. There are some differences around the work requirement, how much can be outsourced versus a minimum work requirement in the STTRs and the principal investigator. So, the work requirement, the SBIR, you may outsource up to 33 percent in the phase I or 50 percent in the phase II versus the STTR requires a minimum of 40 percent of the work be done at the small business versus 30 percent at the research institution partner. In an SBIR, the principal investigator must be primarily employed with a small business, versus in the STTR the PI must ... may be employed by either the research institution partner or the small business. Regardless of if you're doing an SBIR or STTR, the award is always made to the small business. This is very important. The award is always made to the small business.

This is a big myth because I bet, you're thinking back to that slide when I first introduced SBIR and STTR., and you're thinking, "Well, wait a minute. The STTR program is so much smaller. That must not be the best way to go." Well, I want to bust this myth. The size of the program doesn't necessarily correlate with the chance of getting awarded, and in fact, STTRs or even smaller NIH institutions, they have far fewer applications. And so sometimes they're really looking to fund great innovations, and they may have less competitive programs than some of the larger institutions. So don't just look at budget size when determining where you might want to target your application or when you're thinking about what you want to do. I'd really look at what is the best fit for the project that you're planning to propose. Another thing you might have noticed in those notices of funding opportunity is clinical trials required, clinical trials not allowed. It's really important to note that not all of our funding opportunities support clinical trials, and not all of our ICs, our institutes and centers, support clinical trials through the SBIR or STTR program. A definition of a clinical trial may be broader than you think. You can see it here, and we really encourage the use of the decision tool.

It's important for you to reach out and talk with us before applying if you're doing any human-subjects research so that you can make sure that the institute and center you're likely to be assigned to supports clinical trials if you are a clinical trial and determine if you are, in fact, a clinical trial, because, again, this is a very broad decision, a broad definition, and it is not necessarily the same as the FDA or others may use. And in fact, this leads to one of our myths, that if the project risk is low or only has a few human subjects, it's not a clinical trial, and that's unfortunately not the case. Again, the definition is very broad. It's not based on risk. It's not based on number of subjects, so it's very important to talk with us. So, let's talk about the application process. We do use the NIH review process, and the entire process from application to award takes about 6 to 9 months, but it's important to note that companies do get feedback 3 to 4 months after submission. Now, one of the big myths that I hear is that novice applicants to the program aren't successful, and I really do want to bust this myth. About approximately a quarter of all of our SBIR, STTR awards do go to new investigators. We strongly encourage new applicants, particularly from underrepresented innovators or underrepresented parts of the country.

And we have a number of resources to help support you as you're putting together your application, application instructions, an annotated form set, sample applications. We also have programs for applicants. We have an Applicant Assistance Program, the Health Disparities Pre-Application Program, and NIAID has their own specific application-assistance program. So, we encourage you to submit. We encourage you to take advantage of these resources. The sample applications are particularly popular. And if you are new to the program, take advantage of the applicant-assistance programs if that's an option for you. One of the things I want to point out as part of the application is the opportunity to request technical and business assistance funding as part of the award, and you can do that if you want to use your own vendors for technical and business assistance. You need to, and I just see a mistake here. It's \$50,000 per project for phase II, so we will correct that in the slides when we post them. So that's 6,500 per year for a phase I and \$50,000 per project for a phase II, so we will correct that in the slides. My apologies. And you can follow the instructions to request funds in the application if you would like to use your own vendor. But I do want to point out particularly for our phase Is, we do encourage you to take advantage of our needs-assessment program.

If you don't ask for funds in the phase I for the needs assessment, you can ask for a needs assessment that will provide a third-party, unbiased assessment to help you kind of determine what your next steps and needs are to then help you as you're thinking about, "What do I want to request?" for the technical and business assistance in the phase II. So, since this is really part of the application process and something you do need to think about as you're putting together your proposal, I encourage you to look at the technical and business assistance, and if you have any questions on that, you can reach out. And again, we will correct the slide with regards to the \$50,000 per project for the phase II. A couple of other highlighted recent changes that I want to point out, particularly for those who may not be new to the program, we do now require data management and sharing plans. Now, it's really important to note that just because we do require that there is a plan, but acceptable plans can really reference and incorporate the data rights that small businesses have through the SBIR and STTR program. It's important to note that you can retain the rights to data generated during the performance of the award for up to 20 years after the award date. And so, again, a successful plan can

incorporate that in. That's part of the plan because that is your right. That is a specific right to retain that data.

It's also important to note that we may make those plans public, and so the plans should not contain any proprietary information. So again, I would ... We have a wealth of information online around data management and sharing plans. I encourage you to take a look at those, but we do require them for the SBIR/STTR, but they can incorporate that you can retain the rights to data generated for up to 20 years. The other new component is facilities and other resources. We now are requiring that you ... You must describe the business environment and resources or how you will obtain them, and you can certainly talk about how you're going to obtain those resources for completing the project and commercializing the product or service, and that should include any relevant intellectual property associated with the project. I actually see this as a positive. One of the things that I was asked often as a program officer is where you put that information. Individuals wanted to put the information around what business environment and resources they had as well as their intellectual property. This gives a good place for individuals to provide that information. But again, the most important piece of advice, since we're going to have a number of questions today, is to reach out and talk with us. Talk to a program officer at least a month before the application deadline. If you're not sure who to contact, as we noted, there is a list of small business program managers that are on our website, seed.nih.gov.

You can see ... Look for the big NIH building. Right underneath that, that's where the list is located. You could always go to the Research Portfolio Online Reporting Tools, or RePORT tool, report.nih.gov. You could see the different kinds of technologies that have been funded previously and where they were assigned, which institutes and centers they were assigned to. You can also always ask your questions or ask who next to talk with at SEEDinfo@nih.gov. We're happy to take your questions there as well. Now, this is a big myth, and I've talked a lot about the 24 different institutes and centers. And we note that applications are submitted to a specific institute, and we ... People think that that is the case. I'm submitting to Allergy and Infectious Diseases, so I need to choose that you ... Individuals think that they need to select their specific institute or study section. Well, that's just ... That's also not the case. You are

submitting your application to the NIH. We are then assigning that to a specific institute and study section. Now, some individuals may prefer or have a preference for one institute or center or another or may have a preference for one study section or another. And you can request a specific institute or study section, but you don't have to. The Center for Scientific Review makes the assignment, so they'll take your requests.

But they're going to make that assignment based on what is in the proposal, what's being proposed and the mission areas of the individual institutes and centers. So, it's always helpful to reach out and ask us, "Where do you think you're going to fall?" so that you can figure out which institute and center you're likely to be assigned since there are those differences in the programs. But again, you're not required to. It is not a requirement. But we do encourage you to contact us ahead of time. But again, one of the big questions I get is that ... and the myth is that you're really coming into the NIH, and we're assigning you to the individual institutes and centers. So those individual ... You're not coming in for a specific institute. Now, the application and review process, we do utilize the peer review process. So once an application is submitted and it's been assigned, it goes to a specific scientific review group or study section. Now, the scientific review officer, who is your point of contact during that part of the process, recruits peer reviewers with the appropriate experience, and that includes scientists, clinicians, individuals with small business experience. Really, our small business study sections have kind of a wealth of different kind of perspectives that are brought to the table. Now, at least three reviewers are assigned to each application, so let's talk a little bit about the review process.

So, there's three assigned reviewers, and those three assigned reviewers are looking at five review criteria that are scored individually, and I've put them here. And for those who are familiar with the NIH process, these should look very similar: significance, investigators, innovation, approach, and environment. But it's really important to note that these aren't the same as some of our other research grant applications, and that's because funding opportunities contain specific questions that the reviewer should consider. So, each Notice of Funding Opportunity has specific questions under significance, investigators, innovation, approach, and environment that the reviewer should be considering when looking at that specific criteria. We really encourage applicants to review those questions, particularly for the

omnibus solicitations this year, as these have changed, and they've really become more focused on commercialization and product development. This is not hypothesis-driven research. It's focused on product development. So, for significance, we're really looking at a real problem or commercial potential. For investigators, we're looking at the investigator and the team including, again, how they're going to take this through the product development process. Innovation, it's not about doing innovative ... having an innovative approach necessarily, but is this a new or improved project? Is this something that is really looking at the competitive landscape of what is currently on the market or what is under development? For approach, we're looking at the research design, feasibility. And then finally, the environment, we're looking at facilities and resources.

And again, all of these have that focus on product development, and there are some additional questions around commercialization as well. The Overall Impact Score is determined after discussion and scoring by the scientific review group. So, it's important to note that the Overall Impact Score doesn't just include the assigned reviewers but the overall ... Everyone who is eligible within the review group scores it, and the overall score is an average of that. It's also important to note that approximately 50 percent of our applications are not discussed, so they have those three assigned reviewers, but they're not discussed. They're in the bottom half based on preliminary scores of what is being considered, but all applications receive reviewer comments, and that's the great thing here, is you're going to get feedback. Now, I talked about the scored review criteria, but it is important to note that the Overall Impact Score does also include additional review criteria, and this is not scored individually. That's around phase-specific considerations. For a phase II, you're ... how well ... whether or not you met the milestones of the phase I, for example, human subjects, inclusion of women, minorities and children, vertebrate animals, and biohazards. And then we've also got additional review considerations, and these are not factored into the overall score. I want to highlight not factored into the overall score is the budget and period of support. This is a piece. This is, again, another myth or misunderstanding that we often hear.

So, the budget and the period of support is not part of the overall impact score. For more information about the review process, I encourage you to go to the Center for Scientific Review.

They have a wealth of information there, and so it's important for you to take a look at that, as well. This is a big myth, "My application didn't get discussed or funded the first time. It's a waste of time to try again." Please do not be discouraged. Many companies are funded after incorporating feedback into their resubmission. Please read your summary statement carefully. Again, everyone gets a summary statement. Everyone gets those reviewer comments. Contact your program officer. The summary statement will have a contact for the ... a program officer contact in the upper, left-hand corner. Reach out. Talk to that person. I do suggest email. And talk to them about the comments. See what your next best steps should be. And then, finally, offer to be a reviewer. Yeah, you can be a reviewer, and we really do ... It's peer review. Please, offer to be a reviewer. The best thing you can do, the best way to understand the process, is to be part of it. So, we would love to have you be a reviewer. You can do that either by reaching out to a specific Scientific Review Officer, who might ... specific within your area of expertise.

If you're not sure, you can always reach out to us at SEEDinfo@nih.gov. And if you don't believe me, I would encourage you to believe some of our innovators. These are two individuals who successfully navigated the system, but they'll even tell you, it is a process. And so, I would encourage you ... Both of them have been through the process. They've received scores that were not competitive, but they have revised and resubmitted and were successful. And so even the most experienced individuals do need to revise and resubmit. That is part of our process here. So, once you get past the peer review process, there is an Advisory Council and due diligence process. Now, one of the big myths that we have is that the study section determines if you're going to get funded. And I always like to point out that when you're a reviewer, and you're in study section reviewing an application, you're not allowed to say the F word, which is funded. So, you're not making the funding decisions. What you're doing is you're providing guidance. So, NIH staff uses the score and summary statement when developing a funding plan, and the Advisory Council and Board has access, but the final funding decision is made by the Institute and Center ... or Center Director. So really, NIH is taking that information from the summary statement. It may be very important for you to look at the summary statement and address those concerns, but the study section does not make funding decisions.

Now, one of the new requirements that we have is part of the due diligence process, and we do have a due diligence process where we're looking to determine if an individual is eligible, that you're meeting all the requirements of the program. In addition, we also have a new requirement around foreign disclosure, and this is part of the SBIR and STTR Extension Act of 2022. This foreign disclosure is required, and you're going to utilize the Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries Form. And you can find a link to that form as well as instructions on how to fill out that form on our website. This is submitted as part of Just-in-Time, so once there is an application has gone through the peer-review process, as it's moving forward to be considered by council, there's a Just-in-Time request that requests additional information that we actually are going to ask for after that peer review, as we get closer to award. And as part of that additional information, we are going to request this Required Disclosures. This is required for award. We cannot make the award without receiving the Required Disclosure Form. And this disclosure of foreign affiliations or relationships is required for all owners and covered individuals, and a covered individual such as ... is a key personnel, a senior key personnel as identified on the application.

It's really important to note, and I encourage you, again, to read the full instructions that are online, but it's important to note that the SBIR and STTR eligibility criteria have not changed. Again, the SBIR and STTR criteria have ... eligibility criteria have not changed. A disclosure or finding of foreign affiliations or relationships does not necessarily disqualify an applicant, and so it's important we encourage you to please disclose any foreign affiliations or relationships that you have. This foreign disclosure process is not associated with purchasing of supplies, so this is not about if you're purchasing pipettes, where are you getting those pipettes. This is not about the foreign work requirement. This is separate from the foreign work requirement that I ... the foreign work ... the requirement to do work in the United States, so the foreign work ... the fact that we really do require that work be done in the United States and not outside of the country. That's a separate thing as well. This is really about foreign disclosure of affiliations or relationships. Another component of the Extension Act was establishment of a due diligence program. Prior to award, NIH is going to be assessing security risk, and this includes cybersecurity practices, patent analysis, employee analysis and foreign ownership, including the

financial obligations of the small business and employees. If possible, we are going to work with applicants to address any security risks that are discovered during the due diligence process, but we may decline to move forward with an award based on security concerns.

And I'd encourage you, if you do have questions, again, I would encourage you to reach ... to look at the notice that was released around Implementation of the NIH SBIR and STTR Foreign Disclosure Pre-Award and Post-Award Requirements as well as the Foreign Disclosure and Risk Management web page that's on our website. But again, it's really important to note, this is not about eligibility. Our eligibility criteria have not changed for both the SBIR and STTR programs. And finally, post-award, there are requirements for reporting. The small business is really responsible for monitoring their relationships with foreign countries, and you do have to submit updates to that disclosure form during annual, interim, and final progress reports, as well as if there's any changes: changes to ownership, entity structure, covered individuals, like we were talking about previously, or substantive changes to circumstance. And that's within 30 days. If a security concern is identified, NIH may withhold funding until the risk has been addressed, and again, for more information, you can go to the notices or ... that notice or the Foreign Disclosure ... And/or the Foreign Disclosure and Risk Management web page. So, once you've received your funding, one of the big myths that I get is that's it, that it's only about the money, but I really want to finish out and talk about how it's not just about the money.

Our office here, the Small Business Education and Entrepreneurial Development office, really provides technical and business assistance, education, partnership/ investment opportunities and commercialization support. And we have a number of support programs that we provide for entrepreneurs around entrepreneurial support and education. That's the I-Corps program, the Concept to Clinic Commercialization Innovation Program, or C3i. We have administrative supplements to promote diversity. I'm going to take a couple minutes to talk about those, as well as partnering and investment opportunities and regulatory and business development consultants that because we recognize that many of our businesses and many of our entrepreneurs, this is the first time an entrepreneur is starting a small business, and you really need that additional guidance and help as you're navigating that product development process and business development process. And so, we're here to help you with consultants as well as,

again, that partnering and investment opportunities to help with that handoff. I want to take an extra moment to talk a little bit about our diversity supplement. We do provide administrative supplements to small businesses with active small business awards to recruit and support individuals from diverse backgrounds. We've supported over 100 individuals to date, and if you've got an existing award, please take a look at the supplement program. It may be right for you. And I'm going to do a bonus myth here, that NIH bureaucrats are unapproachable, and I should minimize my discussions with them. I really hope we are busting that myth today. We are here to help. We're here to answer those questions.

We're here to help you, so please do reach out. Talk with us if you do have questions. Reach out by email. Reach out to your program officers. We are here to help you. And with that, I encourage you to connect, and we've got some time for some questions. And I did see there was a number of questions coming in, so I assume there's a lot to talk about today.

Adam Sorkin: We do have a lot of great questions. I do want to point out that we may not be able to get to everything today. Anything that we don't address, you can always send a request to us at SEEDinfo@nih.gov. We'll be happy to address your questions. Particularly if you have specific questions about your grant application or your award, we can best address those there. We also have an extensive FAQ on our website, so I encourage everybody to go review that, and we will likely be updating that FAQ based on a lot of the feedback we get today. So, with that, let's start with this extensive list of questions we've got, and we can start easy. "Can we apply to an NIH and NSF grant at the same time? How about DoD?"

Stephanie Fertig: You can. So, you can apply to multiple agencies at the same time. Now, keep in mind, agencies. So, HHS, as a whole, is considered an agency. So, you can apply to NIH and NSF, but you do have to declare that on the application. So, there's a checkbox that indicates that you've submitted to more than one agency at the same time. With regards to Institutes and Centers, I figure I'll take this question too because we get it a lot. You can submit more than one application, but they cannot be overlapping applications. So, you can submit more than one application to the NIH, but they can't be overlapping. So, you can submit on two different topic areas at the same time, but you can't submit the same application thinking one

is going to go to one Institute and one is going to go to another. We will reject that, so it's important to make sure, again, that you're not submitting overlapping applications to us.

Adam Sorkin: All right. And let's see. Here is a good question. "How does one show 30 percent work at an institution and 40 percent effort at a company?" And this is ... These are the requirements for an STTR application. And the question is, "Is it the total budget between the two?" And yes, effort is generally assessed as the percentage of total budget, that's total cost attributed to each participant in the award. Following up on the question about PI eligibility. "Is there any flexibility around a PI in the over 50 percent work requirement?"

Stephanie Fertig: There is some flexibility. We do have the opportunity in the SBIR for a deviation. I would reach out to a program officer and talk about that well in advance. That is something ... Anytime you're doing a deviation, it's important to reach out and talk with us. With regards to the STTR, since you have the option of being either with the partnering institution or with the company, it's ... you have to be one of those two. But with the SBIR, there is some flexibility there, and there's also some flexibility there with regards to the subaward as well. You can ... We can provide some deviations around the subaward percentages. So again, this is something ... great questions to ask your program officer and talk with them about prior to submitting an application.

Adam Sorkin: And here's a good, fundamental question. "How can I fund ... How do I find somebody that I can talk to before applying?" And so, there are a lot of ... I'm happy to take that.

Stephanie Fertig: Oh, yes. Please do.

Adam Sorkin: So, there are a lot of great ways to do that. We do have a list, if you have a rough idea of the Institute or Center you think your application will go to, of all the small business program managers and their contact information for each Institute and Center. However, if you're really unsure about where your project might land, you can always reach out to us with a brief overview of your plans at SEEDinfo@nih.gov, and we'll be happy to make some suggestions. Let's see. "We're requesting TABA Funds. Should I do that as part of my application, or should that be done after I receive an award?"

Stephanie Fertig: Great question. So technical ... We do get a number of questions around technical and business assistance. If you have your own vendor, if you really know what you need to do as next steps and you have a vendor that you are ... you know you want to use that vendor to provide technical and business assistance to your company, you can ask for those funds within the application. And I did see in the corner of my eye someone asking, "Well, wait a minute. You're differentiating per year, per project." So, per year is per requested year, and some of our Institutes and Centers do allow for Phase Is to be more than 1 year. And so, in that case, they could ask for 6,500 in one year and then 6,500 in another year. But for a Phase II, for your entire Phase II ... You're going to submit your Phase II, regardless of how many years it is, the total amount you can ask for is \$50,000. So that's the total amount you can ask for in a Phase II. However, if you've already submitted, or if you've got an active award, some Institutes and Centers do allow ... If you didn't ask for TABA initially, but you identified a vendor, and you have something you'd like to do, some Institutes and Centers do allow you to submit an administrative supplement to request those funds.

However, particularly for Phase Is, we really do encourage you to look at our Needs Assessment Program because many of our Phase Is aren't quite sure what their next steps should be or aren't quite sure what their ... It's a good third-party assessment to determine what are your big gaps, what are the next technical and business goals, what are your next steps in that technical and business process to help determine for your Phase II what you should be requesting, what should be the focus of the technical and business assistance in the Phase II. And so oftentimes, we really encourage our Phase Is to look at the Needs Assessment Program, and then in that case, you wouldn't ask for that in your application because you can ... If you ask for technical and business assistance within your application, you can't participate in the Needs Assessment or the Phase II program, which is a little bit more limited in size. You can't participant in those if you've already received Technical and Business Assistance Funding. So, we really do encourage you, if you're Phase I, take a look at the Needs Assessment Program, and you can request that after the award. So, it's a little bit tricky, and again, I'd encourage you, if you have specific questions about an application you're going to put in, we're happy to address those as well.

Adam Sorkin: Great. Thanks so much. And here is an interesting question about formulating your proposal. "It takes 9 months from proposal submission to fund disbursement if successful. That's a long time for a company. Should the proposal describe the work that will be done at the moment of submission or at the moment of fund disbursement, i.e., 9 months later?"

Stephanie Fertig: So, you should really be focusing on ... in the application on what you need to do. What are you going to spend? What are you going to do with the money? I like to say, you need to tell us ... We're going to give you money, and you should tell us in the application what you're going to do with that money. That's really important. Make sure you're putting in the application what you are planning to do with the funds, if awarded.

Adam Sorkin: Perfect. Let's see. Well, we have a question about the changes to the review criteria in the Omnibus Solicitations. "Can you speak a little bit to what specifically has changed and how those have been updated?"

Stephanie Fertig: Sure. So really, the big change is that we've refocused some of the questions. For those who have participated in the program in the past or really reviewed and looked at the notice of funding opportunity previously, what you'll see is that the notice of funding opportunity previously had questions that were maybe more tailored to some of our other research programs, so they're more broad and not specifically focused for the SBIR and STTR program. And we really took a hard look at those questions and wanted to make sure to tailor those questions so that they were really, again, focused on product development and commercialization. So, it's not that those questions were bad questions, but they were more broad in general. And what we really did was look at those questions and tailor them down to look at technical and ... to look really at product development and commercialization and really target those questions a little bit more for the small business program. So, I think it is a welcome change for many individuals who have been around a while. I think this is a positive change that will really allow us to focus some of the ... focus and help the reviewers as they're reviewing the application. So, I would encourage you, again, take a look at those questions. I think that really is there to help you. And I would say, also, for anyone if you're looking at a specific notice of funding opportunity, look at the questions in the section five when ... section five specifically looking at application review information.

We're giving you the questions that the reviewers should be asking themselves as they're scoring the application. We're giving those to you. Read them. Read them carefully, and they can change for specific notices of funding opportunity. Some of the specific funding ... notices of funding opportunity, they will have specific questions for that notice of funding opportunity. So, we really do implore you to read those questions in advance.

Adam Sorkin: Okay. We've ... let's see ... got a question about the Fast-Track transition from Phase I to Phase II. "Is it a typical noncompeting renewal, or is it more rigorous? Are there outside reviewers involved?"

Stephanie Fertig: Great question, and I know I kind of glossed over this. So, the whole ... The Fast-Track, you're submitting the Phase I and Phase II at the same time. You get a peer review of the entire project, so the peer reviewers are going to look at the Phase I and the Phase II. If you are funded, you're going to get the Phase I, and then once you're completing the ... once you've completed the Phase I, you're going to submit a special kind of progress report that's going to talk about how you've completed the Phase I, if anything has changed with regards to the Phase II. And that's going to undergo administrative review by NIH staff, so there's no outside reviewers. It's administrative review by NIH staff. Now, it's important to know that NIH staff will review that Phase II, and they will look at it in relation to if there's been any changes scientifically. They'll look at it with regards to their own budget, what their budget constraints are, and they'll look at it to determine whether or not you've met the milestones, whether or not you've really done the feasibility necessary to continue to move forward. There's no obligation for an Institute or Center to move forward, but what it ... the real benefit is you don't have to go back through the peer-review process, so the time between the end of the Phase I and the beginning of the Phase II can be much shorter, because that administrative review can be a much shorter process.

And then once that's complete, if the Institute or Center chooses to move forward, you can then get the Phase II. So, it's meant to really reduce that time between the Phase I and Phase II.

Adam Sorkin: Great. Thanks so much. Here is a question. "Where in the application do you request a specific IC? Is there a form specifically for this request?" And yes.

Stephanie Fertig: Go ahead, Adam. I know you get this question a fair bit.

Adam Sorkin: We do. And so, the application package will include an Assignment Request Form. You can use that form to prioritize your top three requests for assignment for an IC. The ultimate decision is left to the NIH Center for Scientific Review, but they will honor your requests if they can. Let's see. Well, we're getting a fair amount of questions about the Data Management and Sharing Plan. Here is a question. "What happens after the 20-year period? Will data belong to NIH at that point? What are the start-up's requirements at that time period?"

Stephanie Fertig: That's a great question, and I would ... I think we really do recognize that in 20 years, it might ... that might ... it might not be relevant to require sharing at that point. The scientific community may have moved on, so there's really an understanding that the 20-year period is a significant one, and so ... and we're going to be releasing ... Potentially, we're going to continue to release more guidance and more frequently asked questions around this issue, but I would state that there isn't an expectation that the company would then, in 20 years, have to share data from grant ... their Phase I grant that they received. I think there's a real appreciation and understanding. And I will also state that while you are ... that data is protected, companies can share. You're allowed to share your data or any data that you think is relevant, and you're certainly allowed to make publications. You're allowed to do any sharing you would like, but you don't have to. You're not required to share. So certainly, again, you really should look at that data sharing ... Data Management and Sharing Plan and write ... You should obviously be managing your data. That's important for all companies to do, to really think about data management. That's something you should be doing anyway. That's best practices.

But whether or not you share, when you share within that 20 years, that's really up to you as a company and what makes the most sense for your company.

Adam Sorkin: Okay. Great. Thanks so much. Let's see here. A number of questions about the new requirements about foreign disclosure and the due diligence program. "So, one thing that

might be helpful to reinforce, is this process done via Just-in-Time at notice of intent to fund, or is a new form required at application?"

Stephanie Fertig: So, this is the ... The new disclosure form is required Just-in-Time. We are not requiring it as part of the initial ... that initial application form side. We're requiring it as part of the Just-in-Time because we do want to manage the burden of this new requirement on our applicants and really just focus getting that information from the individuals who are going through the Just-in-Time process. So, if it's going to be a requirement as part of Just-in-Time, again, I would encourage you to take a look at the form, read through the form carefully and make sure that you disclose. And I really want to emphasize, again, this isn't a change in eligibility, just a company that discloses ... A disclosure does not automatically mean that you're not ... you're disqualified from receiving an SBIR or STTR. We really do want you to disclose. We recognize that there is foreign collaborations that occur that are necessary for successful scientific knowledge and for the science ... for science, but at the same time we really want to make sure that you disclose that and so that we can, again, have the applications and we can really go through the due diligence process to identify any security risks. And again, we are going to try, whenever possible, to work with companies to mitigate that risk.

Adam Sorkin: Okay. Thank you. Let's see. And I'm seeing a lot of questions about how this comes into play when they propose including foreign involvement on an award. Would you like to speak just a little bit to that specifically?

Stephanie Fertig: Absolutely, and as I mentioned, while this is different from the requirement around the work being ... needing to be done in the United States, we do recognize that there may be specific situations where work does need to happen overseas. And the example that we generally point to as a great example for this is say you're doing a clinical trial. You've got a small population, and you really need to ... because there just isn't the population in the United States, you need to have sites, or you need to do some work outside the US to be able to conduct that clinical trial. So that might be an example where you can kind of clearly show and justify why you need to do that work outside the United States. Again, so in that situation, you would put on the foreign disclosure form, you would disclose that you've got a relationship with that organization as ... within the appropriate section within the disclosure form you're going to

be disclosing that you have that relationship. It'll be pretty obvious that you do because it'll be part of the application. And then we're going to look at that and, again, assess that based on security risk, and we'll be going through the due diligence process on that. So, I would state that a lot of this is about disclosure, making sure that it's appropriately disclosed, and then we'll be looking at it again from the perspective of really determining if there is a security risk or similar risk.

And really if this is going to ... what we're looking for is situations that are posing a risk to national security. Things that violate fed law or terms and conditions of our wards weren't appropriate disclosed. So, again, that's why it's so important to make sure that you do disclosure. Present concerns about conflicts of interest or create duplication with activities that we're supporting. And some of these are things that we were already looking at within the NIH as well. For example, duplicative funding is something that we were always looking for to make sure that we weren't funding something that have been supported already with other funds. And then, finally, anything that might interfere with the capacity of our activity, so really, we're looking for conflicts of interest, duplications, things that aren't appropriately disclosed, and things that pose a risk to national security, and so that's what we're really looking for here.

Adam Sorkin: Great, thanks so much. That's very helpful. I am noting a number of questions about how we define innovation in the context of grant review and evaluations.

Stephanie Fertig: I'm so glad to hear that. And I know we're a little bit over, but as I've stated to my team, we're willing to stay on for a little bit longer, hopefully you are as well, as we address some of these questions. So, the question around innovation has been one where we round a lot of questions in the past as well, and we're really hoping that some of the modifications of around the questions under innovation are going to help provide a little bit more guidance for that topic area. We recognize that the FDA or other regulatory components, they don't want innovative talk studies, is always my comment. So, they might ... What's required, the steps required to bring a product to market may not be that innovative, but the proposed product or service may be very innovative. And so, if you read the innovation, the first question for example is, does the proposed product or service represent an innovative approach to addressing an important problem, barrier to progress, or unmet need in research for clinical

practice? So, it's really focused on, does that proposed product or service represent an innovative approach? Does the end product or service proposed in the application challenge and seek to shift current research or clinical practice paradigms? Will the end product or service proposed have specific advantages over existing approaches or methodologies, instrumentations, or interventions or those in development?

So, it's really looking at the innovation of that product or service, and I think that kind of clearly calling that out a little bit more clearly in the innovation criteria will hopefully help address some of the questions that we've really been hearing about the innovation section.

Adam Sorkin: Great, thank you so much. Let's see. Oh, here is an interesting question. For a specific targeted funding opportunity, if we apply can we apply to other NIH opportunities at the same time?

Stephanie Fertig: Great question. And, again, this falls under that whole duplication. You can't submit the same application ... you can't have the same application under consideration. So, you can't have two applications that are exactly the same under consideration at the same time. So that means that you can't submit to the Omnibus and have under consideration at the same time as the same application under an RFA. You can't do that. Really you need to pick one. Now, I would encourage you to reach out and talk to the program officer about that application, particularly the RFAs, specific notices of funding opportunity. If you go to the bottom, scroll all the way to the bottom of the funding opportunity, that's where you will see a link. And at the bottom of the funding opportunity, you will see points of contact. And the point of contact that you really want to go to is the scientific and research contacts. That point of contact for that specific funding opportunity can help answer any questions that you might have about that funding opportunity, including whether or not what you're proposing would fall within what's being sought for that specific funding opportunity. So, I would encourage you, particularly for specific funding opportunities, to reach out to the scientific and research contacts, prior to coming in for that opportunity.

Adam Sorkin: Let's see. Here is another interesting question about review. Can you discuss what is most important for phase 2B reviews? What should we focus on for our phase 2B application?

Stephanie Fertig: That's a great question, and I think that really depends on the institute and centers. Some institutes and centers only allow phase IIBs through those specific funding opportunities, others do allow them through the general Omnibus solicitation. I encourage you to reach out to your specific program officer. If you're looking at doing at phase IIB, you've had a phase two, and if you've got that phase two, you have a program contact. Reach out to that program contact, talk to them about what does their institute and center look for when they're looking to support that additional phase IIB because that's really ... or would they suggest doing a CRP instead, the commercialization readiness pilot. So, you may really ... You should really talk to a program officer in advance. And I did hear ... I did see something here about instructing reviewers on the points around innovation. Part of the reason that we really looked at those questions really hard and modified them to be more specific is that that allows us to give clearer instructions, we think, to the reviewer. So, we're really trying to address that concern and address that comment that you have there about what are we really looking for in innovation.

Adam Sorkin: I see, thank you. I did see a question asking for examples of a phase two commercialization plan, and I do have good news for you. If you go to our website and look at the how to apply info graphic, and specifically the preparing your application bullet, we do have links on the bottom of that page to sample applications, including a number of phase two applications complete with your phase two commercialization plans. So, I do encourage you to go take a look at those.

Stephanie Fertig: I did see a question. I want to jump in here ...

Adam Sorkin: Please.

Stephanie Fertig: ... as we're getting towards the end. But there was a question specifically around, what is just in time? You mentioned this whole just-in-time thing. What's that? Well, NIH uses just-in-time procedures for certain components and certain parts and elements of the

application. And we allow those certain elements of the application to be submitted later in the application after the peer review process, but as a grant application is being considered for funding. And those different elements can include a variety of different elements. And so, anything from specific support information about senior and key personnel, so other support information. Certification of the IRB approval. Verification, looking at verification around the use of vertebrate animals, evidence of compliance. So, as well as for the small business program, part of the just in time has been around the certification around eligibility, so the SBIR and STTR funding agreement certifications are all part of just in time. And so now in addition we're going to be adding this foreign disclosure form and we're going to have that be part of the just-in-time process as well. So just a quick discussion of just in time, and we can pop into the chat the grants policy statement information around just in time. I can do that here as well. And that really is a link directly to what just in time is and how it's used.

Adam Sorkin: Great, thanks so much. Let's see. Lots of fantastic questions and not a lot of time. Perhaps we can take a couple quick questions. Do I need to speak to my PO before requesting a diversity supplement request?

Stephanie Fertig: You should. You should talk to your program officer before submitting any supplement request, and that includes the diversity supplement. Strongly recommended that you reach out and talk to your program officer.

Adam Sorkin: Is it too late to apply for this cycle?

Stephanie Fertig: Well, it's never too late to apply for this cycle. But it really depends ... until the due date. It really depends on how far along you are with putting together the information and how much ... where you are in your process. If you've already started gathering application information, you really feel like you have a solid application, and you're pretty far along, you may be perfectly fine to submit for September 5th. But if you're not sure it's almost always better to submit the best application possible. One of the tools and tips that I do give to people is don't be afraid to share your application. Give it to other individuals. Look, you've been eating, sleeping, and breathing your application for goodness knows how long, and that's great. You're very passionate, I'm sure, about the project that you'd like to submit. It's important to

hand that project, that application off, to someone else if you can. I generally tell people find the most critical person that you know. Give them a red pen, tell them to go to town. You really want someone else to look at it to make sure that you haven't missed explaining some important component because you've kind of taken it as a given, but it's not really a given or that something might be a little unclear. Make sure that someone really reads through that application who hasn't been eating, sleeping, and breathing it for the past however many years and really can take a look at it and make sure that you're submitting the best possible application.

And that might take a little bit of extra time, but it is really worth it at the end of the day.

Adam Sorkin: I did not apply for technical business assistance in my application. Can I apply for it after award?

Stephanie Fertig: So, depending upon the institute and center. I'd encourage you to reach out again to your program officer. You can see if it makes more sense to do a supplement for your technical and business assistance, or if you can take advantage of one of our programs. If you're phase one, maybe the needs assessment is really the next best step for you. And so, there's a number of different opportunities. Again, because we have options and opportunities, once you are a recipient in our program it's really important to reach out and talk to your program officer about what resources are available. Because we do have a number of programs, we do have a number of opportunities of things that you can take advantage of, and we want to make sure that you don't miss those. In addition, look for emails from NIH. They may come from other individuals than your program officer, look for individuals ... NIH. Make sure that we're not getting caught in your spam blocker because we will let people know when there are opportunities that they are eligible for. We will put that information out there. Please do make sure that you take a look at those. I'm always amazed. We offer free resources or free opportunities and people don't take advantage of them. Please do. Once you're a recipient, there's all sorts of resources that you can take advantage of.

Adam Sorkin: Great. Well, we have run pretty long on time, do you have any final thoughts or any last things you'd like to address before we wrap things up?

Stephanie Fertig: Absolutely. I would just state that I know there was a number of questions in the chat that we didn't get to. Please do reach out to us, SEEDinfo@nih.gov. We'll be happy to address those within our help desk. In addition, do reach out and talk with us. Or, if you've been a recipient, reach out to your program officer. They're a wealth of expertise and knowledge. Talk with us. Hopefully we've proven that we're approachable and we're here to try to address your questions. So, with that, thank you so much. Thank you for sticking around. I know we ran a little long. But it was great to see a number of you today, get these great questions, and we look forward to interacting with you all more in the future.

Adam Sorkin: Great. Well, thank you so much, Stephanie, for a fantastic program. Thank you very much to our team, Laura, and Vicky, helping run the program and answer some of the questions, and thank you, everybody, for joining us today. Please reach out to us at SEEDinfo@nih.gov with any further questions, and we look forward to speaking with you. Bye, bye.