Small Business Transition Grant for New Entrepreneurs Webinar Transcript

June 11, 2024, Small Business Transition Grant for New Entrepreneurs Webinar Transcript

Laura Bonilla: Thank you for joining the Small Business Transition Grant for New Entrepreneurs webinar. I am Laura Bonilla, Outreach Specialist at the NIH Small Business Education and Entrepreneurial Development Office, and I will be your moderator for today's program.

Some housekeeping items before we get started, today's webinar is being recorded. The recording transcript and slides will be made available on our website, Seed.NIH.gov, in approximately a week. There will be a Q and A session at the end of the presentation, so please submit any questions you have using the Q and A feature located at the bottom of your Zoom window. In addition, links and other important information will be made available in the Chat.

With that, I would like to introduce our speaker, Ms. Stephanie Fertig, Director of the NIH Small Business Program. Stephanie, I'll hand it over to you.

Stephanie Fertig: Thank you, Laura. And again, for those who are just joining, we will make this available, both the recording as well as the slides on our Seed.NIH.gov website, so don't worry if you missed something. You will have an opportunity to take a look at it in about a week or two.

And again, that website really is a wealth of information. I do encourage you to take a look at that. Again, if you do miss some specific piece of information, it's on the website; I encourage you to take a look at that, and specifically, with regards to these funding opportunities, there is a transition grant website. You can see it here, most importantly. There are Frequently Asked Questions, but we've already started getting some of those Frequently Asked Questions. We are putting them up on the website as well. But it's important to note that you need to follow the instructions in the Notice of Funding Opportunity, so this webinar, as well as the website, doesn't take the place of the funding opportunities, it's merely there to help walk through and help guide you through those Notice of

Funding Opportunities. But it is very important you follow the instructions in the Notice of Funding Opportunity.

Now, this is part of the Small Business Programs here at Health and Human Services and the National Institutes of Health. And on this specific set of funding opportunities, we have two parts of the agency; both NIH and CDC have specific institutes and centers that are part of this specific Notice of Funding Opportunities. But these really do help us fulfill our mission, and they do follow the overall mission of the Small Business Programs, which is to help get those great innovations that are out there into the hands of the patients, clinicians, caregivers and researchers that need them.

Now, this is part of, again, the Small Business Programs here at NIH and CDC, the Small Business Innovation Research -- SBIR -- and the Small Business Technology Transfer -- or STTR programs. Now, these are a set of congressionally-mandated programs. They're about $1.3 billion of dedicated funding set aside for small businesses. Collectively, these are known as America's SEED fund, and they're really providing that SEED funding to small businesses. And we're actually one of the largest sources of early stage capital for Life Sciences in the United States. We're really fitting in that early SEED fund stage, providing support to small businesses as they move through and do their research and development. This is non-dilutive capital, it's not a loan. And really, many of our awardees leverage this funding to attract investors and partners to take their great innovation to the marketplace. So this program is part of the SBIR and STTR programs.

Now, these set of four Notice of Funding Opportunities are specifically targeting and trying to foster early career scientists transitioning to entrepreneurship. And the purpose is really two-fold; one, to support the research and development efforts at the small business, and also courage and support entrepreneurial training, mentoring and career development. Investigators are really expected to grow their entrepreneurial skillset while working in the small business to develop promising technologies and products. You can see the four Notice of Funding Opportunities here listed, and in the slides, there will be specific links. We will also put that specific information in the Chat. So these transition grant funding opportunities are really part of the Small Business Program, and really do fall in line with its goals.

Now you'll note, those funding opportunities come in both SBIR and STTR, and there are some critical differences between the SBIR and STTRs, but they can all be boiled down to this. The SBIR permits partnering, while the STTR requires a nonprofit research institution partner, such as a university. And really, the differences that you see here really fall out from that significant partnering environment. But regardless of whether you're coming in for an SBIR or an STTR, the award is always made to the small business.

Now, what is the Small Business Eligibility? Well, again, this is part of the SBIR and STTR program. So they follow the Small Business Eligibility Criteria. If you look at the Notice of Funding Opportunities, you will see that they do follow the Small Business Eligibility Criteria. This is determined at the time of award. I placed it here; I do encourage you to read the notice of the funding opportunities specifically, as well as take advantage of some of the guidance that the Small Business Administration has provided, and you can find that on our website.

In addition though, this funding opportunities has specific guidance around who can be the contact program director or principal investigator PD/PI, and I'm going to call this the "PI" for short as we move forward through this webinar. The PI is really limited to those who were new to research entrepreneurship and have not independently led significant research programs. So what does that mean? Well, I've put what that is per Section 3 of the funding opportunities, that the contact PI must never have been an independent PI on an NIH or CDC research grant, and that means in our series or equivalent. Or corresponding non-NIH peer-reviewed research grant over $100,000 in direct costs per year, or the project lead on a sub-project of a program project, or center grant. So really, again, we're looking for those individuals who have not independently led significant research programs. They must be a U.S. citizen or a lawful permanent resident, and an individual may serve as the PI for no more than one application.

Now, the contact PI should really possess the skills necessary to lead the project, just like any contact PI. They really need to possess those research skills and experience in the scientific discovery or technology development. They can be a new employee hired for the purpose of leading this program. They can be an existing employee who's newly elevated to a position of genuine leadership or responsibility. In addition, we do allow for the multi-PI role. Additional investigators can serve as multiple PIs, and provide support; however, that transitioning scientist -- so the person who's that transitioning scientist needs to be that contact PI on the application, have a clearly-defined role that allows for sufficient autonomy to really get that genuine leadership and experience. So again, it's very important you read the Notice of Funding Opportunities around the requirements associated with the contact PI.

The other thing you might have noticed is that since we have four of these, is that some of them either require clinical trial, or don't allow clinical trials. So it's very important to know if what you're proposing is, in fact, a clinical trial. Now the NIH definition of a clinical trial is a broad one, and we often find that individuals who come into NIH may not realize they're a clinical trial if they're doing human subjects research, and that's because the clinical trials definition is not the same clinical trials definition as, say, if you were going to seek regulatory approval. And so it's important to note that the definition that you see here, which is that anywhere one or more human subjects are prospectively assigned to one or more interventions to evaluate the effect of those interventions on health-related, biomedical, or behavioral outcomes -- it's a fairly broad one.

You'll note what's not included in this definition -- any aspects of risk or size of the clinical trial. So please do utilize the tools online, the decision tools, read the definitions, read some of the examples and case studies carefully, and determine if you're a clinical trial. If you're not sure, please do reach out and talk to either us or the Program Officers, and we'll get to where to find those on the Notice of Funding Opportunities in a minute, but it's important to reach out and talk to us well in advance of applying.

Now when we're talking about reaching out and talking to us, who is that? Well, there are participating institutes and centers on these funding opportunities, and you can see them listed here. It's important to note that not all of them allow for clinical trials, and so I've starred which ones don't allow for clinical trials that are not on those clinical trials funding opportunities. We also have a couple that are only SBIRs, so they don't do STTRs as part of the programs. And so that is also designated. It's also important to note that not all institutes and centers participate in this set of funding opportunities;

however, they may have their own funding opportunities or ways that they can support transitioning scientists. I do encourage you, if you end up following one of the missions of one of those institutes or centers, do reach out, talk with the Program Officers.

And again, we'll have points of contact, we'll be talking about how best to connect in a couple of slides. It's also important to read the institute and center priorities, and the Notice of Funding Opportunity, located in the section that specifically talks about the purpose and the background. There are scientific research priorities. You can read those. Each institute and center really does put what their scientific priorities are, and again, it's important to reach out and talk to a Program Officer in advance.

And you can find the specific Program Officers at the end of the Notice of Funding Opportunity. You can see the scientific and research contacts -- that's the people that you can reach out and talk to and determine, hey, is what I'm proposing within the specific NOFO, does it fit within your priorities? If you're not on this Notice of Funding Opportunity, we also have a list online where you can reach out to specific scientific Program Officers.

Now, the Small Business Program does follow -- it's phased, not the same as a clinical trials phase, that's unfortunate similarity in the nomenclature. Phase I is a feasibility study, Phase II -- full research and development. Now I'm putting this up because this is the standard structure of the Small Business Programming, and you can see there's a number of ways that individuals can enter into the Small Business Program, including utilization of a Fast-Track, which takes that Phase I and Phase II, combines it into one proposal, as well as the Direct to Phase II, which allows those companies that have already done the feasibility to go directly to full research and development. And as you can see, we also have a number of ways to support the gap between the Phase II, regardless of how you get to that Phase II, to the commercial market partner or investor.

I'm going to point out that with this specific Notice of Funding Opportunity, this allows for Phase I and Fast-Track, but it's important to note that not all institutes and centers -- and this is true not just of NIH, but also CDC -- CDC doesn't support Fast-Track, for example. So you should again read those institute priorities and determine what their interests are with regards to what they will support through this specific funding opportunity.

We do not allow for Direct Phase IIs through these funding opportunities, so if you're interested in doing a Direct to Phase II -- don't worry, the Omnibus might be right for you, and the vast majority of the applications we do receive come in through the Omnibus solicitations -- that's our general topic solicitations that we have, and I encourage you to take a look at those if you want to do a Direct to Phase II. I'm keeping the budgetary guidance up here, as you can see we have budgetary guidance from the Small Business Administration.

This set of funding opportunities does follow that similar guidance, but it's important to note that individual institutes and centers may have their own budgetary guidance. It's also important to note that there is some flexibility, that we do allow, in some cases, for some topics, some applications to receive more than this. But again, it's important to reach out and talk to the institute and center prior to your application submission.

Now as I noted, funding opportunities -- the majority of our funding does go to investigator-initiated grant applications through our Omnibus solicitations. And you can find all of our opening funding opportunities here on our website -- big, blue button, right as you go to the website. So please do take a look again, if -- this is one, these are one set of funding opportunities that we have, but we do have a wide variety. Now our transition grant does utilize the standard receipt dates, which are September 5th, January 5th and April 5th. If any one of these does fall on a holiday, it does move to the next business day.

We also have a number of resources online for how to prepare your application. Links to the annotated form set, sample applications, links to application instructions -- this does follow. It will be a very similar application to a standard SBIR or STTR application. And it's important to note that there are programs for applicants even -- and I do want to encourage you to take a look at these, even though both NIAID and Minority Health and Health Disparities, Allergy and Infectious Diseases and Minority Health and Health Disparities aren't on the specific set of funding opportunities; they do have programs to help applicants, individuals who are coming into the Small Business Program.

So I do encourage you if you're in one of those areas to reach out and talk with them about what different resources are there to support you as well. And there also a number of state resources through the SBA Fast Program, and you can find those on our website. But there are different ways to support and help you as you're writing that first application.

Now, part of the application is, there is a Letter of Intent. This is not required, it's not binding, and it isn't included as part of the final application that gets reviewed by the peer review. So this is really here to help us be able to put together the best review group possible. So again, it includes the following, and you can see what information is required as a Letter of Intent, and you can send those to our office, the NIH SEED Office at SEEDinfo@nih.gov.

Now in addition to some of the standard components of the application, you'll see a couple of different pieces that are unique to this set of funding opportunities. One is mentorship. Applications must identify at least one mentor who will facilitate successful completion of the project, both from a technical and commercial standpoint. Now it's important to note that the mentoring Letter of Support is required, and again, I'm not going to go through all of the instructions in detail, but I really encourage you to read the Notice of Funding Opportunity carefully and determine what is required as part of the mentoring Letter of Support.

A mentor is expected to be committed to the goals of the transition award, and again, those two-pronged goals, both the research and development as well as the entrepreneurial career development component, so both components of the award. They're expected to have prior experience in mentoring entrepreneurs and must be listed as a key personnel. But they're not required to be affiliated with the applicant's small business. They may not serve as one of the multiple PIs, if that's what you're doing in this application.

And they are required to commit at least five percent of their time, or 0.6 calendar months to this specific award. Now you can use a mentoring team. You don't have to have just one person. But one individual must be identified as the primary mentor and fulfill the criteria that I've noted. Other members of the mentoring team don't need to fulfill that mentoring criteria, but again, oftentimes -- sometimes it does take a team to be able to give you and meet all of the components of mentoring that you would like.

Also required is a Career Development Plan, and again, important to follow the instructions and the Notice of Funding Opportunity. It cannot exceed three pages. It should include clear milestones and success criteria, and there are three sections, and you'll see them listed here. Now, it's important to note that those three sections, there are specific things required for each of those sections, so again, do read the Notice of Funding Opportunity carefully. I'm not going to go through every piece that's required for each of the sections, but it's important to note that you do need to have that Career Development Plan. And the mentor should play a key role in developing and identifying appropriate training opportunities for that transitioning PI.

Now, this set of funding opportunities do use the standard NIH application and review process, and I've put the standard process here. We do have two levels of peer review process, so once the application is submitted, it's going to be assigned an institute and center and review group at the Center for Scientific Review. The Center for Scientific Review is going to evaluate the scientific merit -- oh, it seems to have moved forward a little bit there -- has evaluated the scientific merit there, and then they will release a summary statement. The good news there is, everyone will get a summary statement, regardless of the outcome of that review. Then it will go to the Advisory Board, and then go through the due diligence process, and potentially receive funding.

So let's talk a little bit about that review process. So again, details about the review process can be found at the Center for Scientific Review. Each application has three assigned -- at least three assigned reviewers. And there are five review criteria that reviewers score individually. And then there's an overall impact score that is determined after discussion and scoring by the scientific review group. Now in addition to those five scored criteria, there are as well additional review -- there will be additional review criteria as well as review considerations which are not part of the score, so again, it's important to read the Notice of Funding Opportunity.

The great news is, you can see on the Notice of Funding Opportunity those different components, the scored review criteria, the additional review criteria, and the questions that those reviewers are going to be asking themselves about each of those review criteria. About 50 percent of applications are not discussed, but again, all applications receive reviewer comments. Now, these five scored review criteria should look very similar if you've had or been part of an NIH review before. However, for this Notice of Funding Opportunity, we're going to be evaluating for scientific and technical merit of the research project and the contribution to the career development of the PI.

So, we do have some additional questions that are specific to this set of funding opportunities, both in the Investigator section as well as the environment, and as part of the additional review criteria associated with the entrepreneurial career development. So again, it's really important to read the review criteria -- that's Section 5 in the funding opportunity. And that really will provide you those questions the reviewers are going to be asking themselves.

Again -- and I always like to mention this -- be prepared to resubmit. Even experienced individuals who have been successfully navigated our programs and the review process, and successfully made written applications that have been funded, have had to resubmit before. Resubmission is part of our process. Don't believe me? Please believe the individuals on this slide, as well as if you talk to other successful entrepreneurs who have gone through and received NIH funding -- they're going to tell you, many of them have had to revise and resubmit. So don't feel bad if you don't get it the first time. Take a look at those reviewer comments, reach out to your Program Officer. There is a Program Officer on the upper left hand corner of every summary statement -- and ask them about it. Reach out, talk with them, take that information, revise and resubmit.

But the most important piece of advice, and I've hinted at this before, the most important piece of advice is to talk to a Program Officer at least a month before the application deadline. Now, there's a list of agency contacts -- again, under the scientific research contacts in Section 7. And that's part of every Notice of Funding Opportunity -- you can scroll down to the bottom and you can check out who's on that funding opportunity -- apologies there, it seemed to move forward. If you're not sure who to contact, not sure what area might be the best fit, you can reach out to us, SEEDinfo@nih.gov.

We're happy to try to connect you with the best institute or institutions, individuals you should speak with. In addition, there's a list of FBR Program Managers at SEED.nih.gov. And you can see - look for the very handsome picture of the building at NIH, and what you'll see there is right under that is the list of SBIR Program Managers. Now, the good news there is, even if an individual institute or center is not on this set of funding opportunities, there are other ways that you can get your projects supported, so I do encourage you to reach out and talk to the Program Managers.

One other piece of advice for determining which institute and center is likely to be assigned your application, is to use report.nih.gov. And that is a database that has all of the funded projects, and it has the abstract of the funded projects for all of our SBIR or STTRs, as well as all the R01s and other research projects. You can use the matchmaking tool to see, based on where your project and other projects like yours have been assigned in the past. And that is a very helpful tool, and we do encourage you to take a look at that as well. But again, if you're not sure, I'm going to go back one and just state -- you can always email us at SEEDinfo@nih.gov.

And with that, we're happy to take questions. I see a number of questions in the Chat, so I think Laura is going to help with some of that moderation. But can't wait to see what great questions there are.

Laura Bonilla: Yes, and please everyone continue to submit your questions in the Q and A box, and we will try to address it during the session. So could you talk a little bit about what the criteria is for what is defined as a "health professional" for this opportunity?

Stephanie Fertig: Absolutely. And I think this question, as well as a similar question, which is, do you need to have a doctoral or medical degree? And there's no degree-based eligibility requirement associated with the program. So that individual that was asking specifically, I think, about nursing, is absolutely part of, and what we would consider part of this program. Really, the reviewers are going to assess whether or not the investigator has the appropriate technical or professional proficiency to lead the proposed project, but we don't have a degree-based eligibility requirement.

Laura Bonilla: Thank you. And is this transition grant different from the NIA REDI entrepreneurial Small Business Transition award?

Stephanie Fertig: That's a great question. So this program was really based on similar -- on that effort by NIA, the National Institute on Aging, and their transition award. It's also very similar to the transitional award that the National Cancer Institution has. Now you'll note that the National Cancer Institute, as well as a couple of other institutes, are not on this set of funding opportunities, but they are part of that National Cancer Institute funding opportunity, so we'll try to include that in the Chat as well. But again, even if the institutes and centers aren't on this set of funding opportunities, there are funding opportunities that might be a good fit for your technology. But I will say this -- the NIA is on this set of funding opportunities, and we really did look to that program when developing this one.

Laura Bonilla: And what would qualify as a new employee for this?

Stephanie Fertig: That's a great question. I think when you're looking at -- again, we want someone who is -- really, we don't want a situation where this is not a -- we really want individuals who are not experienced entrepreneurs or individuals who have been in the program, in that position for an extended period of time; we're really looking for the spirit of this award for that transition. So we're really looking for those individuals who are transitioning into that new position, as noted in the slide.

Laura Bonilla: And can PIs having one SBIR award apply?

Stephanie Fertig: So for individuals who have already won an SBIR award, is not really transitioning -- if you're saying that there is a principal investigator who has, again that SBIR awards are our awards, so they are considered research and development awards, and that would not be considered someone who is transitioning to the SBIR program.

Laura Bonilla: Is 100 percent funding available in April, or is the percentage given up front to fund activities and salaries up to April 2025?

Stephanie Fertig: Okay, so I'm seeing a number of questions here about the April 2025, and how the awards work. So this is very similar to the standard SBIR, STTR programs. So when someone applies for an SBIR or STTR, that earliest start date is really to help basically provide an idea of when the earliest time that a funding -- when you can receive funding. Individuals will put a requested start date on their application, but again, NIH may -- that is a request, and we may or may not have a specific -- you may or may not get funding at that specific start date. So these work just like a standard NIH SBIR or STTR grant, in that the Notice of Funding Opportunity is made, and the money gets obligated, and it acts just like a standard NIH SBIR-STTR grant.

I did see when we were talking about deadlines, a question about the SAM registration -- I cannot emphasize this enough, and this is true across the board -- it's really important to get that SAM registration started earlier rather than later. Please do start it earlier rather than later -- you do need to have all of your registrations done in order to submit the application -- that includes SAM, that includes the ERA comments, and that includes an ERA comments account not just for the company, but a separate ERA comments account for the principal investigator as well.

So you do need to have all of your registrations in hand, and I would encourage you to take a look at our website. You can see the registrations that are required, start your registrations now. Really, they can take a little while, it's important to do that. You don't have to have your application all done before you can start getting those registrations done. I would actually say if you're interested in applying for the September 5th deadline -- start your registration today.

Laura Bonilla: And along deadlines, is there a deadline for a Letter of Intent for that September 5th application?

Stephanie Fertig: That's correct, there is a deadline. It's 30 days ahead of time, so you do need to have that into us. But again, remember, it's not required. It is not something that, while we certainly encourage a Letter of Intent, it's not required, it's not binding.

Laura Bonilla: Great. And how would an applicant know which institute their project would fall under?

Stephanie Fertig: Great question. And that's certainly, again, and I'm going to take control of the slides for a minute here -- again, you can go to that report.nih.gov and use that matchmaking tool. Also, you can take a look at the list of different institutes and centers. Sometimes it's very easy, and people find it very straight-forward to determine the institute or center that you're likely going to be assigned, but sometimes it can be tricky.

If you're still not sure who to contact, you can always reach out to us at SEEDinfo@nih.gov, and we're happy to help connect you if you provide a brief description of the proposed project. Even if it's just a couple of sentences, that can help us connect you with the right institute or center.

Laura Bonilla: And if the institute of interest is not listed on this NOFO, can applicants still request funding from that institution?

Stephanie Fertig: So, unfortunately, no. If you submit -- if you're going to submit to this Notice of Funding Opportunity, it really needs to follow within one of the institutes or centers that participate. However, there's great news -- there are other funding opportunities that might be right for you, as I noted. For example, there is one that is run by the National Cancer Institute. For those who are in that space, they have a specific RFA. In addition, there are other opportunities, programs and funding opportunities at some of those other institutes.

I would encourage you to reach out to the Program Managers, one of the Program Managers that's appropriate. And you can see, again, that list of Program Managers on our website, and give them your situation, say what resources are available. You might be surprised what's there.

Laura Bonilla: And we're getting a number of questions about review. So does this NIH opportunity have its own review panel or group?

Stephanie Fertig: Well, we actually have someone from the Center for Scientific Review on, with us today, so I don't know -- great, I see you're on Mute, so jump on in, introduce yourself, and talk a little bit about the review process. And I think, Laura, if you've got a couple of those great review questions, this is the expert to ask.

Krystyna Szymczyk: Hi there, I'm Krystyna Szymczyk. I'm in SRO, which is a Scientific Review Officer in the Center for Scientific Review, CSR, and we do the first level of review for the proposals. So that's the peer review. And the reviewers will be assessing your application for the Scientific and Technical and Commercial merit of your application. So I'm happy to answer any questions that are related to review as best I can. So Laura, if you have those questions --

Laura Bonilla: Sure. So I guess we can start with, can you tell what the review process is going to be like?

Krystyna Szymczyk: Yeah, there was a great slide, I think it was Page 20 that went over the process. But very briefly, your application after submission is reviewed for completeness for field of scientific area. And after that, it is assigned to a study section or a review branch, where the SRO, the Scientific Review Office will assign your application to at least three assigned reviewers, and those reviewers will receive training in how to review your proposal, and how to really look at Section 5 of the review criteria and use that review criteria to review your proposal.

There is a critique template that they will use, and all applications will receive a completed template with reviewer comments. They'll fill out comments regarding the overall proposal, and then they use scored review criteria that are listed on the left. The top 50 percent of applications, approximately, will be discussed at the meeting, and then all applications, like Stephanie emphasized, will receive reviewer comments. So that's the review process in a nutshell.

Laura Bonilla: And not sure if you answered this, but is there an opportunity to have a specific review group, is there a scientific review group for this?

Krystyna Szymczyk: So with proposals, review is based on the area of science. And so these applications will go into a study section that is a good fit for the scientific topic. And then the reviewers will be experts in those fields that are able to provide an opinion and evaluate the proposal.

Stephanie Fertig: I think one of the things that we do want to emphasize is, and one of the great parts of this is, this is a PAR. And I like to always note the "R" stands for special review criteria. So there are some specific review criteria, and to Notice of Funding Opportunity. And again, that is located in that investigator's environment and the entrepreneurial career development.

So those peer reviewers are going to be looking at those sections, asking themselves those questions, and really looking at this with -- through the lens of the purpose of this notice, this set of funding opportunities. I don't know if you want to add anything there, but I think that's the important thing to remember, is that there is -- they do get the information about these funding opportunities.

Krystyna Szymczyk: They do. They read Section 5 very carefully. We also educate them to make sure that they're well-versed in their review criteria, that they stick to the review criteria. And like Stephanie said, in the special review criteria, there's two additions, the mentorship and contribution to career development. So in addition, there are those two areas that will be evaluated as well.

Laura Bonilla: Thank you. And that's all the questions I'm seeing for review for now. Another question we received was if mentors are required for this opportunity.

Stephanie Fertig: Mentors are required, and again, as noted, you will need to have a mentoring Letter of Support is required. I did also see something about committing a question of, hey, can mentors be paid and written into the proposal budget. And if you look -- and again, I'm going to take control of the slides here and try to move us up to that mentorship -- they are required to at least commit some time to those obligations, which means they can be part of the budget.

Laura Bonilla: Great, thank you. I did see a question here; can a non-U.S. citizen be a PI for this opportunity?

Stephanie Fertig: Great question. So if you take a look, and I had talked about this earlier -- we do allow under the Eligibility -- and again, this is why it's so important to make sure to read the Eligibility section very carefully, there was a number of questions I saw about eligibility, and I did answer some of them just by a quick written answer, because we had touched on this a little bit earlier. But the contact PI does need to be a U.S. citizen or lawful permanent resident. And so you don't need to be a U.S. citizen, you can be a lawful permanent resident as well.

Laura Bonilla: And I am seeing a couple of questions about how this opportunity is different to the Omnibus solicitation. Also, what's the main advantage for a transitioning PI to apply to this, versus the Omnibus?

Stephanie Fertig: I love that question. That's a great question. It's actually number one in our Frequently Asked Questions that we have online. So I love that that was a question here as well. So really, the Omnibus solicitations are not focused on this career development, or mentorship, or transition component. They really reward the experience of an applicant PI. So applications that are led by PIs that may be lacking in that entrepreneurial experience maybe a little bit earlier in their career, may be more competitive in the transition program because there is these other sections around it, and there's that real focus on career development.

In addition, there is this component around career development and mentoring that is allowable under a transition award. So again, it's really -- you can look at the Omnibus solicitation, and certainly we have funded individuals who are earlier in their career through the Omnibus solicitations, but it is something we do encourage you, if that you are transitioning, if you're earlier, if you're one of these early career scientists, this might be a good and a better fit for you.

Both programs do undergo technical evaluation of the proposed research plans, this is a research and development program, it's not just career development. There is a research and development component as well. So it's just important to note that. But again, the Omnibus solicitation, if you're looking at this and, gosh, you don't, for whatever reason, meet the eligibility requirements with the contact PI in the funding opportunities -- that's okay, we do fund the vast majority of our projects through the Omnibus, and that might be an appropriate way to go. In addition, if you're interested in doing a Direct to Phase II, that's also the Omnibus.

Laura Bonilla: And are SBIR applications able to be submitted by individuals at research organizations, or only venture capital firms, things like that?

Stephanie Fertig: So it's not venture capital firms -- so I'm going to go back to that eligibility -- I think that's an important thing to go back to here. And I'm going to go back to the eligibility. So this is the Small Business Eligibility -- so again, it's really important to note, regardless if you're doing either an SBIR or an STTR, the award is always made to the small business. So the award is made to the small business, not to the individual and not to an academic, and not to a venture capital firm -- it's a small business. And those small businesses have to fall within the eligibility criteria that you see here. If you're not sure if the small business that you're working with falls under eligibility, I do encourage you to take a look at our website.

We do have the eligibility criteria spelled out in detail, as well as some eligibility guidelines from the Small Business Administration, that really walk through several different iterations and case studies to help small businesses determine if they are eligible.

Laura Bonilla: And along eligibilities, is a company required to have employees besides just the grant applicant?

Stephanie Fertig: So we don't have a requirement around how many employees a small business has, and in fact, many of our small businesses are really, really small. And that's okay. Again, remember it's determined at the time of award. Now, it's important to note that in general, we do -- I would, again, really look at the eligibility of the Small Business Programs, both the SBIR and STTR. It's important to note -- and I'm going to move -- let me see which slide, if you go to -- here we go -- look at those critical differences between SBIR and STTR, what those work requirements are, as well as the guidelines around the principal investigator. It's important to note that these are both, SBIR and STTR, funding opportunities. They do follow the requirements and policies of the SBIR or STTR programs. And again, the award is always made to the small business.

Laura Bonilla: And since you have this slide up, can you expand a little more on selecting SBIR or STTR, especially if the project involves efforts with a university and small business?

Stephanie Fertig: Absolutely. And this is a question we get a lot in our office, not just for this program, but in general, whether or not we should do SBIR versus STTR. So there are often times when an organization may be able to pick either of these. They may fit into either of these, depending on if they've got that nonprofit research institution partner. I would say it really depends on what makes the most sense for the company and for the project.

Now, some of it's based on that minimum work requirement, some of it's also based on the principal investigator, if that individual is employed by the institution partner. They may be not ready to move yet to the small business, but they want to transition -- this might be a good option for them.

So again, it really depends on your individual product. This is something that you can talk through with a Program Officer if you've got specific questions about your specific project. But again, often times this is something that you will have to determine, based on the needs of a particular project.

Laura Bonilla: Thank you. And does a PI need to be working in the company more than 50 percent before the SBIR application is processed?

Stephanie Fertig: So the good news is that the -- again, all of this is determined at the time of award. So when you're submitting, you don't -- the principal investigator doesn't need primary -- and this is always true of the SBIR-STTR program. The requirements around employment of the principal investigator don't come into play until the time of award.

And so what we will often see, and this is again true across the board, not just with these programs, but the broader SBIR-STTR programs -- there are times when someone may not be working majority with a company, but they're going to wait to see once they get the award, they're able to move forward and become primarily employed at the small business. And so again, this is really at the time of award.

Laura Bonilla: And can someone who has been a PI on NSF SBIR grant previously be a PI on this transition grant?

Stephanie Fertig: So that's a great question. And I'm going to go forward again to that eligibility. It's all about whether or not that non-NIH peer-reviewed research grant was over $100,000 in direct costs per year.

Laura Bonilla: And can someone apply to this opportunity and also an SBIR grant opportunity for another agency for two different acknowledges at the same deadline, for example, September 5th?

Stephanie Fertig: So individuals can always submit multiple applications, and in fact, we sometimes do see individuals submit multiple applications, even to a different agency. I'm going to use NSF as an example since Laura just mentioned NSF -- let's use NSF as our example. We certainly had situations where an individual will submit -- a company will submit one project, a project to us and a project to NSF at the same time. And you can do it to two separate agencies, so again, not within HHS, two separate agencies.

And you can just designate that on the application, that you are submitting to another agency. And it's just about transparency, so make sure that you tell us that you've submitted to another agency, you're transparent about that submission, and also let us know as we move forward, we want to make sure that you're not going to get funded for the same work by both agencies. So that's the real important thing. So I think I actually took it one step further and said, same application -- so hopefully, that addressed the question.

Laura Bonilla: And what is the maximum allowable percent effort for the PI?

Stephanie Fertig: There isn't a maximum allowable percent effort. I mean, you can't present -- you can't do more than 100 percent effort on something, that is -- although sometimes it certainly does feel like it. But you can't do more than 100 percent. But there is no maximum allowable percent.

Laura Bonilla: Thank you. And can nonprofit organizations apply to this funding opportunity?

Stephanie Fertig: So again, you do have to be a for-profit organization. It does have to fall under the Small Business Eligibility.

Laura Bonilla: Okay. Let's see. And can you please briefly talk about the budget allocation for mentors?

Stephanie Fertig: So again, I think this is a question -- and I do see a number of questions here about mentors being paid, mentors being within the budget, how that mentoring and that budgeting works. And again, I would encourage you to read through the Notice of Funding Opportunity specifically around the requirements of the percentage effort of the mentor and the requirements associated with that. And again, if you have any specific questions about your specific situation, that is something that you can reach out to your Program Officer and ask about the budget.

We do often get questions about the budget. But I would encourage you to reach out and ask those questions as well. So I would say, again, I see a number of questions here about the mentoring and the budget, but I do encourage you to do that.

I did also see something about the mentors, and asking about -- and I'm clicking forward to the mentoring section here -- but specifically with regards to the mentoring and whether or not and how to manage and deal with mentoring -- keep in mind that the mentors must be listed as a key personnel, and therefore, they do need to have an eRA Commons username.

Laura Bonilla: Thanks. We did receive another review question. How do reviewers prioritize innovation versus commercial success of the project?

Stephanie Fertig: So Christina, I don't know if you want to come off of Mute and answer that.

Krystyna Szymczyk: So we would ask that you really look at the review criteria, Section 5, and look at the description of innovation and commercialization. For the fees, these are Phase I studies, or Fast-Track studies, so you would not be expected to have a formal commercialization plan with your Phase

I, but rather, commercialization potential. And for innovation, you would carefully read the criteria, and in your application you would want to emphasize anything that was new or novel, and-or you would want to describe your product technology service, etcetera. It is advantageous to what exists on the commercial market today.

There are more details to that definition of innovation, and while being completely new and novel is good, it doesn't have to be completely new and novel to have a high-impact application. So given those points, you would want to describe that well in your application, so the reviewers could appreciate the innovation and the commercialization potential. Stephanie, did you want to emphasize anything with that?

Stephanie Fertig: No, I think that -- far be it from me. I think that covers it.

Laura Bonilla: Thank you.

Stephanie Fertig: Sorry, I did see a question here about affiliation with an academic institution, and I have seen a number of those questions around affiliations. So again -- with the SBIR on that permits partnering, but it's not required. And so you don't need an affiliated academic institution, you don't need an institution, an academic institution for the SBIR. The STTR does require a nonprofit research institution partner, and so that's one of the big differences between those two.

Laura Bonilla: Thank you. And can you please elaborate on the work must be done in the U.S.?

Stephanie Fertig: Absolutely, so again, this is part of the Small Business Program, and for the Small Business Programs, the work really does need to be conducted in the United States, with only a few exceptions, and those exceptions really aren't around the work being unable to be done in the United States.

So if you cannot do the work in the U.S. -- an example I always use is, if you are doing a clinical trial and that's a very small population, and you need to pull in some individuals to make sure that you are able to conduct that clinical trial outside of the United States, that could be a situation where we might allow for some small portion of the work to be done outside the U.S. But in the vast majority of the cases, the work must be done in the United States. Again, the bar for that is very high.

Laura Bonilla: And I'm seeing a number of questions about how they can select a mentor. What are the requirements for that?

Stephanie Fertig: That's right, I did see a couple of those questions as well. If there a list of mentors available, how do we find mentors? We do not have a list of mentors available, that is something that you do need to have as part of the application, and we do not have a list of the mentors that are available. I do like to joke, I'm not a matchmaker in my personal or professional career, and so I really do encourage you, though, you can, again, utilize your local resources, utilize some of the state and regional resources, utilize your networks to really find mentors. But at this time, we don't have a list of active mentors available.

Laura Bonilla: And can mentors serve as co-PIs, or be part of the research team?

Stephanie Fertig: So they can't serve as a multiple PI, but they can be part of the team, because they need to be committed to the goals of that transition award.

And I do see something about what makes a mentor suitable for a competitive application -- great question. I encourage you to take a look at that Notice of Funding Opportunity -- it really talks about prior experience in mentoring entrepreneurs, and what some of those examples are. And so that should really help, as well as if you look at that mentoring Letter of Support, you can see some of the different components that are required as part of that. And that should help guide you as to what might make a good mentor for you.

One other option you might want to look at is to see, again -- don't hesitate to reach out to different successful small businesses in your area, and you can look at that utilizing the reporter system. And this is actually true not just for this funding opportunity, but for other funding opportunities as well. I'm always amazed at how much small businesses and other small businesses are willing to help people who are just getting started. I've seen that time and time again, where different entrepreneurs are willing to help those entrepreneurs that are just starting out. So don't -- I would encourage you to look and see what small businesses have successfully competed for awards in your regional area -- reach out and talk to them. You'll find that, one, it's a great way to build your network, but also it's a great way to get new contacts and learn from other individuals' experiences as well. So I would say, I'm always fascinated at how much small businesses are willing to help people out.

And I will state that how we got those sample applications was because small businesses were willing to give us those sample applications to put online, even though they're redacted, it's still a significant step for them to agree to put their sample applications online, and they were willing to do that for the greater good. And so I just want to point out that there are small businesses out there who are willing to work with you.

Laura Bonilla: And are there progress reports required for multi-year projects?

Stephanie Fertig: Absolutely. So this, again, follows the standard small business grants that do require progress reports, do require all the standard reporting. They do follow the standard requirements that are for small business grants.

Laura Bonilla: And what determines the amount of grant that's going to be given?

Stephanie Fertig: That's another great question. And that's something hat definitely you're going to want to reach out and talk -- so first off, I'd say make sure to reach out and talk to a Program Officer, because again, each individual institute and center has their own budgetary guidelines. So I did talk a little bit about those budgetary guidelines, and I'm going to move back towards that, and just go here. So you can see these budgetary guidelines -- but again, it's important to ask for a budget that makes sense for the project that you're proposing.

And you're going to include -- these do have detailed budgets, so you're going to have, as part of your application, a budget justification. So you should really make sure that your budget is well-justified for the work that you're preposing.

Laura Bonilla: And how important is having a patent prior to application?

Stephanie Fertig: So you don't have to have a patent filed prior to the application, but we do -- and again, I am not a patent attorney, I don't do that, I'm not an attorney, that's not my background. But I will say we don't require that you have a patent filed, but many of our applications do have at least a provisional patent filed or have started the filing process.

Now, the good news is peer review does not count as making your idea public, so it does not count as a public disclosure. However, it's really important to note that many individuals do start reaching out and talking with professionals to protect their intellectual property early.

Laura Bonilla: Okay. And in terms of the application, do all members have to have a bio sketch when submitting?

Stephanie Fertig: So you should follow the instructions associated with bio sketches that are located in the application instructions, and that includes the requirements associated with a bio sketch for each of the key personnel. So it's important, again, to follow all the instructions located in the Notice of Funding Opportunity, so those do follow a lot of the same requirements and instructions for the small business grants.

I did see a question here that notes that the Notice of Funding Opportunities do encourage and obviously welcome individuals from diverse backgrounds. It is important to note, though, and this is something that was clearly stated in the Notice of Funding Opportunity that race, ethnicity, gender, background will not be utilized as part of the selection process.

So it's important to note that certainly we do encourage all applicants who are eligible for this to apply, and we encourage that anyone who is eligible to apply, we certainly encourage all of those individuals, and we will not be using race, ethnicity, gender, background -- any of that. We will not be utilizing that to determine to make any funding decisions and will not be part of the application review process.

Laura Bonilla: And can a company submit two different proposals, one for each PI?

Stephanie Fertig: So a company can submit multiple proposals. Again, make sure that you follow the instructions in the Notice of Funding Opportunity associated with the requirements for specific mentorship, and make sure that you're following the requirements associated with the eligibility, and make sure that you can really meet the goals of the Notice of Funding Opportunity.

I do see a number of questions here about whether or not there are age requirements, or anything like that. And I would say again, just the eligibility requirements listed in the Notice of Funding Opportunity -- that's the only eligibility requirements, so you'll know that the age of an individual is not part of that.

It is, again, important to remember to take a look at the Notice of Funding Opportunity. That is the final determination, all of the eligibility components are listed there.

Laura Bonilla: And along with eligibility, if someone's a second-time entrepreneur that just started a new company, would this be an appropriate funding opportunity for them?

Stephanie Fertig: Did you say a -- and I'm just going to check -- so a second entrepreneur?

Laura Bonilla: Second-time entrepreneur, starting on --

Stephanie Fertig: Again, it really depends. Are they eligible, are they meeting that eligible criteria? Did they have a research grant previously? Do carefully read the eligibility criteria and the Notice of Funding Opportunity.

Laura Bonilla: And do mentors need to have a track record of successful applications for this?

Stephanie Fertig: So again, I would encourage you to take a look at the requirements in the Notice of Funding Opportunity specifically for mentors. And it does talk about a track record of mentorship associated with entrepreneurship, so it's really about, have they been mentors before? And again, read through the Notice of Funding Opportunity specifically around mentors, and that mentoring section.

Laura Bonilla: And are there any templates available of successful SBIR grant proposals?

Stephanie Fertig: Great question. There are specific -- SBIR or STTR applications, successful applications that we do have online, and we can make sure to put that in the Chat again. And those specific successful applications are really meant to help you see how an application is constructed.

They are not meant for you to take components of, or really see how to phrase something specific. But it's really there to help you determine how to structure and application and the different components that are required.

Laura Bonilla: And can you elaborate on the budget for training activities? Are there any specific restrictions?

Stephanie Fertig: That's a great question. And again, that's something -- I think love that we got Frequently Asked Question number two, which is, what can be supported with this funding?

And again, these are NIH grants, they're subject to the required cost principles and the standard cost principles and regulations. So it's important to really review the allowable cost activities, and if you look at our Frequently Asked Questions, there's a link directly to that when preparing your budget and determine what is and is not allowable.

And you can reach out and contact an institute or center if you've got a specific question. And so I appreciate that each project is a little bit different, and there might be a specific question in there, so this is a great example of when to reach out to the institute or center about a specific cost question.

And I know, we have a lot of questions, still. I am taking a look, there's a ton of questions. We will certainly, again, if you find that your question isn't answered, I can speak for Laura here, that is one of the reasons why we have that SEEDinfo@nih.gov email box, as well as the different points of contact at each of the individual institutes and centers. Oftentimes those individual points of contact at the different institutes and centers can really address any of those specific questions around your specific project. I know we have a number of them here today, and that just really goes to show their specific dedication to the interest in this program.

So again, I don't -- don't hesitate to reach out and ask questions of the different Program Officers. I am going to move to that part of the slide deck, just as a reminder, because I think that's just such an important thing to remember, as we will likely not going to be able to get to every one of your questions today. But I would encourage you to reach out to the list of agency contacts, that's scientific and research contacts that are at the end of the Notice of Funding Opportunity if you have specific questions.

And here's a fun tip -- every Notice of Funding Opportunity has points of contact as part of the funding opportunity. And so it really is a way that you can make sure to reach out and talk with us. We are here to really help address those questions. I encourage you to reach out by email -- email is usually the best way to get in touch with our Program Officers, for those specific questions that you might have.

Laura Bonilla: Thank you.

Stephanie Fertig: So I do see a number of questions around -- I'm going to just jump ahead and say around eligibility of an individual. And I'm seeing a lot of permutations of, well, am I eligible if I do this?

Am I eligible in this situation? And there are some specific situations that are being put in here. I will state that instead of us going down each individual potential iteration and potential way that -- and different situation, again, read the Notice of Funding Opportunity -- that's it. That's the eligibility. That's everything in there. So don't feel like you have to add eligibility to that.

Really focus on the eligibility requirements in the Notice of Funding Opportunity. If you're still not sure after reading the Notice of Funding Opportunity, that's when you can reach out to a Program Officer -- that's when you can reach out and ask them your specific question and your specific situation. But again, I really appreciate there's a number of different questions here around eligibility, and so I encourage you to really reach out and look at that Notice of Funding Opportunity, because a lot of them are very much that question of, well, what about this specific scenario, what about that specific scenario. And again, it is very much focused on that eligibility criteria in the Notice of Funding Opportunity.

Laura Bonilla: Thank you. I do see a lot of questions about that. And also, just as a reminder, the slides and these webinar materials and recording will be made available on our website, seed.nih.gov. We will have this available.

Stephanie Fertig: I do want to answer one question that I'm seeing here, which I think is a great question, particularly since these funding opportunities are really going to be potentially for individuals who may not have worked a lot with the NIH previously. One of the questions was, when talking to a Program Manager, what topics are you allowed to discuss? And that's a great question. So one thing is, really, to make sure that what you're proposing is within the mission of that specific institute or center. Each institute or center utilizes the Small Business Program a little bit differently, so it's important to reach out and say, hey, is this something that falls within your mission?

If not, where should we go? The second thing is, because they each use it a little bit differently, often times the allowable budgets are going to be a little bit different. So each, again, institute and center, one may allow for a higher budget than another, and often, again, that's because of their different mission space. Another reason to reach out and talk with them is, hey, if you're doing anything with human subjects research, do they allow for a clinical trial? Is this going to be a clinical trial? Having those conversations ahead of time is really important.

It’s helpful to talk with them about providing your specific aims. Institutes and centers, they may provide information about whether or not, again, that's allowable. Those specific aims can be very helpful for some of those conversations about which institute or center you're likely to be assigned, and again, whether or not you fit within the mission of that specific institute or center.

Finally, it's important to reach out and talk with the different institutes and centers, because again, if you look at Section 1, which is specifically focused on the funding opportunity description, you'll see a section on Scientific and Technical Scope. And that includes the institute and center priorities. So it's going to be really important to note that, for example, not all institutes and centers are going to fund or prioritize Fast-Track applications. So you if you want to submit a Fast-Track application, you're going to want to make sure that the institute or center that you're likely to be assigned is going to accept that Fast-Track application.

So again, those are some of the kinds of questions that you can ask, in addition to some of those questions that we've already reached out and talked about today. So some of those questions about, well, wait a minute, would this be something that I am eligible for, here's my specific situation. But again, we're going to really rely heavily on that eligibility that's specifically laid out in the Notice of Funding Opportunity. So we do encourage you to really read that as well. So again, those are some of the topics that you can talk about.

And then lastly, one last thing, some institutes and centers do have special programs or other programs beyond the SBIR-STTR program. They might be a good fit for you as well. And so you can -- oftentimes Small Business Program, the Program Managers can help connect you with other resources that are located within a specific institute or center.

Laura Bonilla: Thank you. And before we end, could we just go back to the slide that shows the upcoming deadlines in case anyone missed them?

Stephanie Fertig: Absolutely. And again, these do follow the standard receipt dates -- that next receipt date is September 5th. But then after that it's January 5th and April 5th. And again, if a receipt date falls on a holiday, it will move to the next business day.

Laura Bonilla: Thank you, Stephanie. Any final remarks?

Stephanie Fertig: I would just state, I know again we were not able to get to every question, and we knew that might be the case. I'm looking and there's over a hundred questions, so there's no way we can address all of these today. But that is okay. That's one of the reasons why it's so important to reach out. You can email us, and I'm going to go to that slide that had that information about how best to reach out. Again, you can reach out to us and -- one more back, here we go -- SEEDinfo@nih.gov, if you do have a specific question. Again, you can also look at the list of agency contacts.

Oftentimes what we're going to do, if you have some specific questions and we see about your targeted research area, we're going to hand you off to those scientific and research contacts, which is really where you're likely to be assigned. So you should start building that relationship, have that conversation with that scientific contact at those different institutes and centers. We do encourage you to reach out to them. If you're not sure who to contact, you can always email us at SEEDinfo@nih.gov.

Again, even if the institute or center, even if the area that you're likely to be assigned is not on this set of funding opportunities, that's okay. They may have different programs that fit you. And so we really do encourage you to take a look at that list of SBIR Program Managers, reach out to the specific institute and center, they might be able to connect you with some other programs that could make sense for your project. So don't hesitate to reach out by email, ask those questions, and we'll be happy to get back to you.

Laura Bonilla: Thank you so much, Stephanie, and thank you for a great program. I also want to thank the team for helping put this webinar together. And thank you, everyone, for joining us today. Once again, I'm just going to emphasize, please reach out to us at SEEDinfo@nih.gov with any further questions. As Stephanie said, we didn't get to them all, but we'll be happy to answer them via email.

And then once again, the slides and webinar materials will be made available on our website, that seed.nih.gov.

So thank you again, everyone. Thank you, Stephanie. And I hope everyone has a wonderful day.