NIH SBIR/STTR REACH Awards Webinar

Transcript

Dr. Matthew Portnoy:

>> Good afternoon. Welcome to the NIH webinar on the funding opportunity RFA-OD-14-005: NIH Research Evaluation and Commercialization Hub or (REACH) Awards (U01). My name is Matt Portnoy and I will be your host today. I am the NIH STTR SBIR Program Coordinator. Before I introduce our speaker and begin, a few housekeeping notes.

First, this webinar is being recorded and the recording, the slides and a transcript of today's webinar will be posted within a few days at http://sbir.nih.gov. Stay tuned to the top of the page at the news flashes and it will take you to a link to the webinar page.

Second, we will be taking questions and answers after the presentation is completed, and you can send your questions in through the question or chat box in your webinar console.

Also, all attendees are automatically muted because of the high volume of folks we have on board today. We will be taking questions via the chat; and if we don't get to your question, or your question is not answered during the course of the webinar, you can feel free to contact our speaker afterwards and that information will be provided to you.

With that, it's my pleasure to introduce your presenter for today's webinar, Dr. Kurt Marek. Kurt is the Deputy Director of the Office of the Translational Alliances and Coordination from the NIH National Heart, Lung and Blood Institute. So Kurt, take it away.

Dr. Kurt Marek:

>> Thank you very much, Matt, and thank you everyone for joining us today for an introduction to the NIH REACH awards program. This is a new type of program for the NIH that we're very excited about, so we're happy that there's so much interest in learning about it.

Today I'm going to go through some background information; talk a little bit about the scope of the program, eligibility. I'm going to go through what we expect you to provide in your research strategy of your application; talk a little bit about review criteria; and finally, field questions and provide some answers.

As Matt mentioned, you can enter your questions into the webinar chat console and I will do my best to answer as many of them as possible after my presentation.

If we do not get to your question during the webinar or if you have additional questions, feel free to email me. My email address is shown here. I will also have it up at the end of the presentation.

So the purpose of the NIH REACH award program is to support proof of concept centers at academic institutions to facilitate the translation of technologies developed at those institutions into commercial products that benefit patients and enhance health.

There are four key elements to this program. We want to support the development of infrastructure to solicit and select the most promising technologies at those research institutions. We want you to develop programs to fund product definition studies. What I mean by that is feasibility studies or prototype development or proof of concept.

We want you to develop coordinated access to expertise in your local region, or wherever you may find it, that is required for early stage technology development. That expertise would include scientific, regulatory, reimbursement, business, legal, project management, as well as other types of expertise that might be required for the early technology development process.

And finally, we want you to develop skills development programs, and train innovators and entrepreneurs through hands on experience.

This program comes out of an identified need in bridging a gap in funding between basic research and the development of technologies that can be translated out of academic institutions.

A lack of knowledge and understanding by academic innovators in how new technologies are actually brought to the market.

And a lack of access to sufficient technology development and commercialization resources.

This program is designed to implement a specific section of the SBIR/STTR Reauthorization Act of 2011.

There are very specific eligibility requirements. Applicants must be a university or other research institution that participates in the NIH STTR program.

Since academic institutions and research institutions cannot apply to the STTR program, what that eligibility requirement means is that those institutions must have participated as a formal partner to a small business on an NIH STTR grant. There can only be one application per Institute, so you need to coordinate across your Institute, across your departments to submit a single application.

Finally, small businesses are not eligible to apply. This is not a small business award.

We released an additional notice along with the RFA that explains the eligibility a little bit more, and that notice is listed here. It's NOT-OD-14-087.

The scope of the program is trans-NIH. This is not specific to a disease area or any one Institute's mission. We state in the RFA that we have an interest in a broad range of early stage technologies, including therapeutics, preventives, diagnostics, devices and tools. You do not have to submit an application as a consortium, but if it is necessary to meet the goals of the RFA, we do encourage that you develop partnerships to submit the strongest application possible.

In addition, applications from or that include institutions from IDeA states are encouraged. This map shows you the states in blue that are traditionally underfunded by the NIH. And so inclusion of institutions from these states in an application is encouraged, but not required.

I'll just spend a second on the award budget and duration. You may request up to a million dollars per year for up to three years. That million dollars is total costs, which means that it includes your direct costs as well as the F&A from all components of the application.

And what I would like to spend the bulk of the time on during this presentation is discussing the different parts that we outline in the funding opportunity of the research strategy and what we expect you to provide as far as documentation to support your application.

So there are seven components that are specifically called out in the funding opportunity related to a REACH application. The first is leadership and governance. Who is going to lead the program and how are you going to communicate across partnering institutions, if you include partnering institutions, and how are you going to govern the Hub?

We expect you to address explicitly any collaborations, partnerships that you develop. There's also a non-Federal funding component that is expected in your application, and you need to address that.

You must tell us what your plan is for soliciting and selecting technologies from the source research institutions. That should include an external review board. And I'll get into details on what that means in a few minutes.

You need to provide information on how you will give funding to selected projects, what resources and expertise you'll put in place to make available for technology development.

You need to describe a project management plan for the development of technologies that are accepted into the Hub.

You also need to describe skills development, education and mentoring for the innovators that apply to be supported by your Hub.

And finally, although we don't expect your Hub to be completely self-sustaining by the time the award ends, we do expect you to present a credible plan for developing a self-sustaining infrastructure.

So I'm now just going to go through these components in detail. I'm going to stick very closely to the information that is in the RFA, so I would encourage you very strongly to read through the RFA. All of these details are contained in it.

So as it relates to leadership and governance, we expect the PI or the co PIs of the REACH Hub will have the necessary experience as well as operational, business and scientific expertise to lead the Hub. And that experience should be demonstrated through a documented track record of success in transitioning technologies from the discovery phase at an academic institution to the commercialization phase of the technology.

It's required that you develop appropriate metrics, including tracking the progress of technologies after the exit from the Hub. So you need to present a plan. You need to present short and long term metrics for determining success.

And you need to describe a plan to disseminate information related to the research outcomes to the research community at large, and that includes successes and failures and best practices.

We expect that Hubs will establish and manage necessary collaborations and partnerships to meet the goals of the RFA.

Examples might include incorporating other research institutions into a consortium in order to source appropriate technologies. Might include law schools or business schools, partnerships with state

economic development agencies, local incubators or accelerators, CRO's as well as clinical trials networks.

We expect you to present a plan that will ensure the appropriate communication between partners and we also expect that you will present a plan to facilitate licensing and technology transfer. We expect that there will be institutional leadership commitment from any partners identified.

We also expect that you will obtain non-Federal funding that is at least equal to what you're requesting from the NIH. That funding can come from numerous sources, including foundations, the participating institutions themselves, state or local governments, investors, and individual benefactors.

You may value in kind support if it represents a substantial resource available to the Hub; however, we anticipate that we are not giving you enough money to develop all of the technologies that I described earlier. For example, therapeutics can be very expensive to develop and so it will probably be necessary for you to have access to additional money that can help support the development of individual projects through the Hub.

You should clearly itemize any resources in funding that you are attempting to secure or have already secured, and you should tell us what the total value is, and you can provide additional information on your non-Federal funding in the Appendix.

If the fund raising efforts are still in progress or contingent upon an award, then you should clearly describe what those contingencies are.

You should also include letters of support from any organizations that are contributing to your application. And as I mentioned you can include additional documentation on your fund raising in the Appendix.

A key aspect of a REACH Hub that is successful is the ability to solicit technologies from the research institutions. So you must develop an infrastructure to actually pull appropriate technologies out of the institutions and select the most promising technologies.

The most promising technologies will be those that have demonstrated medical need, scientific merit, but also commercial potential. To make those selection decisions, you will need to put into place an external review board that includes expertise in translational research as well as proof of concept research. The board should include industries, start up, investment, technical, financial and business experts, as well as university technology transfer officials.

Applicants should describe the process for establishing their external review board and the types of expertise that will be represented on the board as well as the processes by which the Hub will solicit the appropriate technologies and that the ERB will be using to evaluate them.

It is important that you not contact potential members of the external review board in advance of your application or name them in the application.

After technologies are solicited and selected for support by a REACH Hub, you need to have processes in place to fund the technology development, as well as to provide necessary resources and expertise that are required for early stage technology development.

So you need to provide a plan in your application for funding individual investigators to conduct the product definition studies. From the award, you can only include up to $100,000 for funding each of those projects; however, you can, and it will probably be necessary for some technology types that you subsidize those awards with additional money from other sources.

You need to describe the resources and expertise that are going to be available, including the scientific expertise, domain expertise, business development, market research, regulatory, intellectual property, etcetera.

When the technologies are funded, you need to use industry standard project management techniques. You need to have a market focused oversight process to enable the development of the technologies.

The technology transfer offices should facilitate the best path forward for the technologies. Any agreements that are designed to reduce the burden of licensing should be described and can be included in the appendix.

And you need to demonstrate a commitment from the institution for this effort. You can include letters of support from leadership of the institutions and from the technology transfer offices.

You need to assemble project management boards for projects that are accepted into the Hub. Those boards should consist of industry representatives, start up, venture capital, technical experts, financial and business experts.

And you should describe the process that those boards will use to assess the progress of technologies. You need to have processes in place to make milestone driven go/no-go decisions to terminate the development of projects that are not meeting their milestones so that you can return resources and reallocate them to other projects when necessary.

Another essential component of a REACH Hub will be the skills development. You need to provide a plan for providing hands on experience to innovators as well as educational and networking activities that go beyond just the projects that are accepted into the Hub.

You need to make linkages to local as well as virtual resources. So you should describe your plans for developing these types of activities or collaborating with other partners where these activities already exist in your ecosystem.

You should discuss how mentoring and professional development of the innovators that are actually accepted into the Hub will be achieved. Finally, we're very interested in integration and leveraging of the NSF I-Corps program, so if you already participate in the NSF I-Corps program or if you're planning to submit an application to the NSF I-Corps program, we would encourage you to include in your application a brief summary as well as how you envision those activities integrating with the skills development requirement of the REACH Hub.

Finally, we expect that the REACH Hubs will become self-sustaining. That means that you have to submit a sustainability plan that includes any support you might get from partnering institutions to continue developing to continue the program after our award ends.

You should include descriptions of institutional support as well as any financial arrangements that you may have or you might put in place, for example, to get royalties or equity positions on technologies that exit the Hub.

You should provide documentation to support your sustainability plan, including letters from institutional leaders as well as any agreements, MOUs that you might put in place.

I think you can tell that this is a very different type of NIH application and award. The scored review criteria have been modified and there are additional review criteria that will contribute to the overall priority score of the applications.

You can find all of the information on these modified review criteria in review Section V of the RFA. I would encourage you to read that information very carefully. That is the information that the study section will use to review the applications.

All of these details and others can be found in the Funding Opportunity Announcement. Please read it carefully. The slides and the frequently asked questions will be posted at the website shown here. A slightly easier way to get to that URL is to simply go to http://sbir.nih.gov and there will be right at the top of the page a news flash that links to the slides and the FAQs.

You can now start entering your questions in the webinar chat console and we will attempt to answer as many as possible. If we don't answer your question, you can follow up with me with my email address shown at the bottom of this slide. The receipt date is June 26th, and we encourage you to please submit a letter of intent one month prior to that. Thank you.

Dr. Matthew Portnoy:

>> Thank you very much, Kurt. As you can imagine we have a number of questions already coming in, and we have plenty of time to hopefully get through as many of them as we can.

And so, either you will be able to answer most of them, and if needed I can jump in as well.

So here we go: What is the perspective of NIH with regard to co-PI and/or co-PI configurations? Would a strong co-PI configuration be negatively viewed in relation to a single PI configuration?

Dr. Kurt Marek:

>> So the co-PI mechanism is allowed, and we would encourage you to develop the appropriate partnerships that you need to submit a strong application. And if that includes having co-PIs at different partnering institutions, that's perfectly fine.

It is important, however, to present the communication and governance plan if you are going to be submitting an application with co-PIs.

Dr. Matthew Portnoy:

>> Great. The next question is somewhat related. How important is multi-institutional participation given funding levels?

Dr. Kurt Marek:

>> Right. So it's important that you are able to meet the goals of the RFA. And there are in many ecosystems multiple academic research institutions that could serve as a source for technologies. There are also resources available at certain institutions that may not be available at others and there might even be nonacademic institutions in your ecosystem that provide value and work in this area.

And so leveraging those resources, as necessary, to fulfill the goals of the RFA is important.

It is not, however, required that you present an application with multiple partners.

Dr. Matthew Portnoy:

>> Great. The next question is can you provide any detail regarding the makeup of the study section?

Dr. Kurt Marek:

>> So as you can imagine, this is a different type of application and award and so it will have a different type of review. The review criteria I mentioned, they are listed in the RFA and you should review them.

The expertise that will be required to review these applications will be different from most of our standard NIH applications. And so we will make sure that the study section includes appropriate expertise to be able to evaluate these applications, including the processes that you will be proposing.

Dr. Matthew Portnoy:

>> Great. A question about eligibility. How recent does the NIH STTR participation for the applicant institution have to be?

Dr. Kurt Marek:

>> I don't think there's a limit on that. Matt?

Dr. Matthew Portnoy:

>> That's correct. As long as they've been a research partner in the past or currently, that will suffice.

There is also a related question regarding eligibility: the FOA calls for institutions that have been a formal partner to a small business on an STTR. Can you extrapolate on the definition of formal partner? Does that include institutions that received a subaward on an STTR?

Dr. Kurt Marek:

>> That's exactly the requirement. So only small businesses can receive STTR grants, so participation in the STTR program by a research institution means that that research institution was a subawardee on an STTR award.

Dr. Matthew Portnoy:

>> Yes. And I would say also the formal research institution partner.

Dr. Kurt Marek:

>> Correct.

Dr. Matthew Portnoy:

>> Is the 100,000 dollar cap for investigator support for the entire award or per investigator/project within the award?

Dr. Kurt Marek:

>> That is per project.

Dr. Matthew Portnoy:

>> Great.

We did that one.

Is there any preference for well-established, well-funded programs versus more nascent, but hopefully high impact initiatives?

Dr. Kurt Marek:

>> So there is no preference. We state in the review criteria that we are looking for awards that will make a difference to the local ecosystem in translating technologies out of research institutions. So that could be by bolstering an existing program, by leveraging resources in a local ecosystem to work better together or by creating something completely new.

Dr. Matthew Portnoy:

>> Great.

Should applicants explicitly describe the potential product definition studies, ie feasibility, validation, prototype development, that would happen in year one of the grant or simply describe the pool of investigators the Hub will have access to?

Dr. Kurt Marek:

>> So it's important that you demonstrate an access to technologies at the appropriate stage of development. The technologies themselves will not be reviewed. We're not going to review individual projects, we're going to review the processes that you will use to develop those projects.

But it is important that you demonstrate that you have access to a sufficient pipeline of technologies.

Dr. Matthew Portnoy:

>> Great. Thank you.

So we've got a couple of questions on this: The scope of this program resembles the recently launched National Accelerated Innovation Centers, the U54s, yet the budget is approximately five times less. How is that different?

Dr. Kurt Marek:

>> So the programs are quite similar. There are some important differences. The NIH Centers for Accelerated Innovations are focused on the NHLBI mission. The reach Hubs, however, are trans-NIH, so there's no disease specific mission.

The awards are slightly smaller, however, we do believe that the goals of the RFA can be attained along with the additional matching funds that you're required to bring to bear on the award.

Dr. Matthew Portnoy:

>> Great. This is related. Can you elaborate between the REACH RFA and the NSF I-Corps nodes or site grant?

Dr. Kurt Marek:

>> So we believe that the I-Corps program is a demonstrated educational entrepreneurial program. It is aligned with some aspects of the skills development requirement of the REACH Hub RFA. So we would encourage you to leverage any existing I-Corps program that you might already have awarded at your site or that you apply to become an I-Corps site.

Dr. Matthew Portnoy:

>> Great. Next question: Even though small businesses cannot be the primary applicant for this RFA, can a small business be part of a consortium in which a university is the primary applicant and the university is eligible because they've partnered or are an STTR?

Dr. Kurt Marek:

>> Yes, I believe so.

Dr. Matthew Portnoy:

>> Great. Explain again how to address the review board in the application without contacting individuals prior to submission or naming them in the application.

Dr. Kurt Marek:

>> So I'll give you a little bit more information on this. The reason we have this requirement is that if everybody provided the names of review board members that they've contacted, we would be reducing our pool of potential reviewers substantially. So we ask that you tell us the types of expertise you envision putting on your review board, the processes that you will undergo in order to identify the right expertise to staff that review board.

If you have experience in putting together these types of review boards, you can certainly mention your successful experience.

Dr. Matthew Portnoy:

>> Great. Could the REACH program be applicable to a university technology that is already licensed? Also, is there eligibility criteria for the licensee, for example, university start up versus bio tech company, etcetera?

Dr. Kurt Marek:

>> So the program is designed to transition technologies out of the academic institutions and into the commercial sector. So we would expect that the technologies would be within the academic institution

when they enter into the Hub, but that they would transition out either as a small business or that they would be derisked enough to be able to be licensed out to another entity when they exit the Hub.

That does not mean, however, that you can't use other resources that may be at your disposal to enrich a program with other types of technologies that might be in your ecosystem. But this award should be used for academic innovations.

Dr. Matthew Portnoy:

>> Great.

Can you explain the reason for STTR in more detail?

Dr. Kurt Marek:

>> Sure. So this program was developed as a result of a Reauthorization made directly by Congress to use STTR funding to support this type of proof of concept work. And the 2011 SBIR/STTR Reauthorization Act explicitly states the eligibility requirements.

Dr. Matthew Portnoy:

>> Great.

We did that one. Can you elaborate on the metrics for success after exiting the Hub?

Dr. Kurt Marek:

>> So the types of metrics we're looking for are short and long term. The short term metrics are most likely related to project management and technology development, skills development, exits from the Hub. Longer term metrics are more likely to be related to commercial success, economic development, cultural change at the institution.

Dr. Matthew Portnoy:

>> Okay, great. Does there need to be a focused research theme or should the REACH Hub be broadly defined in terms of R&D?

Dr. Kurt Marek:

>> So we don't state explicitly in the RFA what your scope needs to be, but this is a trans-NIH funding opportunity.

Dr. Matthew Portnoy:

>> Great. Must all of the universities in the consortium have already participated in NIH STTR?

Dr. Kurt Marek:

>> No. Only the lead institution has to meet that requirement.

Dr. Matthew Portnoy:

>> Great. Along those lines is it expected that the PI be a faculty member or professor?

Dr. Kurt Marek:

>> So the PI needs to be affiliated with the lead institution. There can be co-PIs at partnering institutions. The person that leads the application and the award should be somebody with demonstrated experience in transferring technologies out of academic institutions and developing them commercially.

Dr. Matthew Portnoy:

>> Okay. And that's the same question. We've got a few of these and I can answer these. Will the RFA be issued again in the future, in the past, is it one time?

And so the answer is this is a one time RFA for three awards for up to three years per award.

Can the co-PI be from industry?

Dr. Kurt Marek:

>> Were you going to answer that one too?

Dr. Matthew Portnoy:

>> Sorry. Please answer this one, can the co-PI be from industry?

Dr. Kurt Marek:

>> Yes.

Dr. Matthew Portnoy:

>> Okay. Let's scroll up here. Do you promote the leveraging of the smart business model, the SMARTT, the NHLBI program?

Dr. Kurt Marek:

>> So we encourage you to leverage any NIH or other federally funded programs that are available to you. That would include the CTSA's, perhaps the commerce department's I-6 program, the I-Corps program that I mentioned earlier, as well as any other programs that you might have access to.

Dr. Matthew Portnoy:

>> Great.

May a system level department apply on behalf of all universities to maximize life science technology pipeline for the project? We got a similarly related question for a medical center that is comprised of dozens of member institutions, does the program support multi-institutional submission?

Dr. Kurt Marek:

>> So there would have to be a lead institution.

Dr. Matthew Portnoy:

>> Correct.

Dr. Kurt Marek:

>> Do you have anything to add to that, Matt? I'm not quite sure I understand the question.

Dr. Matthew Portnoy:

>> I'm not quite sure I understand either. It does need to be a single lead applicant institution that meets the eligibility criteria. And if that happens to be a higher level organization, then that's okay.

Can an institution be a subcontractor on more than one application?

Dr. Kurt Marek:

>> So we expect that you will have institutional commitments on any application and so dividing commitments among multiple applications may not demonstrate a truly high level of commitment to any individual application.

Dr. Matthew Portnoy:

>> Thanks. We've gotten a couple of questions on a copy of the presentation. If you look on the webinar screen, you will see the link where the slides will be posted within a day or two, as well as the recording of this webinar and the transcript.

Could you please elaborate on the licensing tech aspect? What is the view of NIH on this?

Dr. Kurt Marek:

>> So as we state in the funding opportunity, we expect that a successful REACH Hub will put processes in place to reduce the burden on licensing and technology transfer. And we expect institutional commitment to that effort and anything that you are doing to facilitate licensing and technology transfer in the most appropriate way possible for the technology we want you to provide evidence of, so that could be an example MOU or example streamlined agreement.

Dr. Matthew Portnoy:

>> Great. And this is a question about the letters of intent and what that process is. How serious is a letter of intent review and what proportion will be allowed to go on to the full grant?

Dr. Kurt Marek:

>> So letters of intent are optional, very short. It only includes limited information. They are not reviewed. They're only there to help us prepare for the review process to understand better how many applications we might be receiving and from which institutions.

Dr. Matthew Portnoy:

>> Right. I'll follow up so what you said, letters of intent are not required, they are optional, and if you do not submit a letter of intent, you still may submit an application and you will neither be advantaged or disadvantaged for not submitting a letter of intent. It's solely to allow us to plan for the review.

All right. Next question: Although funding to establish the Hubs is not open to small businesses, once the Hubs are open for business, would small businesses be eligible for funding through the Hubs?

Dr. Kurt Marek:

>> So I think we answered a related question to this. Not through the REACH Hub award itself, but if as part of the local ecosystem that's being advanced by the REACH Hub, an awardee had additional sources of funding and they wanted to use that funding to allow other sources of technology, they could.

Dr. Matthew Portnoy:

>> Great. Then we have a few questions that are all related. We've covered this before, but we'll go through it quickly about the budget. Is the $100,000 amount per project per year or cumulative? It's per project. It's not cumulative, it's per project.

Dr. Kurt Marek:

>> It's per project.

Dr. Matthew Portnoy:

>> Is the 100K per project total cost or direct cost?

Dr. Kurt Marek:

>> Total cost.

Dr. Matthew Portnoy:

>> Is the award cap of one million dollars per year per participating institution, or is it the cap for just the lead institution?

Dr. Kurt Marek:

>> It's total for the award.

Dr. Matthew Portnoy:

>> No matter how many participating you have.

Dr. Kurt Marek:

>> Correct.

Dr. Matthew Portnoy:

>> Is there a preference for the ratio of operational funding versus project funding?

Dr. Kurt Marek:

>> There's no preference. You need to, however, present the most appropriate structure for your ecosystem to meet the goals of the RFA.

Dr. Matthew Portnoy:

>> Okay, great. We already touched on I think the expected involvement or connection with the I-Corps program. There were a few questions on does being a subcontractor on a SBIR account, a Small Business Innovation Research?

Dr. Kurt Marek:

>> That does not count. It must be an STTR award.

Dr. Matthew Portnoy:

>> And that may sound very odd, but as Kurt said that is because that is the way Congress wrote this part of the law. It's an STTR specific law. Where can we examine past STTR awards?

Dr. Kurt Marek:

>> So you can go to the NIH public awards database, which is called the NIH RePORTER. And we'll include a link in the FAQs. Probably the easiest way to get there is just to Google it.

Dr. Matthew Portnoy:

>> Another one about eligibility. What if the STTR is pending?

Dr. Kurt Marek:

>> Go ahead, Matt.

Dr. Matthew Portnoy:

>> I would say if the Notice of Award is issued before the due dates of the RFA, then that would be okay. If not, then I think it's not going to be possible. Although you should check with the institution, they may have received STTRs in the past, which would be okay.

Do the technologies developed in this call need to have been generated from an NIH grant?

Dr. Kurt Marek:

>> No.

Dr. Matthew Portnoy:

>> Okay. How is NIH viewing stages of technology commercialization? Should they focus on one stage or other stages of proof-of-concept that's necessary to bring research to a viable stage of commercialization?

Dr. Kurt Marek:

>> So it will vary depending on the technology of the project. We expect that you will focus on the types of technology development required to move technologies out of academic institutions.

So NIH traditionally funds hypothesis driven basic research. We do not traditionally fund the non-hypothesis proof-of-concept type work that might be necessary to develop a technology to the point where it's of interest to an outside investor or strategic partner. That's the gap that we expect you to focus on.

Dr. Matthew Portnoy:

>> Okay, great. Do you have any vision that successfully funded projects will become a company or be licensed, any particular expectation on the outcome of technology that comes out of Hubs?

Dr. Kurt Marek:

>> Those are absolutely two exits that we would expect. We do not simply want you to perform additional hypothesis driven research with these awards. The goal should be to develop them to point where they can exit the academic institution to be developed further by either an existing or a new entity.

Dr. Matthew Portnoy:

>> Great. Can the funds be used for second stage funding of proof-of-concept projects that have already been groomed by a concept like process with the $100,000 per project and which is ready for the next level of investment, 200K or more per project?

Dr. Kurt Marek:

>> So that's certainly possible that you could submit a grant proposing that. The only caveat is the specification of $200,000 per project in the question. Just to reiterate, you can only make project awards up to $100,000 from the REACH award. You can, however, make up the difference using another source of funds.

Dr. Matthew Portnoy:

>> Great. Do we build a corporate structure at the end of the REACH funding? How does the NIH view the relationship of the Hub to the parent institutions?

Dr. Kurt Marek:

>> So I'm not quite sure what they mean by do they build a corporate structure at the end of the reach funding. I think they're getting at the sustainability question. And we do expect that you will have a plan in place to sustain the activities of the Hub after our award ends.

Dr. Matthew Portnoy:

>> Okay. We have a couple of questions all related to the matching. Can you elaborate on the expectation for levels of non-Federal funding and similarly for matching non-Federal, what percentage can be from in kind resources?

Dr. Kurt Marek:

>> So we expect that you will have at least one to one contributions from non-Federal sources. Beyond that, we simply expect that you will have enough in kind and cash resources to meet the goals of the RFA. We do not state in the RFA, nor do we have any particular expectation of a percentage mix of in kind versus cash contributions.

Dr. Matthew Portnoy:

>> Great. And related to that, are matching non-Federal funds required for a total cost requested or just directs?

Dr. Kurt Marek:

>> The matching fund expectation is total costs.

Dr. Matthew Portnoy:

>> Right. So a million.

Dr. Kurt Marek:

>> We expect you to have a million dollars per year.

Dr. Matthew Portnoy:

>> Great. Can the PI be from a tech transfer office if he or she has the appropriate experience with commercialization?

Dr. Kurt Marek:

>> If they have the appropriate experience, that's fine.

Dr. Matthew Portnoy:

>> Can a lead institution apply with a mission to get other institutions to join after award?

Dr. Kurt Marek:

>> So that would be fine. We do have a desire to see practices that you put in place become scalable, but we would expect that you would have commitments from the necessary partners at the time of application to achieve the goals of the RFA. But if after the award you want to expand through additional resources, bring on additional partners, that's perfectly fine.

Dr. Matthew Portnoy:

>> Great. A couple of questions, folks want to know how many people are on the webinar. Perhaps they're wondering what their competition might be. We have over 200, and I wouldn't necessarily go take that and think 200 folks are going to apply. It just depends on what the interest is. And whether folks think they can do it. And the other question related is that we are told that there's a lot of paperwork required. Is there a two-step process where you can Guide a person to know whether it's worthwhile, cost effective process?

I would say if you have questions, whether or not you think what you have in mind is within the scope of the RFA, please contact Kurt by email offline and you can set up a discussion about your idea and he can give you some advice on that.

Dr. Kurt Marek:

>> And just to elaborate a little bit on the 200 people on the webinar. I'm not looking at the list here, but I assume, Matt, that a lot of those people are probably from the same institutions.

Dr. Matthew Portnoy:

>> And they will be. I'm not looking either. And they could be from a lot of different areas as well.

Dr. Kurt Marek:

>> Correct. So I would imagine that the total number of institutions represented is probably smaller than that.

Dr. Matthew Portnoy:

>> Sure. A question about what kind of project volume per year would be considered acceptable for this award? I think that relates to how many 100,000 dollar projects would be considered reasonable.

Dr. Kurt Marek:

>> So we would expect you to use the money to put together an efficient and effective infrastructure to develop projects. So that's something you need to propose to us.

Dr. Matthew Portnoy:

>> Great. And related, can you clarify that the 100,000 per project is allowed? Yes.

Could the entire budget, the million, be used towards funding projects?

Dr. Kurt Marek:

>> If you have other sources of funding to meet the other goals of the RFA, so for example, paying the necessary salaries or putting together skills development programs, then absolutely.

Dr. Matthew Portnoy:

>> All right. Is it more favorable that the applicant is already an I-Corps site?

Dr. Kurt Marek:

>> No. We simply are encouraging participation through the RFA, but it is not a requirement.

Dr. Matthew Portnoy:

>> Great. Back to the matching funds for a moment. Are the matching funds required to come through the university, for example, as sponsored research? The alternative is for funds to be expended for such projects, but for funds to flow directly to a startup, certification, documentation to show match. I guess the source of the matching funds, if you can reiterate.

Dr. Kurt Marek:

>> So the projects would be university based projects. So to get money to them I think you will have to go through university.

Dr. Matthew Portnoy:

>> Right. And somewhat related, can you comment how this award could partner with the CTSA infrastructure?

Dr. Kurt Marek:

>> Sure. There are at different CTSAs that are programs in place to facilitate clinical trials as well as other research cores available. There are also skills development programs. As those relate to the goals of this RFA, we would encourage you to leverage them as much as possible.

Dr. Matthew Portnoy:

>> Okay. A couple of questions that maybe we'll cover very quickly that we've answered. Is this a one-time award? Yes, this is a one-time RFA. We don't anticipate offering it in the future.

How many Hubs are being funded? Three hubs across all of NIH, not three per Institute. So three in total from this RFA.

How much equipment can be purchased?

Dr. Kurt Marek:

>> I'm not exactly sure what kind of equipment you would purchase to meet the needs of this RFA. I suppose there could be some sort of core equipment.

Dr. Matthew Portnoy:

>> That's true. It would depend on the specifics in the application.

Dr. Kurt Marek:

>> Yes.

Dr. Matthew Portnoy:

>> Will there be a final review of projects by NIH prior to funding the projects in the Hub?

Dr. Kurt Marek:

>> So this is a cooperative agreement and we state in the RFA that we will participate in the selection process of projects.

Dr. Matthew Portnoy:

>> Great. And so let's see here. I think we discussed NSF and I-Corps.

Okay. Here we go. Is it the NIH's intent to model REACH after I-Corps nodes which have a regional, if not multi state focus not based on geography, but on other factors like commercial readiness of the technology. Or is it the intent of REACH to establish a critical mass of innovators within a specific geographic region or institution?

Dr. Kurt Marek:

>> So if you are developing a collaborative application, consortium, there's no specific requirement that it be regionally based. You could include institutions outside of your local or state region. And we explicitly encouraged applications to include participation of institutions from IDeA states.

Dr. Matthew Portnoy:

>> Great. Would a REACH Hub that is more focused on one or two disease areas be as responsive to the RFA as one that is more broadly addressed in many NIH disease areas across NIH?

Dr. Kurt Marek:

>> So we don't explicitly state the disease scope, but this is a trans-NIH funding opportunity.

Dr. Matthew Portnoy:

>> Great. I think we have a few more and then I think we'll be in good shape. Are technology and co-development projects in collaboration with an industry partner permitted?

Dr. Kurt Marek:

>> Yes. Let me elaborate on that. If they are technologies that originated within the academic institution. If you have a co-development partner for that technology from industry, that's fine.

Dr. Matthew Portnoy:

>> Okay. Great. Are the technologies of interest focused on biologic devices or do they span all technologies and healthcare such as computational software development?

Dr. Kurt Marek:

>> All technologies within the NIH mission.

Dr. Matthew Portnoy:

>> Great. We have three awards. Again, this is just in response to some of these questions, there are three one million dollar awards per year, so a total of up to nine million dollars over the course of three years.

Can a nonprofit biotech incubator that works with all local universities be the lead institution?

Dr. Kurt Marek:

>> No. The lead institution must be a partner in an NIH STTR award. So it would have to be a research institution that took the lead, but a nonprofit incubator could certainly be part of the consortium.

Dr. Matthew Portnoy:

>> Okay. We answered that one about it can be past or present STTR for the lead institution.

Can you address how REACH is going to be different than the recent White House blog about NIH participation in the NSF I-Corps program?

Dr. Kurt Marek:

>> So we are very interested in leveraging programs across the Federal government that are aligned. And we certainly see alignment between the goals of the reach Hubs and the NSF I-Corps program, in particular the skills development aspects of the REACH award and the entrepreneurial education provided by the NSF I-Corps program, which is why we are encouraging people to take a look at the I-Corps program as a potential part of their skills development portion within their reach Hub.

Dr. Matthew Portnoy:

>> Okay. Does the STTR need to be from NIH?

Dr. Kurt Marek:

>> Yes.

Dr. Matthew Portnoy:

>> Okay. This is important to make sure we clarify. We did provide an update to the RFA with a Notice indicating that we opened up the RFA to nonprofits, in addition to universities. But these nonprofits must still have been the formal research partner on an STTR. And that's important to clarify for everyone.

By what date will applicants hear back regarding the award? Can you maybe talk about the general timeline after receipt on June 26th?

Dr. Kurt Marek:

>> I'm going to have to pull the RFA out. Hang on.

Dr. Matthew Portnoy:

>> I've got it up right here.

Dr. Kurt Marek:

>> Do you have it in front of you?

Dr. Matthew Portnoy:

>> The receipt date is June 26th, 2014. It will undergo peer review roughly in November of 2015. Go to advisory council, a required second level of review for all NIH awards in January. Earliest possible start date is April 2015. So there we go. And of course if you apply, you'll receive a summary statement after the review and you can call Kurt after review if you're an applicant to find out what's going on.

Related to the review, how seriously are support letters going to be reviewed? Do they have to show financial commitment or in kind commitment?

Dr. Kurt Marek:

>> So it depends on why you're submitting the support letter. If you're submitting a letter of support to demonstrate institutional commitment, then having that come from the leadership of the institute would be of value.

If you are including the letter of support to demonstrate financial commitment for your non-Federal funding requirement, then you would want to have as strong a statement of commitment as you can that you will be able to receive the funds.

Dr. Matthew Portnoy:

>> Great. Are there limitations or expectations or budget commitments to consultants, vendors and intellectual property costs? I think they're asking how much can you spend of the budget on these types of costs?

Dr. Kurt Marek:

>> So you would want to make sure that you have a reasonable balance between the technology development costs and the amount of money you're putting into infrastructure to bring the expert advice to the technologies.

Dr. Matthew Portnoy:

>> Okay. So how will NIH determine which ICs will participate on any given award with the cooperative development mechanism?

Dr. Kurt Marek:

>> So we will put in place an appropriate management committee for the cooperative agreement.

Dr. Matthew Portnoy:

>> Okay. So we have a little bit more time. Let's try to get through a few more questions.

In terms of scouting ideas, would it help to have a focus in a specific area such as devices or broad capabilities for a variety of areas? We've discussed this a little bit before and we do have a couple of questions in this. So the general question is smaller focus on one or two or three areas or broader focus, what's going to be more ideal?

Dr. Kurt Marek:

>> So we don't stipulate a required scope in the RFA. We do state an interest in a fairly broad range of technologies, including therapeutics, biologics, small molecules, devices, health IT, diagnostics, but we do not state that you have to cover all of them. You should arrange your application to be as strong as possible.

Dr. Matthew Portnoy:

>> Great. What information is needed to verify that the research institution is a former STTR partner? Grant number?

Dr. Kurt Marek:

>> So that would be very helpful, but I think we'll also be reviewing them for responsiveness here.

Dr. Matthew Portnoy:

>> Yes. Will the PI of the Hub be ineligible for receiving project funding through the Hub?

Dr. Kurt Marek:

>> I don't think we addressed that specifically. You would, however, want to make sure you have appropriate institutional conflict of interests rules in place.

Dr. Matthew Portnoy:

>> Yes, very good. And then we answered about the scope of it. This is all about the scope. Can a research hospital in close collaboration with the university be the lead on a REACH proposal?

Dr. Kurt Marek:

>> If they've received an STTR award.

Dr. Matthew Portnoy:

>> That's right, yes. The presentation will be available at the site above; there's some questions on that.

What kind of person would be the ideal PI for this RFA?

Dr. Kurt Marek:

>> I think we've addressed this a couple of times. I'll reiterate, we're looking for someone who has experience that can be demonstrated in translating technologies out of academic or research institutions into commercial products.

Dr. Matthew Portnoy:

>> Very good. Questions about peer review. Will the PI be able to obtain the preliminary impact score after the November review? Yes. As with any funding opportunity, you will get the impact score within a few days of the meeting. The summary statement a few weeks after that.

I think we're going to do two more questions and then we will end the webinar. And so important IP pipeline question. We're an academic institution. We have clinical partners that also perform research. Can clinical partner IP be a part of our Hub IP pipeline?

Dr. Kurt Marek:

>> Sure. Unless I'm missing the question, I don't see a problem with that.

Dr. Matthew Portnoy:

>> Right, I agree. And then if there is more than one PI, are they defined as co-PIs or multiple PIs? And so I guess I can answer that in general. Co-PI is a very informal designation that NIH doesn't formally recognize, so you can have of course many co-PIs on an application. They can be from the same institution or multiple institutions.

If you choose to invoke the actual multiple PI mechanism then yes, everyone you name as a multiple PI is a formal PI on the project. You have one as the contact PI, which should be from the lead institution, and that also using the multiple PI model you must also provide a separate leadership plan on how you're going to manage the project with many multiple PIs.

So with that we're going to end the webinar. I'd like to thank Kurt very much for all of his time and patience in answering all these questions and putting together a great presentation.

Again, the slides, recording of the webinar and transcript will be available on the site that you see on the screen or more easily through the main NIH SBIR website within a few days. We thank you very much. And if you have any follow up questions or we were unable to get to your question, please contact Kurt at kurt.marek@nih.gov.

Thank you very much. This concludes the webinar.

[End of webinar]