

NIH Research Evaluation and Commercialization Hub (REACH) Pre-Submission Webinar

Good afternoon, the webinar will start in five minutes.

Hello, the webinar will begin in two minutes.

Hello, this is Matt of the National Institute of Health welcome to today's webinar, discussing the NIH Research Evaluation and Commercialization Hub for REACH.

This webinar will be approximately two hours long with the content, we will have plenty of time for questions and answers at the end, in terms of logistics, this is a webinar, so all attendees are automatically muted and will not be able to speak, you can send questions in, through the webinar counsel and the question box. We will do questions at the end, and we will have plenty of time to do questions. With that I'm going to introduce our speaker, who is Doctor Kathleen from the national heart, lung and blood Institute, office of translational alliance and coordinations will be delivering webinar content and will be answering most of the questions in the end, Kathleen? Please take it away.

Thank you Matt for the introduction, good afternoon everybody. As Matt said my name is Kathleen I am your presenter today, and I currently manage two existing sister programs that share a similar focus to this new opportunity. The purpose of the webinar today, is to give you an idea of what we are trying to accomplish through this program. And address any questions you might have. As Matt said, at any time, during the talk you can type a question into the console and we will consolidate questions and try to answer as many as we can today.

For any questions we do not get to today, we will answer and post along with the slides and transcript on our small business website within one week or two. Matt, I am having trouble advancing the slides. There we go. Okay. So, why this program and what we want to get out of it, NIH is a major funder of biomedical research and reset spend a lot of money on science, one of the big problems is that many discoveries are not still being translated from the academic setting to the patients because there is exist in moving the discoveries out of the lab.

Congress and NIH have heard from the community about how difficult this is, this process of getting technologies out of the lab, and Congress recently reauthorized the law, which allows for a proof of concept program to address this issue. NIH designed this program with congressional support, with the intent of speeding up the creation of small business, and accelerating the process of moving academic discoveries into products that improve health. Because the technology will be surrounded by the appropriate team and develop the correct way, we expect that spin out companies will be released on companies, well put together and in a position to attract the necessary support for continued development and this would include submitting strong, small business applications to NIH. As important as business creation, for this program, is to provide entrepreneurial education to innovators. By providing the appropriate technology support and innovator education. We hope the program will move breakthrough innovations to products

that will help people and benefit economy. This slide shows what the program will provide, in order to have more technologies reach their full potential. They are going to be funded to establish processes to solicit and select the most promising technologies money will be provided to innovators, to support their product definition studies. Also provide access to early stage technology development expertise and innovators, and this includes in areas not typically seen in the academic setting, such as IP, regulatory and reimbursement.

We also want to, whether there is a skills development to the program, we want to provide hands-on experience in entrepreneurship, so we can train a globally competitive by medical and scientific research technology development and entrepreneurship. The due date, for the application is March 19, 2019. At 5 PM, applicant institution local time. We do ask that if you are interested in submitting, you submit a letter of intent, 30 days prior

by February 19, this is not required but it helps us to get our review process in order, if we know how many applications to expect. After we receive the applications we anticipate peer-reviewed, to be in June, and the awards can start as early as September. NIH is launching this program and launched previous existing product definition programs, because we recognize that many barriers and still do exist at getting the technologies out of the lab, into beneficial treatment and cure. There typically is not money to fund these early-stage technology validation studies. They are needed to define the product. Innovators haven't been trained to do not quite understand how to bring a technology forward.

And what needs to happen to meet downstream business case requirements. For example, academic scientists are not used to thinking about it for, or how the product will be immersed, for reimbursed.

And often, at some institutions innovators do not have access to the technology development and commercialization, these resources that are needed to move the technology forward. In 2015, NIH launched the initial REACH program which we are now calling REACH 1.0, REACH 1.0 was supported as a phase of zero proof of concept pilot partnership program, in accordance with the SP IRS PTR reauthorization act of 2011.

The program is written into the law is exactly how NIH is administering it, this act was recently reauthorized through September 2022. So it gives NIH the ability to continue to support a program using as PTR funds and this is what you see in the current solicitation that we are calling reach 2.0. This slide shows two main programs that make up what we call our proof of concept in our network. The programs are reach 1.0, and the NIH centers for accelerated innovation, or and CAI, it is a large consortium through which we are learning the best way to move academic technologies forward. The REACH program launched in 2015 and is a trans NIH program so it supports technology that target multiple disease area. The awards were made at Louisville University of Minnesota and Stony Brook University. Per the law, the REACH was a reach program to your program, it was modeled after the NCAA program was launched earlier in 2013. The NCI a program is in Boston, Cleveland, and California. Multiple institutions with a bunch of many consortia, this is a seven-year program funded specifically by the heart, lung, and blood Institute, because heart, lung, and blood have the instant who and experience when it was launched, we took the lead in managing REACH one point on behalf of the NIH and will continue to

do so for REACH 2.0, collectively, the entire network has six sites, four are many consortia with multiple partners, so we have 33 institutions working together to educate innovators and develop best practices and product definition. Part of the reason for the success of REACH 1.0 is because they were able to hit the ground running by taking some of the processes that have been developed by the NCIA awardees and we expected the REACH 2.0 awardees will be able to do the same. The next two slides list, some initial promising outcomes and show that the program seems to be working. We have a team surrounding these programs that is focused on evaluating activities in an effort to identify the best practices and lessons learned. This slide shows a high-level outcome, only for reach 1.0. The top row shows application and funding numbers on the bottom row, shows funding and small business creation. So today, the sites have received 394 pre-applications.

And 284 innovators were invited to submit full applications. Of these full applications, they were reviewed at the site, and also by REACH in program partners and 109 technologies have been supported.

Of the technologies that have completed their time on the site, they have received 12.5 million

of the funding and there has been 24 licensing events and 22 new company forms from these products, of companies are interested in applying for small business grant from NIH the success rate for funding is over 40%. With five awards having been made, since the program launched. This slide shows the aggregated result for both REACH 1.0 and the NCIA program, today 1132 applications,

pre-applications have been received. 609 full applications reviewed and reviewed at the site with the program partners and 244 technologies have been supported. Of the exited technologies, they have received 548 million in funding, there have been 49 licensing events and 55 new companies formed. This is over 31% new business is formed from the exited technologies, and of the companies that applied for small business grants, the success rate for funding is over 60%. And we have made 19 awards now. This slide shows the entire network including partner institutions, so you can see the full extent of the program, most awards are regionally localized. You can see and green, are REACH awardees, Long Island Minnesota and Louisville, you can see the NCIA's in blue, Boston, Cleveland and the state of California. Also shown here, our newest partners for the program, that are part of program recently launched by the general medicine Institute, this program is called the SPTR regional technology accelerator hub, the goal of this program is to set up hubs for entrepreneurial education, and the idea state region, the idea state are those states where NIH wants to broaden the geographical distribution of NIH funding to support faculty evaluation, one award in each of the state regions, so, there is a western region, in black, a central region, and that is an orange, Northeast region, in red, and Southeast region, in purple. Again, these the program has multiple partner institutions that include Puerto Rico, Hawaii, Alaska, and most of the continental U.S. Together there is about 70 sites that support these programs, and all of the programs share the same end goal and we are working together to move academic discoveries towards impact in September, the reach 2.0 awardees will be brought into the greater network, so that we have a large number of institutions from which to learn and figure out how best to advanced technologies in educating people in this area. So, now I will switch

gears and talk about the specific funding opportunity, reach 2.0, the program has some unique requirements, applicants must be a university or other research performing institutions. That participate or have participated in the NIH small business transfer program. You are only allowed to submit one application per institution. Part of the goal of this program, when the technologies exit the program is to form a small business. So, the program said a little bit before you when the company is formed so we do not want small businesses to apply, they are not eligible. And, current NCIA and reach institutions are not able to serve as the primary applicant. This is a list of eligible institutions and institutions of higher education, nonprofits, other than higher education, nonprofits with or without 501(c) 301 status.

This is a trends NIH funding, so they need to develop a program that they developed the for the whole mission, with a suitable portion of the technologies targeting technology, the addresses highest burden of disease, partnerships are encouraged for this grant, if they are needed to meet the goals of this, and the partnership does not necessarily need mean a formal partner on the grant, other participating institution, but you can have a partnership for example, with the local economic development agency, helped put on programs to support innovator education, so we envision legible types of different partners for this award. We want technologies to come to the program to advance to the next source of independent financing. Such as starting a viable company, that might be in the position to apply for a small business grant, or to promote licensing opportunities. Just as important as bending out a company as this development component of the program. We are really interested in educating innovators across different stages in their career. And we would like to see funded hubs be able to expand and provide opportunity for participation of women and individuals from underrepresented groups in innovation and technology development and commercialization. NIH anticipates making five awards, each award is up to \$1 million per year. And this includes direct cost and all components, and this is a four year program. That is set to center in 2022. There are seven components that you will see in the funding opportunity, and they all should be addressed in your applications for the research strategies to describe the overall objective of what you are proposing. For this particular application the research strategy, can be 30 pages, and is a longer than typically allowed. I will walk through these seven parts, but please see the follow-up for more detailed information on any of the parts. Leadership and governance. The hub needs to be led by somebody who has experienced bringing technologies out of the lobby, commercializing, leadership needs to demonstrate the necessary operational business and scientific expertise needed to run the center and show a track record of transitioning technologies from discoveries phase to market. We would like to see the hub leveraging the best practices from current pilot programs, an example of this, is something we worked on with the current NCI REACH awardees, as was to develop an application this was to make sure that the innovators were thinking about having, how to move their technologies forward. And, the application includes sections that speak to commercial potentials as a technology, including having innovators address market size and potential, IP regulatory reimbursement. The application, the application's on the

NCI REACH website and is available for anybody to take a look at, our website also shows some of the entrepreneurial education efforts that are, the current sites have posted or have their YouTube channels on you, for lots of different topics in you know, how to write a business plan, commercial potential, how to navigate the FDA, this has already been established by some of our site and I website posted on it. So we definitely want you to leverage what already exists.

Your application should plan how, should show how you plan to collect, analyze and report, milestones and project management, and standardize metrics across a network. Including tracking the progress of technologies that have already exited your hub. We want to see how you're going to share lessons of what you are creating in your application, you could describe a plan to promote information exchanged and how you're going to disseminate research outcomes to the community. Forming partnerships might help your site be successful in meeting the goals of the federal programs that we think might be helpful to leverage, federal programs might be colocated in your region, and, they might have sharing similar goals what you're trying to do. I have already mentioned, the reach the new hub, and NSS has entrepreneurial educational program with ichor, we have worked with ichor in the past, with our site, SBA runs growth accelerated to help support small businesses and startups. The EDA has Icx regional innovation strategies program, that awards grants to build regional capacity to translate innovations into jobs. Through commercialization assistance to innovators and entrepreneurs. If these are local, you know, something you can access, for your ecosystem that would be good to present in your grant, application. There are designated centers for cancer and AIDS research, you might be able to leverage, many of our funded sites have a CTS, have CT essays, they leverage, the education, the infrastructure, staff, resources, possibility, the bioengineering Institute, as a C3 I program and a point-of-care network, C-3) boards performs medical devices and innovation sharing tools for use of the point-of-care. Any federal program that already exist that might be able to help you, would be good to leverage. More examples of partnerships are collaborations, you can evolve other research institutions that would have technologies that are appropriate for development, if your application contains multiple partnering research institutions for sorting technology, you should present a plan to ensure the appropriate communication and to facilitate licensing and tech transfer. Law schools and business schools can be leveraged. You can use the students to do market analysis, that sort of thing. State economic development agencies. Local incubators or accelerators. Okay, this is light is really important and talks about the matching funds, we do expect you to obtain nonfederal funding, equal to or exceeding the total direct costs requested from NIH. Examples of sources of these funds include foundation, participating institutions, state or local government, Angel or VCs. Individual benefactors. It doesn't matter what the source of the match is, but it cannot be other federal grants or federal funds, you can work with your development offices, to see if there is a some kind of innovation funds that might be available. You can look, for funds at individual departments in the office, or

third-party Excelerator, and in your application, we want you to itemize your resources and funding. You want to know that you have the funds available if you receive the award. Please include detailed

nonfederal funding secure or not anticipated. If you are in the middle of fundraising, or third-party funding is contingent upon award, please provide a letter of support from the entity that says if, you know, this institution gets the award, I am willing to put up X number of dollars include all of the stock you mentation documentation and letters of support in your application you need to provide evidence of access to nonfederal funding, that at least equals the direct cost of the year one award, in your application.

Technology solicitation and selection, you need to show how you're putting together the infrastructure to find and select the most promising technologies that address the burden of that have commercialized and commercial potential, or you can develop disease without a market that have compelling reasons

for further development and this might be a rare disease or pediatric indication. In your application, describe the processes of how you're going to solicit technologies you have scouts that are walking down the hallways, going to hold webinars, seminars to market the program and find your innovators and find those, sing technologies describe all of this in your application. You will have an external review board that is going to review your application and this board needs to have certain amount of expertise on it. Including industry startup, BC, technical financial and business experts. Tech transfer, officials. Describe how you are going to find the expertise and describe the process for how you are going to get applications in and review the applications and then, put them forward you know, to NIH for secondary review. There is a table requirement we are asking you to submit a table that shows you have access to a pipeline of appropriate technologies that are at the right stage to enter the site. We want you to describe existing activities and what you plan for that technology, if it is success it into the hub, we will know if you can afford 3 to 6 technologies per year so you will want to evaluate double this amount, 8-12 and select a subset of those based on the review, the purpose of this table is to show us that you have access to those technologies it is not a commitment that you're going to select and fund that particular technology but is just showing us that you have access to these technologies. And there is a sample table on this slide, the name of the technology, what's the technology type, description of the study, is it from a partner institution or a lead institution, who is a signing official, that is going to make sure it is okay to develop the technology and is there an agreement, so that you can develop it, that technology in the context of sites. Funding resources expertise for technology development, you need to explain how you're going to support your innovators. Through individual grants.

We envision that different applications are going to have multiple award strategies, you might be planning one site might be planning one award that has funding and other site might have a tiered funding model with different levels of support. However you're going to do it, you know, described as clearly, in this section in your application. The funding amount for individual technologies, maybe up to \$100,000 from this award, federal funds, this requires whatever, you're going to put 50 K in 100 K in. Of federal funds, you need to match, with nonfederal funds. The matching fund we talked about a little bit, but this should not be the responsibility of the individual innovator. You should be figuring out how to get matching funds in there as a program as an

institution, and not sending an innovator out to secure those funds because that is very difficult. We want you to describe resources and expertise available, to facilitate early-stage technology development. This is going to include scientific business plan development, market research, IP protection, regulatory submissions, reimbursement, legal project management, all that needs to be described in your application. One of the strongest attributes of our current program is the project management piece. And we need you to build this into your application.

We want to see proof of institutional commitment and as a technology transfer commercialization office is on board and partnership with the program, to decrease the burden on licensing and enable the best path forward for that technology. Any agreement, designed to reduce the burden of licensing and hurdles to stay commercialization should be deprived. We want you to describe plans to put together your project management team. Both academic innovators are used to this oversight and budgeting for PMs should be considered and included. The team will participate in setting milestones and making go, no go decisions including you know, ending products and maybe reallocating resources to another product. Please describe in detail, all of this and how you're going to do it in your application here. NIH needs to make that there is transparency and there are progress reports, when writing your technology development plans, include how your innovators are going to be expected to address rigor and reproducibility requirements, there is a link on this slide that provides guidance on how to address rigor and reproducibility in your grant application. You can take a look at that. Skill development education and mentoring, I mentioned the importance of this component a couple of times, and educating innovators on how to bring the technologies out of the lab towards treatment and care. We want to understand, how you will do this to target a diverse audience for education. This is a learn by doing program, and we want to see how you're going to accomplish innovator education you may have education through mentorship, you might be setting up seminars, webinars, putting on workshops, having guest speakers come in, if you plan on leveraging the programs, describe how you are going to do that and how it is going to support the goals of this.

Self-sustaining infrastructure, the intent of the program is to kickstart your technology development program with the hope that you're going to develop into an independent in transitioning technologies and keeping this work going, we want to understand how your thinking about becoming self-sustaining. By the sunset of the grant, explain how your habits and hubs are going to support future studies and related activities in the absence of federal funds. In your application you can include support from partnering institutions or other financial arrangements, descriptions of all institutional support, agreements for equity positions or royalty payments that the hub will receive from successful projects. In the application and the appropriate documentation, letters of support, from institutional leaders, agreements, MOU's that you might have in place, talk about the review for a minute. The review criteria, the scored review criteria for this has been modified to include specific, review criteria for the reach program. And you will see that listed in the section under a title of specific for this and it has more of the partnership and commercialization language in there so you really want to take a look

at how the reviewers are going to be instructed to review your grant applications and make sure that all of these points are addressed in your application.

The additional review criteria, that are not individually scored, will contribute to the overall priority score. And all of this is in section 5 of the application application review information. So you want to review this section carefully before submission. So I have walked through this, the seven main component and talked about the review criteria in the background, again the due date for this application is March 19, 2019. Much more, many more details can be found in here. All slides recording and transcript are going to be available in a couple of weeks, on the website. And hopefully you got a chance to answer some questions in the chat, we will try to address questions, many questions as we can today. Post FAQs on the website, from all of the questions we have received prior to this webinar during the webinar, and after the webinar. You can contact us, if you have additional questions. And, that concludes this webinar portion and we will answer some questions now.

Thank you very much Kathleen. I appreciate your government you going through the parts of the RFA in the program, we've got several questions coming in already and we will go through them one by one. We have another hour and a half so we can answer as many questions as we can. I will start with the most obvious and frequent one, in that yes, this webinar is being recorded. The recording, will be posted along with the slides and a transcript on the website within one week, today though, the slides are posted inside the webinar console in the handouts tab so if you open up the handouts tab you can download the slides that were discussed today, but we will post the slides, recording and transcript within one week. So, what we are going to do now is roll through a series of questions that we got. And, we will, get to as many as we can.