NIH Research Evaluation and Commercialization Hub (REACH) Program Pre-application Webinar – December 2022

Matthew McMahon: My name is Matt McMahon. I'm the director of the SEED Office, and you're here with us at the NIH Research Evaluation and Commercialization Hub, or the REACH program, pre-application webinar. Thank you very much for joining us.

Today we're going to give you an overview of this new funding opportunity announcement. And then we're also going to leave plenty of time to answer questions. So, I'll start out and give a brief overview of the REACH program, and then Eddie Billingslea will take over and walk through the FOA. Brett Hodgkins is with us to talk a little bit about some of the grants management aspects of the FOA. We also have Mark Caprara with us, from the Center for Scientific Review. And we also have some other members of the SEED Team here with us, who can also help answer questions. So, I would say if you have questions while we're in the webinar, please submit them using the Q and A function, and there's a pretty good chance that somebody can chime right in and type answers to your questions while we're going. If not, we'll try and answer them on the fly, or get to them in the Q and A session.

So, thank you very much. So, let's get started. What I wanted to do to start is, I wanted to just kind of take you through a high-level overview of the REACH program, and what the REACH program is trying to accomplish. So if you go to the next slide, the next slide, you can see basically what this program is designed to do is, connect the left hand side of this slide, scientific discoveries, to really enable investigators who are working in the academic environment to understand and provide them with the resources necessary to turn those scientific discoveries and science projects into a product development product, and move them towards a promising healthcare solution. So many folks who are on this webinar, especially investigators who work in scientific research, are very used to doing basic science research, or even applied research within the university environment, but once you start trying to validate a discovery as a potential product and move into product development, there's a whole host of other considerations that are relatively foreign to most academic investigators. And what the

hubs are designed to do is to really facilitate an investigator's ability to go down that pathway. So, this box in the middle is really the core of what REACH hubs are all about.

So, the first thing is, these hubs are designed to combine the resources of a local renovation ecosystem to bring in product development and business experts from the local ecosystem, who can give expert feedback on product development aspects of these projects. And they can also provide education and training to help investigators understand all the things they're going to need to do to be successful.

So investigators can come in with these product validation projects, or proof of concept projects, and they can get feedback and advice from their internal hub, and also through a process called the Technology Guidance Committee, where we provide -- NIH provides access to feedback on every single submitted R and D project from experts across the federal government; from the FDA, insurance feedback from the Center for Medicare and Medicaid Services, U.S. Patent and Trademark Office -- so all of this advice is providing investigators with training and advice on how to do product development projects. But really, once a project is accepted into the hub for support, those projects can receive funding to actually do proof of concept work, and that's really important because most of these types of product validation, or proof of concept studies, are really difficult to fund any other way. They're the types of projects that are not really fundable as R01 is basic sciences, discovery science projects -- these are product validation studies; you know, they're testing the concept of that idea. Does it have potential to be a biomedical product?

So, the funding is one part, but another component is kind of a different way of doing R and D, that's really a way of managing projects to milestones, project-based milestones. So that's a real kind of industry-style way of managing projects, like, what is your project development pathway, and what are those milestones along the way? It's a little bit different than the traditional academic investigator, who's using the outcomes of their studies and their scientific curiosity to drive the pathway of their research. This is very much about using milestones to help investigators march through the steps that are going to be necessary to be successful on a product development project. And not every project is accepted for funding, but you can see this little feedback loop down at the bottom of the slide. And this is really critical, because

many investigators within a hub, even if they're not funded on the first go-around, they're able to use that feedback to strengthen their proposals and come back in and try again. So, each individual hub is managed this way. It also includes funding that's contributed by the local hub, and that serves a few purposes. It really leverages the NIH investment, to bring more resources to bear on these projects, and on the operation of the hub, but it also is a way to kind of bake in support from the partners that we're hoping will really participate in these hubs. So, this is kind of the overall structure that we're hoping to build. This is what the REACH program is designed to do.

And if you go to the next slide, you can ask a question like, does this approach work? Well, we know this this approach works. You can find on our website some links, and we can put some links in the Chat here, to some publications that talk about the outcomes in the network so far. But as of now, through the NIH Centers for Accelerated Innovation, which is kind of the precursor program for the REACH hubs, and the two rounds of REACH hubs that we've had so far, we now have 11 of these proof-of-concept centers located across the country. They supported 417 projects, but they trained over three thousand innovators with different types of product development, training, and support that they provided.

Now, one of the goals of this program was really to strengthen the ecosystem that feeds into the small business program. And of those 417 projects, they resulted in 121 startups. So that should be of great interest to the universities, to the transfer community, but also to those investigators that are really hoping to jump across that valley of death and be successful in product development. So, of those companies, 63 of them have already achieved funding from the small business program, from the SBIR and STTR program. But in addition to that funding, these projects have gone on to garner over $2 billion of follow-on funding from other sources. Some of that's from venture capital, some of it's from strategic partners, but much of it is from private sector sources that have enough confidence in these projects based on the system we've designed to de-risk these projects, that they're willing to support future development. And it's a testament to this program that if you look at the private sector funding that's been generated to support these projects, it's 24 times the amount of money that NIH has invested in this program altogether. So, it's a tremendous way to think about the power of this program

to take these innovations and push them forward and push them successfully into further development. Not only that, we've had a number of projects that are resulted in products that are actually available for people to use. And at the bottom of this slide, you can see eight examples of products that are available for people to use. And in the top line, these are projects that actually require FDA clearance to be marketed. So, it's really amazing, in the small number of years that this program has been around, we've got four regulated products, when many of you will know that getting a drug or a medical device approved for use many times can take a decade or two decades to happen. So, at the bottom of the slide, there are four other projects that have resulted in products that are already on the healthcare marketplace, and area available for patients.

So, with that, I hope that I've given kind of a flavor of what we're trying to do, what we're trying to accomplish with these hubs. We want to expand this network. Right now, we've funded eight REACH hubs across the country, but we want to bring this approach, this successful incubation approach, to parts of the country that aren't covered by these hubs currently. And we want to make sure that investigators have access to these resources, who live at institutions beyond the confines of the partner institutions.

So, this is just kind of a brief overview of what we're trying to achieve. And now I want to turn it over to Eddie Billingslea, who's going to walk, in a little more detail, through the funding opportunity and talk to you about the aspects of the application that are going to really be critical for your success. So, thank you for your attention, and I'll turn it over to Eddie.

Eddie Billingslea: Thank you, Matt. And welcome, everyone. My name is Eddie Billingslea, and I will be speaking more about the funding opportunity itself. I am the Small Business Strategic Coordinator at the National Institute for General Medical Sciences. All right, next slide, please.

So just briefly wanted to touch on the requirements for this funding opportunity. There are seven main topics, seven main requirements that each application should have. One is the hub leadership, so the leadership of the hub should have a documented track record of success in product development in the biomedical research space. Collaborations and partnerships -- the application should outline how one plant can develop necessary collaborations and

partnerships with stakeholders, and also certainly make use of existing programs. For example, NIBIB's concept to clinical commercialization, innovation program, their Point of Care Technology's Research Network, for example, NIGMS' Regional Tech Transfer XLerator Hubs for IDeA states. And in addition to those, applicants should strongly consider partnering with other education institutions, particularly those that are minority serving, which includes, historically, black colleges, universities, Hispanic serving institutions, and others. And also, institutions that may be located within IDeA states.

Regional and local impact -- applicants should indicate the impact that small business development will have on entrepreneur climate, workforce diversity and addressing health disparities in their local areas, as well as meeting any pressing local regional demands within that area. Technology development is the fourth. The application should demonstrate the ability to support technology development from early-stage feasibility through pre-clinical technologies. This also includes across the mission of NIH, among its participating institutes and centers. Additionally, budget for any technology development project can utilize a maximum of $100,000 from the REACH award, with any remaining contributions coming from matching funds. And the expectation is that hubs will continuously develop at least four technologies each year.

Project management -- the expectation is that the applicant will develop and implement milestones, market focused project management oversight and decision-making processes. This is to ensure that the hubs are doing what they indicated in the applications, and of course the hubs should also leverage best practices from current pilot programs, including some that Matt had mentioned previously from the NCAI and the other two iterations of the REACH program. Educational activities -- the applications should provide innovators from diverse backgrounds, including innovators from underrepresented groups, access to development, hands-on experience and educational network and opportunities. Such professional development can also include training innovators to assess the commercial potential of their research discoveries, bringing together experienced entrepreneurs for scientists, for guidance and mentoring, providing broader investigator community with access to forms, seminars, workshops, and other related activities. And lastly, the sustainability plan, which should

articulate the plan for ensuring that capacity developed under the REACH award will be sustained at their institution. Next slide, please.

So, this slide really focuses on the types of projects that can be on the taking in each of the hubs, so development of small module therapeutics, biologics and cell-based therapies, interventional medical devices, any other diagnostic medical devices and any health IT, software or apps or algorithms. Next slide, please.

So, this is a key component here, and I want to make sure I spend some time here. So, all applications must include a plan for enhancing diverse perspectives, or a PEDP. This plan will describe the strategies that each hub will undertake to advance the scientific and technical merit of the project, that will help them increase inclusivity. An example should be provided throughout the application. The plan itself should be no more than one page, and promoting diverse perspectives could include things such as transdisciplinary research projects, engagements from different types of institutions; as I mentioned before, institutions, for example, in IDeA states, individual applications and partnerships from an array of geographical locations, as well as teams comprised of folks from different career stages, and certainly participation from individuals from diverse backgrounds, including racial and ethical groups, those with disabilities and other disadvantaged backgrounds. And if you want more information on the PEDP, we provided a link here in the slides to get more information. Next slide, please.

So now, focusing a bit more on award information. Next slide, please. So, this mechanism is a cooperative agreement, which means that NIH will have substantial input into the awards that are made. It's anticipated that five awards will be made, with a maximum budget of $1 million in total costs per year. They anticipate an award project period is for four years, and applicants are encouraged to obtain a minimum of $250,000 in non-federal funding per year. Next slide, please.

So, a little bit more about eligibility -- next slide. So eligible institutions consist of any private or public institutions of higher learning, including minority service institutions, nonprofits with or without 501(c)(3) status, and applicants must -- I want to emphasize that -- be at a university or research organization that currently participates, or has a history of participating, in the NIH

STTR program. Non-eligible institutions include non-US entities, non-US components of US organizations, and businesses are not eligible to serve as the primary applicant organization. Additionally, previous recipients of the NCAI or REACH awards are not eligible to serve as primary applicants. Next slide, please.

So lastly, I'll talk about the application submission process. So, the application due date is February 9th. I would certainly please, please, please read the FOA carefully, because there are additional instructions in the FOA for the application process through the SF 424 guide. Next slide, please.

So, within the research strategy, applicants should provide an overall objective for the hub, including short and long-term goals. Identify challenges that may face the hub's entrepreneurial ecosystem and how those challenges would be mitigated. Also, describe how the hub's expertise, capabilities and partnership and resources will have an influence on discoveries, innovations being developed that will have significant health, economic and societal impacts. As I mentioned before, the main points of research strategy should cover those seven major headings that I discussed previously, in addition to other documents, which I will discuss briefly now. Next slide, please.

So, the other documentation that should be contained in the application should be letters of support, support from non-federal resources, institutional commitment to the program, as well as participation of any tech transfer or commercialization offices at the lead institution. Applicants are also encouraged to include letters of support for the sustainability plan. The resource sharing plan -- applicants, regardless of direct cost requests should address how these resources, whether they're training presentation, slides, videos, best practice handouts and other such documentation, resulting from the award will be shared with the public. And as I mentioned before, their plan for enhancing diverse perspectives should also be included. Next slide, please.

So, the appendix can include additional materials, including template or sample agreements that will decrease barriers from technology transfer and other commercialization, and also the non-matching funds that applicants may obtain. So, this includes the source of those non-

federal funds, and those funds can come from a number of sources, including foundations, participating institutions, any state or governmental bodies within the catchment area, angel investors and individual benefactors, as well as others. And as I mentioned, applicants should include details on these sources that either have been secured or anticipated, and documentation can certainly include a term sheet and-or a letter of commitment from that particular funding source. And I believe now I will turn it over to my colleague, Brett Hodgkins, who will talk through grants management. Thank you.

Brett Hodgkins: Thank you, Eddie. My name is Brett Hodgkins, and as Eddie said, I'm one of the grants management team leaders at NIGMS, and I'm specifically the grants management FOA point of contact for this. So, I was going to, in the time that I have allotted today, talk about a few grants management highlights and things to be aware of, as you're preparing applications, getting ready for this FOA. So, if you could please turn to the next slide.

So firstly, as Eddie alluded to in his presentation, it's worth noting that this FOA is supporting the cooperative agreement. So, the reason why I bring this up is, cooperative agreements, while a bit atypical, at NIH they do certainly exist, and they are different from a basic research grant. So, I thought it would be worthwhile to at least bring that up for highlight, so that you're fully aware of what you'd be potentially getting into, should you apply for funding through this other way, and successfully receive funding. So, a cooperative agreement, while common at NIH, but not as prevalent as a basic research grant, in its simplest form is to provide substantial federal or scientific involvement in the form of a cooperative agreement. What's unique about a cooperative agreement is that NIH staff, specifically the program staff, will actually be very much involved in the project to assist, guide, coordinate and participate in various project activities. Again, the basic research grant, you don't see this. But a cooperative agreement has NIH staff substantially involved in the project itself.

As the third bullet shows, that a cooperative agreement's purpose is to support and stimulate the recipient's activities by involvement in and otherwise working jointly with the award recipients in a partnership role. What's very important to note here is that it is a partnership role; the NIH staff that are substantially involved are not directing the project, nor are they holding prime responsibility or a dominant role in the activities. It's a true partnership of

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responsibilities. As the fourth bullet shows, the dominant role and the prime responsibility truly resides with the awardees for the project. So, in other words, if you successfully apply for and receive funding through this FOA, you will be the driving force, the applicant institution, that is,. And the NIH staff that are substantially involved will be here to share some tasks and responsibilities there within. So, it's important to note here, too, that because this would be a cooperative agreement and not a basic research grant, there are two specific NIH roles that are served programmatically, one of which is the Project Coordinator, and one of which is the Program Officer. What I was going to do here is just briefly define those roles, so again, if you are interested in applying for this FOA, you would know what you would be getting into.

So, a Project Coordinator, in its simplest forms, is somebody who's reviewing and commenting in the critical stages in the research program and all the individual technologies in consultation with NIH staff, other federal agents, C staff, and non-NIH experts in the field. So, the Project Coordinator is providing feedback and guidance from product development and project applications prior to their initiation, and also assisting mission fit, program balance, and other areas of priority. The Project Coordinator would be the individual who would advise the hub on a go, non-go decision making during the actual technology development.

So, this contrasts significantly with the NIH Program Officer, which again is something that [INAUDIBLE] research grant. The NIH Program Officer, more simply put, is responsible for the normal scientific and programmatic stewardship of the award. So, this individual is one that carries out the continuous review of all activities to ensure that the objectives within the research are truly being met. So again, it's worth noting that there are two different, distinct responsibilities for the Project Coordinator versus the NIH Program Officer. And because of this, it's not one individual who fills both roles, they're two separate, distinct individuals.

So, because of this, if you do receive funding through this hub FOA, there would be specific cooperative agreements, terms, and conditions on the Notice of Award. No need to worry about that right now, but it's important to note that when the Notice of Award is issued, there would be direct cooperatives agreements terms and conditions outlined, the individuals' roles and responsibilities within the project. Next slide, please.

So again, as Eddie said, the maximum budget for each hub is $1 million direct cost per year, including applicable F and A. So, what's important to note here is that it includes applicable F and A, it's not in addition to. So, what this means is that the total cost would have to be $1 million, and applicants would have to, in essence, back into that $1 million cost, utilizing their, let's say, 55 percent [INAUDIBLE] at the time. So again, that's $1 million total cost, including F and A, not in addition to.

The second bullet shows something that's very important to know, too, that all forms of foreign components are not allowed via this FOA. This means foreign institutions, foreign applicants cannot apply, and domestic grantees with foreign components as defined by the NIH policy are also not allowed. So, it's truly a domestic-based funding opportunity announcement. Because this is a large award of support, like we said, a million dollars total cost, this requires a non-modular, i.e., a categorical detailed budget, so please follow all FOA instructions for what needs to be included there, in terms of the budgets, the budget pages, the budget justifications and things like that. So, what that means is the actual budget application itself will include details on everything, so consultant costs, travel costs, the supplies, to personnel, to level of effort of those personnel, and things of that nature, so it truly is a detailed budget with corresponding detailed budget justifications.

And the fourth bullet that I think is very important to note too, is that all applicants have to make sure that all required registrations are completed prior to applying for the actual FOA. And this includes SAM, eRA Commons, UEI registrations and grants.gov registrations. So, what's important here to be aware of is that the registration for many of these entities can take six weeks or more, so applicants should begin that actual registration process as soon as possible. Unfortunately, the NIH policy and late submission of grant application states that failure to comply, or incomplete registrations in advance of an application due date is, unfortunately, not a valid reason for late submission. So please, please, please make sure that you have all of those registrations that are outlined in the FOA completed ahead of time. Some of them can be relatively quick, some can take, like we said, up to six weeks, so that's something certainly to be aware of. Next slide, please.

So additional requirements that I think are worth being aware of from a grants management perspective, that all applicants who are presenting, who are proposing human and animal subjects research in their application, which is obviously not required but something that could be proposed, all applicants need to be aware that all requirements, policies and procedures governing human-animal subjects research and compliance are, in fact, in place at the time of the application. The same with clinical trials -- if there is a clinical trial or trials being supported that were proposed in the application. And at the same time, all other support requirements are, in fact, satisfied and in place. So, what this means is, the second bullet mentions at the time of award, NIH needs to make sure that if human and animal studies are being proposed, that IACUC and IRB approval dates are in place, and institutional assurances of compliance are in place, and that all investigators who are conducting research on the grant were contributing effort and-or drawing salary has complied with NIH and detailed policies on other support. And again, these are things that we would be reviewing as grants management and program staff at NIGMS prior to potential award issuance.

So last two bullets are things that obviously we would deal with after an award is being made, but it's still something to be aware of, and that's the submission of the annual progress report, it's called the RPPR, and obviously the closeout documents after the cooperative agreement has concluded. As I said, these aren't thing to worry about just now, but just to kind of be aware of, after the initial award is made, that doesn't mean that you as a recipient are done with all forms of reporting requirements. There's still an annual progress report that needs to be submitted and reviewed by NIH grants management program staff. And assuming that that is all complete and accurate and progress is significant, then year two, three and four. Notice of Award will be issued with the appropriate supportive funding therewithin. Now obviously, after the project is completed, we would be requiring closeout documents, a final invention statement, final progress report and final federal financial report. Those are all due at the end of the project, so several years down the road, but still something to be thinking about, because, like we said, it not that you'd necessarily issue a Notice of Award, and then we're done and separated. That's, in fact, actually not the case. There are still annual documents and then final closeout documents that are, in fact, due. Next slide, please.

So lastly, what I wanted to touch on was just kind of a brief overview of the awards process, so that individual applicants who are interested in applying are aware of what, exactly takes place. This is just a very kind of brief overview of what to expect in the process. Firstly, after an application is submitted, the grant undergoes what's called the "peer review process," where the application is reviewed and is, in fact, scored. Shortly after that time, what's called a summary statement is generated where an investigator and applicant institution can see how the application, in fact, [INAUDIBLE] we know what strengths and weaknesses were identified, areas that could be improved upon, things of that nature. For applications that are significantly scored, demonstrating interest within NIGMS's scientific portfolio -- those would be the ones that would be potentially selected for funding. At that time, obviously, NIH staff, specifically NIGMS staff would be getting in touch with the applicants to let them know that they have been selected for potential funding, and what that means is that NIGMS grants management and program staff would then be reviewing the application in more detail, requesting clarification information that may need additional details, in hopes of potentially issuing that Notice of Award. Upon receipt of the Notice of Award, the applicant institution can then obviously begin spending the research proposal within the application. And the last bullet that's important to be aware of is, obviously, the compliance of the terms and conditions of the Notice of Award.

So, what that is referring to is, assuming that an applicant's successful at compete score and receives NIH funding to this FOA, please, if there's one thing I can certainly advise, it's read over that Notice of Award several times and make sure that you're well aware of everything contained therewithin. The second an NoA recipient starts drawing down funds from that Notice of Award, in essence, spending money on that project, that assumes and constitutes the fact that that applicant and that recipient is understanding the agreement with all of those terms and conditions on that Notice of Award. Obviously after the Notice of Award is generated, NIGMS grants management program staff are available to answer questions about what the specific terms and conditions say, and how to best comply with them, but it's still something to be very well aware of in that awards process.

I believe that's my last slide. Okay, that is all I have. Thank you.

Question and Answer Session

Stephanie Fertig: Thank you. For those who don't know me, my name is Stephanie Fertig, and I manage the Small Business programs within not just NIH, but also HHS. So, we're going to take this time now to get all the panelists back on, and hopefully address some of the great questions that have been coming in, I can see in the Chat here.

So, one of the big questions that has come up several times is around eligibility. And I know I addressed a couple of those as well. So, Matt or Eddie, do you want to discuss, because one of the questions was, well, wait a minute, it says in the eligibility that the participating institution needs to have participate-- the primary institution needs to have participated in the NIH STTR program. Why is that? Is it okay that an institution may have participated in the SBIR, but not the STTR? So Matt, I see you're coming on, so why don't you address that question?

Matthew McMahon: Yeah, I'm happy to address question. Yeah, so I think Stephanie has probably typed at least one answer into the Chat about this, but it is true that to be eligible, an institution must have been a part of an STTR application, in other words, partnered with a small business on an STTR project. And the reason for that is because the authority to conduct this program and the funding through this program is actually taken from the STTR program set-aside. This is a pilot program that's testing out the ability of this approach to stimulate collaboration between academic institutions and to develop projects that will go on to seed the small business program, SBIR and STTR. So that's the reason for that restriction; it's part of the legislation that enables us to do this program to begin with.

Stephanie Fertig: And I would encourage, and I just want to second something that Eddie said during his part of the presentation -- please read the program announcement very carefully. There's actually a very specific section about eligibility, and I do encourage you to make sure that you read that carefully, and make sure that the primary -- if you're coming in as a primary institution, you meet that criteria. But it's important to know that only the primary institution has to meet that criteria. Partnering institutions do not. So, you can certainly have any number of partnering institutions who may not meet that criteria, and that's perfectly acceptable, and

in fact, we really do encourage, as we noted on the diverse partnerships and partnerships from all kinds of entities within our really very general area.

Matthew McMahon: Yeah, I'm glad Stephanie mentioned that super-important point. We're really trying to develop strong hubs that have partnerships that encourage diverse participation, we want to have greater participation from HBCUs, from MSIs. And it may be frustrating for institutions who want to participate when they realize that they're not eligible to be the primary institution, but if you take a look at these other hubs that we've supported, and the strength that they have -- the strong programs that they've developed by bringing together partner institutions, I think that you can see that there's a way forward here for institutions that don't meet the eligibility requirement to be the primary institution to develop super-strong applications together with partners.

Stephanie Fertig: I would also add, because I do see a question here about smaller colleges partnering with major universities -- absolutely. We really, again, we want to see all kinds of organizations can be partnering with the primary institution. So that could include smaller colleges, that could include different colleges that are serving different kinds of students and individuals. And you can look at some of our hubs currently do work with a wide variety of different universities and colleges, again, within the hub. So, I really do encourage you to work with other universities, and other -- we really encourage the hubs to be more broadly connected.

Okay, we had another question here, and I think I really like this question. How can startups and entrepreneurs best work on establishing work on establishing that hub in their state or area of research? And I'm even going to broaden that a little bit to say, how can small businesses and entrepreneurs be involved? Is there a place in this? Or is this really about academic research? So Matt, I don't know -- or Eddie or Matt, do either of you want to jump in?

Eddie Billingslea: Well, certainly there's a place for small businesses and other entrepreneurs to work within the framework of the hubs, is the hope, and certainly others can chime in if I misspeak with anything, but it is the hope that these hubs will certainly, as indicated in the language, will serve as kind of that catalyst for entrepreneurial development, as well as regional

economical and silo benefit. So, the hope is that as these hubs develop and come all on and are funded, that they will begin to reach out beyond the walls of their institution, or the partnering institutions to promote their activities, and certainly the benefits that they can offer to local entrepreneurs.

Stephanie Fertig: So, another question that we've received, and I think we've gotten -- there's been a couple of different versions, so it would be great to discuss this here -- is the intent that each hub cover all the different technical areas across NIH? Or should the hub have some sort of specialty, for example, interventional devices, or a specific topic? So scientifically, what should the hubs be expected to cover?

Matthew McMahon: Great question. I'll jump in for that one. So, the REACH program is supporting technology development projects that span the entire NIH mission space. So, in that sense, the hubs in general on our supporting innovators that are generally funded by any of the NIH institutes and sundries. That said, I think that it is possible to develop a strong application that has focus in certain areas. So, in other words, we have found in some of our previous proof of concept centers, or hubs, that they may have been stronger in medical devices, or they may have been stronger in therapeutics. We would be happy to have a center or a hub that is very strong on health disparities, for example, or other focus areas, but I think the intention of these hubs is to support product development, probably across the different areas that are funded by NIH. But I think that we would be -- it would be responsive to this FOA to explain a strength area or a strong focus area for an application.

Stephanie Fertig: So, one question that we received, is the application expected to include specific projects to develop? Or just the measures that the hub will provide to assist projects identified later? So, do individuals need to put those specific projects in their application?

Eddie Billingslea: Yeah, I'll step in for this one. As indicated in the presentation, the expectation is not that specific projects will be identified at the time of application; more likely that the central hub application will identify some of the areas, the scientific areas that they plan to cover within their catchment area, but not necessarily indicate specific projects that they will fund as a function of the hub.

Stephanie Fertig: Great. And I'm seeing a number of those questions coming in, and I'm trying to work on those as quickly as possible.

One question that is coming in is, does the -- when we say "participate," if you look at the eligibility, it says the primary institution needs to have participated in the STTR program, and so there has been a question, what does "participation" mean? And that means receiving the award, so they have to have received the award in order to have been participating in the program. So, they have to have been part of a funded STTR. But again, that's just the primary institution. If you're a partnering institution, you don't need to meet that requirement.

Matthew McMahon: I'll just jump in on a corollary of that. Someone asked a question -- let's see if I can find it here -- is there somewhere online where you can see a list of these STTR institutions? This is a little bit tricky, because many of you know that you can use NIH Reporter to look up all of NIH's awards. You can go into NIH RePORTER, and you can look up all of the STTR awards but remember that the STTR award is going to the small business, not to the academic institution. And it may not be a trivial task to identify the partner institutions and STTR awards. So, my advice to you would be to talk to the administrators at your institution, and ask them that question, because they will be the best source of information for you to be able to answer whether and when they have been a partner in an STTR award.

Stephanie Fertig: Great point. Okay. So, is there a limit on the number of applications that can be submitted per institution? So, either Eddie or Matt, I don't know if you want to jump in, but I do know that the FOA did not specifically limit one application per institution. That said, it's very important to note, as Eddie noted, that you do need the appropriate letters of support, and you do need the appropriate -- that the institution itself needs to indicate that it is supporting the specific application. So, I think while not specifically prohibited, I think it would be extremely difficult for there to be multiple applications from the same [INAUDIBLE] institution. Matt or Eddie, do you want to jump in and say anything else?

Eddie Billingslea: Thanks, Stephanie.

Matthew McMahon: I don't.

Eddie Billingslea: No. I mean, you summed it up beautifully. Thank you.

Stephanie Fertig: Great. So, another question, how can we initiate a hub in our organization? How should people get started?

Eddie Billingslea: So I would say for that particular question, certainly if you think about kind of -- well, first, if you participated in the STTR program at your institution, and certainly if you have tech transfer commercialization offices at your institution, and then if you've checked those and have been an existing REACH award recipient, or NCAI recipient previously, then certainly you may want to think about what you would like this hub to offer in terms of some of those activities that I described before. And then certainly, review the FOA and review the guidance on the SF 424 form to figure out how to submit your application. I don't know if --

Stephanie Fertig: Great. So, there was another question about this requirement, and it's, can you expand on the STTR requirement? Does it mean that the PI has to be an STTR grantee, or just the institution? And this is a really important thing to remember with all NIH grant applications, is that the -- and grants themselves -- is that the grant goes to the institution, not the principal investigator. So, when we're talking about eligibility here, we're talking about the eligibility of the institution. So that means that the institution needs to have been the primary partnering institution on an awarded STTR. And so it isn't about the PI, it's specifically the institution itself.

Okay. Are there any specific guidance regarding the allocation of PI time for a project? And I know Matt, you jumped off, so maybe you want to answer another question as well.

Matthew McMahon: Yeah, go ahead, I'll let you handle that one, and then I'll come back on for another one here.

Stephanie Fertig: So, I was actually going to say either Eddie or you could answer that. I could jump in and answer that one, too, but I certainly don't need to be answering all the questions. There isn't -- and I'd have to actually go back, I'm trying to pull that specific section. I think the key, like all components around the principal investigator, is, again, it's really important for the principal investigator to make sure that they got enough time to commit to the project, to be able to run it appropriately. So, while you look at the eligible and the specifics around the eligible individuals with regards to the Program Director/Principal Investigator, and that's part

of funding opportunity, there isn't a specific percentage requirement, but there is an expectation that that PI will be spending an appropriate amount of time for what's proposed in the project, just like any other allocation.

So Matt, I know you want to answer maybe another question that you're seeing scroll by here?

Matthew McMahon: Actually, I'm scrolling -- yes. I'm furiously trying to answer questions and address questions at the same time. I see that -- but I do want to -- I see that there's a question here that's related to the challenges of HBCUs and MSIs, of meeting this encouragement for a match, and how that's a major hurdle at the beginning. And there's a few other questions about the matching funds-- it is a true statement that it is harder for MSIs, HBCUs, smaller institutions, institutions in different parts of the country that are maybe not as well resourced, institutions in parts of the country that do not have a strong history of product development. However, we do believe that the matching funding is a critical part of this program because it does really require that institutions work together with partners to develop the kinds of relationships that will be important for success. So, what we're hoping is -- like, I'll just give you an example. One of the previous hubs, it was a center that was based on Cleveland, the State of Ohio provided the matching funding for the NIH center for accelerated innovation that was in Ohio. And in Kentucky, there's been a large interest from the State of Kentucky in the program, to enable the kind of economic and health care benefit that's coming out of their institution. So, my recommendation, I understand it's very hard to get a hold of matching funds. But I would say be creative on where you search for those matching funds and look in places where you might not traditionally be looking for matching funds, because there's a great interest in local economic development and regional economic development. And I think that places that come to the table with those relationships built-in that allow them to achieve both of those goals, the matching funds and the partnerships are going to be the ones that have very strong applications.

Stephanie Fertig: We have another question around eligibility that I think is really important, which is about -- and as noted in the FOA, previous recipients of the NCAI and REACH awards are not eligible. But what about individuals who were partners, or who had worked with those

primary applicant organizations? What about the other partners within the hub? Can they apply, can they be the primary institution?

Eddie Billingslea: So yes, those member institutions of previous hubs can certainly apply to be prime, or lead institutions for a new hub under this FOA, as long as they meet those eligibility criteria that I have mentioned previously.

Stephanie Fertig: Great.

Eddie Billingslea: I did want to mention something to follow up on Matt's point earlier; I believe there is language in the FOA that indicates that there can also be in-kind contributions as well. So, I would say, as Matt mentioned, to be creative in what that could potentially help a lesser resource institution to fulfill the requirements of suggestions listed in the FOA.

Stephanie Fertig: I have been seeing a number of questions around information about the prior hubs, and where can information be found? Vicki VanArsdale did put in the Chat about information on the current hubs and location, and you can find that on our website, SEED.nih.gov. And if you go to SEED.nih.gov, which is a fantastic resource and always a great place to look for information, not just about the small business program specifically, but about the Programs for Academics -- so if you go to the middle of the page, you'll see Programs for Academics, you can click on that and get information about the REACH hubs, the NCAIs and other NIH group or concept programs. So, strongly recommend it. And an actual little plug for our website.

Okay. Do the participating institutions need to be in the same region as the primary institution? So, can you have a hub that may be reaches broader, or may even reach across the country?

Matthew McMahon: Sorry Stephanie, can you say that question again?

Stephanie Fertig: Sure. Do the partnering -- so say you have a primary institution, and they want to partner with somebody outside their region, can they do that? Is that allowed? And the answer is, we don't put restrictions, but I'm going to pass it to you all.

Eddie Billingslea: I would say that certainly, you know, if your hub that you're thinking about composing is inclusive of institutions or organizations outside of your normal state, that's

certainly allowed. There's no restriction on where the hub participants have to be, if they have to be geographically linked. In fact, we encourage to be more inclusive of areas that may not -- in geographical areas that may not have a lot of entrepreneurial activity.

Stephanie Fertig: I do see a number of questions in here, and I'm just going to remind everyone, since there may have been some individuals who have joined a little late -- small businesses are not eligible to be the primary institutions for this funding opportunity. Obviously, if an academic organization would like to work with different small businesses, there's been a variety of different capacities to build the resources within their hub - that's a separate -- that's a separate thing. But with regards to the primary applicant, it must -- small businesses are not eligible.

Okay. I have another one, and I seem to have lost it --

Matthew McMahon: Here, Stephanie, while you're looking for that one --

Stephanie Fertig: Yes, thank you.

Matthew McMahon: -- I just want to say, one of the differences -- in the evolution of this program, you'll notice that there's some language in this funding opportunity that encourages the hubs -- this is related to this last question -- encourages the hubs to figure out how to support technology development projects outside of the confines of their partner institutions. And this is really important, because in COVID times, we realized that a lot of our life had become kind of virtualized, and we were successfully able to support projects in that environment. So, what we're trying to do is, encourage hub applications that figure out creative ways to support technology development projects at institutions that are not their partner institutions, which may or may not be in different physical proximity to those partner institutions. So that's kind of a challenge to all of you out there, because there's a lot of aspects to that. There's the transfer of money, there's the effective management, there's the effective training. So, I think that's an area where we're hoping to see some innovation in these applications.

Stephanie Fertig: Now there was a question -- and I think this is an important one -- are states with existing hubs unlikely to receive a new award?

Eddie Billingslea: So, there's no indication that states that have received an existing award -- an award, rather, would be unlikely to get funding on a new award. So that having a hub already in a state should not discourage anyone from submitting an application to this funding opportunity.

Stephanie Fertig: Now I am seeing a number of questions about, what are the requirements with regards to those partners? Are there specific kinds of partners that are required for that primary partner? Are there specific individuals that you would look on that need to be partners, or their requirements around partners? So Matt, I don't know if you want to talk about the required partners, and the difference be-- you know, which ones we would encourage, and things of that nature? And maybe even what's been done in prior hubs? Around partnerships and the requirements with regards to who they have to partner with. And I'm going to note that if you look in the FOA, there is a specific section focused on collaborations and partnerships, and the importance of developing the necessary collaborations and partnerships with stakeholders. And that includes that you are expected to partner with existing federal government resources, and you're expected to partner with stakeholders to meet the goals of the FOA. And certainly, you are encouraged to partner with several educational institutions, particularly those that are minority serving institutions. And I would encourage you again to read that. But there is no requirement to have a partner with tech companies, but it is important to note that there some -- you know, it is important to develop those necessary collaborations and partnerships. So Matt, I don't know if you want to talk about what prior hubs have done, and the wide varieties of partnerships they've been able to leverage to really be successful.

Matthew McMahon: Yeah, I can give maybe a little bit of a flavor of that. What we're talking about here, overall, with this program is really about effectively incubating technologies and transitioning them into private sector development. So, I would say in general, the categories of partners that I think we're talking about here, in addition to the academic partners that you may have, are mainly industry partners and investment partners, I would say, and technology development partners. So, there's also been collaboration with local economic development partners, as I mentioned before. So, I think that if you think about your local ecosystem and

what types of strengths you can bring to bear on this product development pipeline, that's really what we're looking for. So, we're also looking for partnerships that strengthen your ability to encourage participation by investigators from diverse set of backgrounds. So that's a big focus of this funding opportunity. You may find, for example, in Kentucky, the hub in Kentucky is partnered with all of the technical colleges in Kentucky. I mean, that is an extremely unique structure that they have there. And you can find some information about that on our website, and the answer to some of these questions. Or you can go to their hub directly and see that. But it's those kinds of innovative partnerships that allow the hubs to go after diversity, to go after local and regional strengths in their product development ecosystem, their local industry experts who can help provide advice and guidance. Those are the types of partnerships that we're looking for.

But, you know, the FOA does not lay out specific requirements for exact categories of partnerships. But I think that as you read the FOA, you can understand what the goals are that we expect people to achieve, and then think through how you can develop the partnerships that will help you with those goals.

Stephanie Fertig: And I'm going to jump in and just do a quick correction -- my sincere apologies on that -- it does indicate that there is only one application per institution that is allowed. So again, my apologies on that. And this is -- it is important to very much follow what is in the FOA. The funding opportunity is the final word on any eligibility and issues. So again, I just want to reiterate this -- it does say that only one application per institution is allowed. And was trying to read that, and as I was skimming, I didn't grab it. And so, my apologies on that.

I do want to make sure to hit on a really important component that is part of this FOA, and that is the diverse perspectives. And with regards to this plan for advancing diverse perspectives, and there was a specific question within the plans for enhancing diverse perspectives, and what should really be emphasized in there? And maybe where individuals can find additional information on how best to address that requirement? I don't know, Eddie, if you want to jump in, I know you had mentioned it in your section.

Eddie Billingslea: Right. [INAUDIBLE].

Stephanie Fertig: I understand.

Eddie Billingslea: Certainly, as I mentioned before, there -- well, as I mentioned before, I gave the criteria for coming up with a plan to enhance diverse perspectives. And it is a score criterion. So, it's quite important. And also, there will be some involvement from program staff in reviewing those plans for enhanced and diverse perspectives as well. I wouldn't say that there is a particular section to most closely focus on. It's certainly to -- the whole one-pager should certainly indicate how you plan to integrate those diverse perspectives, so I would say what those diverse perspectives are, how do you plan to advertise or reach out to gain those diverse perspectives? You know, you can indicate the groups that you might want to target -- again, it could be -- want to gain diverse perspectives by having more interdisciplinary researchers involved in the hub, or certainly have early-stage investigators or postdocs. So, we leave it fairly broad in terms of how you want to address enhancing these diverse perspectives, and thereby increasing inclusivity in these hubs. However, what is listed, and the plan will be scrutinized. And also, the Program Officers will hold folks accountable to what was indicated in those plans.

Stephanie Fertig: Great. And I know we are over time, so I just want to thank everyone for asking all of those great questions, sticking with us for a little additional time. And Matt, I'm going to have you say any closing words.

Matthew McMahon: Yeah, well, thank you very much for your interest in this program. We're very happy to see a robust response to this webinar. We hope that we see lots of applications. Yeah, I've been furious typing and listening and multitasking to these questions, and I believe that we will continue to develop answers for these questions. And I also believe that we will, when we post the materials for this webinar, that we will post the answers to these questions. So, I hope that I haven't overstepped my answer there, but we certainly will try to do that. And we hope to see lots of great applications from folks in the near future.

So, thank you very much for attending, and have a great day.