REACH Pre-Submission Webinar - Question & Answer Session

Should the pilot grant programs, already have their companies incorporated?

No. These awards are intended to develop early stage technologies pre-company formation. The program is designed to develop technologies in a manner such that viable small businesses are created as a result of the program.

If you already have a company or university spinout, the small business program is a path to apply for NIH funding. You can contact us about that on the NIH small business website.

Do we have to pick a disease, or can it be broader, such as small molecule drug development? If this is a trans NIH program, how does NIH pick a focus? Is NIH focusing on one disease or something broader?

This program covers the entire NIH mission, so it would be beneficial to develop a holistic approach that focuses on multiple technologies within the entire NIH mission, across multiple technology types. Addressing high burden of disease areas is also important to NIH.

How much of the $1 million total costs per year is expected to be used towards project funding?

NIH wants the awardee to meet the goals of the FOA and it is up to the applicant to describe in the application how this will be accomplished. In a recent administrative review of one of our proof of concepts programs (NIH Centers for Accelerated Innovations), reviewers expressed interest in seeing more streamlined administration, so that more funds could go directly to projects. Too much spending on overhead/staff may result in an inability to fund a sufficient number of projects (4-6 annually).

Should the principal investigator or PI of the overall REACH project be a faculty member, or is it okay to have a tech transfer expert serve as the PI?

It doesn't matter as long as the proposed PI meets the eligibility requirements listed in the FOA. Applicants should provide strong biosketches of the proposed PIs and all key personnel, that include background and qualifications to run a REACH site.

Are there any nonfederal entities that cannot be co-funders?

We do not have any limitations on who can be a non-federal funder. The negotiated agreement is between the applicant and the source of the match. Other federal funding sources are not eligible to be used for the match.

Is this a one-time RFA or does NIH anticipate reissuing this RFA in future years?
This REACH RFA is a one-time award. We do not anticipate reissuing this RFA in future years because the reauthorization language limits NIH to issuing up to five awards at $1 million each annually for four years.

Are any co-funders, or organizations providing matches, allowed to receive equity ownership, or partial equity ownership in the companies that ultimately spin out of this program?

Yes. Ownership positions are between the company and the funder.

If you are interested in having your newly formed company apply for NIH funding through the small business program, you are encouraged to look very carefully at the eligibility criteria on the NIH website regarding ownership, as the company must meet certain requirements (i.e., majority US, etc.)to apply for funding.

Can applicants use resources from industry like labs, education, materials, etc.?

Yes.

On an earlier slide, you talked about the burden of licensing. What does this mean?

Sometimes in academic institutions, the academic innovators do not understand the licensing process and it ends up being overly burdensome. For example, anything that can be done to build partner relationships that reduce obstacles or facilitate licensing process (reduce time, eliminate duplicative efforts, etc.) will be beneficial to this program. The goal is to move technologies forward more rapidly than the current rate.

To reiterate the eligibility of this RFA, small businesses are not eligible to apply. NIH is not soliciting small projects through this FOA. If you have a company or a spin out with a technology currently licensed from the University, you will want to apply through the standard small business route through our small business website.

REACH is a U01 mechanism, or cooperative agreement. How is this different than a standard NIH grant?

The difference between a cooperative agreement and standard grant is that NIH has a significant amount of program oversight for a cooperative agreement. Cooperative agreements tend to be larger programs with multiple moving parts, and NIH plays a role in facilitating activities needed to accomplish the FOA goals.

For example, our current proof of concept center network has 33 institutions. NIH plays a large role in convening committees to discuss program strategy in addition to identifying and developing best practices and lessons learned.

In the FOA, the research plan instructions mention how after technology solicitation and internal review, the technologies will undergo secondary

review by an NIH-convened committee, comprising staff and experts. Can you describe the make-up of the committee and the role of this committee in the decision-making process for funding technologies?

Awardees are expected to set up processes at their local sites to solicit, review and select technologies. The site will then send the most promising technologies to the NIH for secondary review. The secondary review committee will review technologies for mission fit and commercial potential, and comprises NIH staff (including with scientific and commercialization expertise) and program partner representatives (FDA, CMS, USPTO, Kaiser Permanente). The committee will provide guidance and technology development feedback to key site leadership and innovators that will inform funding decision-making processes.

NIH anticipates the TRC will meet quarterly to review technologies that the sites are interested in funding. The sites will be given the date for the NIH secondary review committee meetings in advance, and will be expected develop internal solicitation and review timelines that plug into the quarterly review meetings as appropriate for the awardee's funding processes.

What is the difference between the NIH secondary review committee and the Program Steering Committee (PSC)?

The secondary review committee and PSC are two distinct committees. The role of the TRC, described in the previous question, is to review and provide guidance on technologies that the sites are considering for funding. The PSC is a program wide committee that comprises key leadership from all of the sites, NIH staff and program partners. The PSC will act as the main governing board across the multiple awards and will review the progress of the research activities, develop collaborative protocols, identify technological impediments to the progress, select strategies to surmount them, and identify opportunities for sharing techniques and tools developed within each Hub.

Can you clarify NIH's role in the selection process for members of the External Review Board?

Applicants are expected to describe the process for establishing an ERB comprising diverse experts (including local experts) in translational and proof of concept research, including industry, start-up, venture capital, technical, financial, and business experts and university technology transfer officials. Applicants should not contact potential ERB members or name them in the application. ERB recommendations will undergo secondary review by an NIH committee comprised of NIH staff and experts in all aspects of technology development and commercialization.

Can you define partnering? For the purpose of the application, should the partner(s) be included as subcontractors or is a letter describing the partnership sufficient?

How partnerships are organized is the decision of the applicants. A letter is required in both cases but in the case of a subcontractor, explain in detail what services that partner will provide with the funds you proposed to give them.

Should the format of the application in the research strategy section, (30 pages) follow the seven topics listed, or should it follow impact and approach?

The format should follow the seven topics listed in the research strategy section of the application.

Do you have any suggestions for PI and multiple PI status, with respect to what you're looking for and what will be competitive?

Proposed Leadership proposed in the application needs to show evidence of having the expertise and experience required to complete the goals of the FOA. This expertise may be found in one or multiple individuals and it is up to the applicant to decide.

Is a newly created research institution, that has had former STTR grants transferred over to the new institution, eligible to apply?

Yes.

What qualifies as participation in the NIH STTR program?

Participation in the NIH STTR program means the academic institution, either by application or by award, was the main formal non-profit partner on an application.

Are indirect costs allowed, or expected?

Yes, these are awards to research performing institutions, and the lead institution can request whatever negotiated rate it has. You are entitled to negotiate direct costs so that a sufficient amount of funding goes towards the projects.

How much of the award needs to be matched?

The match is on the total direct cost of the award. For individual technologies, every federal dollar must be matched using non-federal funds equally to or greater than the federal investment.

For instance on a $1 million-dollar award to an institution with a 30% indirect rate ($300,000), you will be expected to bring in a $700,000 match.

How open are you to submission by small non-profit institutions looking at this opportunity?

If you meet the eligibility criteria and can propose meeting the goals of the FOA in your application, you are encouraged to apply. All of these applications will go to a special peer review panel, and will be assessed based on the review criteria in Section V. The review criteria have been modified for this grant, and we encourage you to read the questions carefully and address them in your application.

Can you further discuss what you have in mind when you talk about quote product definitions studies?

This grant supports non-hypothesis driven research, through development of early stage technologies prior to company formation. This includes conducting validation studies leading up to navigating through the FDA or development of a device prototype, for example.

Can a partner, either a subcontractor or source of matching funds, be outside of the United States?

Foreign components are allowed but need to go through an extensive approval process. If you're going to propose a subcontractor that is not within the U.S., you have to do a separate justification and describe how that organization or entity provides a unique capability not available in the United States.

Do subcontracts need to be noted in the grant application, or prior to award?

A letter or MOU that describes the partnership will suffice for the application, but it will be helpful if formal partnerships are established prior to award

Can you clarify what NIH expects for the year one match?

If the partner is an angel, then they require an equity state.

Yes, on the angel, the agreement is between you and your partner. At the time of application, I believe it is

NIH wants to see that applicants have access to matching funds for the first year of the award. At the time of award, NIH expects matching funds to be secured and available. For subsequent years, you will need to provide proof of matching funds prior to the release of federal funds for that year.

Can spending on existing accelerator or incubator programs count as a part of the match?

Yes, that will count as a part of the match, as long as the funds support a REACH technology.

For self-sustaining infrastructure components, do additional small business application submissions as a result of the REACH initiative, count towards being self-sustaining?

No. Spinning out companies and having those companies apply for small business grants is not self-sustaining, because that does not address how activities at the site will be sustained in the absence of federal funding.

Who are the PIs for the REACH 1.0 program (professors, tech transfer people, vice presidents, academic PIs)?

For the NCAI and REACH programs, leadership comprises a mix of expertise.

Do all of the projects developed at the sites need to apply for SBIR or STTR?

Absolutely not, small business grants are just one avenue to secure additional development support. A positive outcome for any project would be its ability to attract and type of independent investment for continued development.

Does the external review board help draft the application for the prospective hub?

No. The role of the ERB is to review individual technology applications. The establishment of the ERB should be described in your application but prospective members should not be named in the application or contacted during the application process.

Is it appropriate for two or more universities to jointly submit a single REACH application or should they submit multiple applications noting and in tensed and intention to collaborate?

An institution may only submit or be a partner on one application.

What restrictions are there for the funding to mature the technologies? Is travel, patent assistance, legal, licensing, allowed?

As long as the activities are within NIH policy, you can spend the funds on different types of research related activities. Activities such as writing a business plans are not allowable using NIH funds. Support of an individual to help you design the product validation studies required to move your technology forward, however, is allowable.

The funds are primarily to support work required for feasibility studies (staff, supplies, equipment), and occasional travel if relevant.
Do contributions with staff time count towards institutional matching?

No, but it definitely would be encouraged to describe how you will provide this type of in-kind support and leveraging existing programs in your application. The reason it doesn't count is because that does not need to be reported to NIH as a cost.

Does this program support only projects that will be exclusively FDA regulated, or will non-FDA technologies be accepted?

NIH will accept anything that is covered in the NIH mission. This is typically biomedical technologies that require regulation, but there are exceptions.

For multi-institutional consortia, should there be a PI or co-PI for each institution, that is to distinguish co-PIs, PIs from other key personnel.

Leadership is the applicant's decision, as long as leadership capabilities are described in the application.

You can submit a multi-PI application. As a reminder, the term coinvestigator is not a meaningful term to NIH, although it is used all the time.

Can the source of matching funding, negotiate a royalty or equity in developed companies?

Yes.

Does the one-to-one match apply to sub award indirect costs which count as the prime applicant's direct costs?

No.

Are there going to be commercialization expertise on the reviewing committee, including but not limited to investors or tech transfer folks?

Yes, the committee will have diverse expertise in multiple areas, including commercialization.

If the funding is provided to individual innovators, is the funding provided directly to the laboratory at the University?

Yes, the funds will be provided to the lab to develop the REACH specific technology, but not for their general lab activities.

Often, the evidence needed to license the technology is early clinical evaluation. Is this allowed through this grant?

For clinical evaluation, yes, but clinical trials are not supported by this grant.

NIH has recently revised the clinical trial definitions and you are encouraged to look up the NIH definition of clinical trial. Funds available through this program aren't typically enough to fund a clinical trial so for that reason they are not allowed. We direct you to talk to your sponsored projects and grants offices for additional information.

Does the match of the award for individual technologies need to occur during the grant period?

Yes.

Can money be budgeted to include salaries for expertise, such as regulatory support as possibilities?

Yes.

Does the STTR participation have to be/been with the NIH?

Yes. The applicant institution must have participated in the NIH STTR program as a formal partner through award or application. NIH has the largest biomedical program in the world and the largest STTR program in life sciences.

Should the application budget include the cost share portion?

No. Just the money you are requesting from the NIH (up to $1M).

Can the budget carryover between years?

NIH normally allows limited amounts of funds to rollover between budget years, and this grant will follow regular NIH grants management procedures for unobligated funds.

Can funding be provided to small companies as collaborators on assigned specific project?

Yes, through a subcontract is the partner adds value to the goals of the FOA. The grant will not support development of a technology from a company partner.

What is the ultimate metric of success for NIH?

Metrics relevant to education. Metrics relevant to getting to the next phase of independent financing. Attracting investor interest. It is not just companies spinning out, but also innovator knowledge of how to do so. A large portion of this programs focuses on learning by doing, and that is the ultimate metric.

Can the PI be part time employee of the University?

Yes.

Can GLP animal studies be supported?

Yes, if appropriate for the project.

Can scientific projects be supported if the technology has already been licensed with a small company?

No. If the technology is already out of the university as a small business, the company may be eligible to apply for SBIR and STTR grants. This program targets technologies prior to company formation.

Can a sub awardee be awarded more than 100 K?

Yes, if the sub has another promising technology. An individual technology is not permitted to receive >100K federal funds.

Can you comment on the language about promoting the participation of IDeA State and the other programs mentioned in the presentation/FOA?

Existing programs are highlighted to let potential applicants know they exist and that there is infrastructure out there that might be leverageable to help you develop your program. For applicants that already have their own infrastructure developed, we are encouraging participation of IDeA States, and other networks (CTSAs, I-Corps, etc.) in general, as partners.

Do we need to get NIH preapproval to request more than 500,000 a year? And

No, because the program was designed to permit applicants to propose larger budgets.

Can a funded project be more than one year in length?

Yes. In general, we will allow about two years for development in the Hub, but no more than $100,000 of federal funds may be used to support an individual project.

If applicants are not showing their cost share in the application budget, what information are we looking for related to the cost share?

We are looking for evidence of accessible cash, or letters of support or that show partners will provide the cost share upon award.

Can you explain a bit more about what the matching funds are to be used for specifically?

Matching funds are to be used for the development of individual technologies. Awardees must match the federal investment on each individual technology. Remaining matching funds may be used for other development activities.

Is there an expectation that the Hubs will be funding innovators projects at only the applicant institution or at multiple institutions?

The source of projects will be the lead institution and affiliated partner institutions. If a you are a single institution and you can source a

sufficient number of technologies across the NIH mission, the award could be to a single institution.

If we obtain matching funds for the direct costs, is the limit per project still $100,000?

Yes, the limit is $100,000 federal funds per project. There is no limit to the amount of non-federal funds used to support a project.

Is a foundation that is affiliated with the University considered a candidate for matching funds? Or a Department of the University?

Yes, absolutely.

Can funds be used on infrastructure or just on programs and experiments?

This is not an infrastructure grant to build laboratory ventures/ incubator space. The intent of the grant is to fund individual projects and the infrastructure to manage that, but not to build lab infrastructure.

What is the ideal amount or length of training, skill element, education and mentoring that they envision for each hub to provide?

NIH would like Hub to provide continual educational opportunities for innovators coming through the center, starting ideally at the time an innovator is interested in applying through development. The program is also expected to educate the scientific community at large, in addition to innovators, through webinars, seminars, workshops, etc.

Can the matching funds be used non-NIH allowable charges such as patent costs, or freedom to operate?

Yes.

Beyond uses of funds that would constitute direct support of technology development (subgrants), what can REACH funds be used for? Can they cover programming to support inventors, staffing of the grant project, education events for faculty etc.

Yes, the listed costs would all be allowable using grant funds.

Do the match funds have to be allocated at the same time as the REACH funds, or can they be sequenced such that REACH funds are only going to projects that have been pre-validated using other funds?

Not necessarily. At the time of funding a project, NIH will want to see a committed match for that project that equals or exceeds the federal amount, with the intent to be used for development of that project. If you first use the federal funds and then the match, that would be allowable, or vice versa.

What is the cap on infrastructure spending vs. spending directly on supporting companies or pre-incorporation market analysis?

There is not a cap on infrastructure, as you need to set up your application to meet the goals of the FOA, but NIH expects that awardees will support 4-6 technologies annually and streamlined administration will allow for more project funds.

What is a typical ratio of infrastructure vs project spending of the prior REACH awardees?

There is no typical ratio, as each of the current sites is set up uniquely for their individual ecosystems, and different sites leverage different resources.

Can the spending on existing accelerator/incubator programs on medical projects count as part of the match?

Yes, as long as the funds are supporting a project supported through your site.

- Webinar materials will be posted on https://sbir.nih.gov/ in 1-2 weeks.

- Letter of intent (optional) are due February 19, 2019

Thank you all very much and have a good day.

[Event Concluded]