

RFA-OD-19-014: NIH Research Evaluation and Commercialization Hub (REACH) Awards (U01 Clinical Trial Not Allowed)



National Institutes of Health
Office of Extramural Research

Please enter your questions into the
Question module in the webinar console



Support proof-of-concept centers that accelerate the creation of small businesses and the transition of discoveries originating from academic research into products that improve health



- Infrastructure for identifying the most promising technologies
- Funding to innovators for product definition studies
- Access to expertise in areas required for early stage technology development
- Skills development and hands-on experience in entrepreneurship

- Letters of Intent (LOI) due February 19, 2019 (optional)
- **Due Date: March 19, 2019**
 - 5PM applicant institution local time
- Peer Review: June 2019
- Award: September 2019

<https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-19-014.html>



- Barriers to translating technologies from academic labs to the market:
 - a gap in funding between basic research discoveries and scientific proof of feasibility or validation studies required to define the product for early stage technology development
 - a lack of knowledge and understanding by innovators about how new technologies are brought to market
 - a lack of access to sufficient technology development and commercialization resources that are required for early stage technology development.

- Phase 0 Proof of Concept Partnership in accordance with Section 5127 of the SBIR/STTR Reauthorization Act of 2011
- Reauthorized through September 2022

- **NCAI/REACH Proof of Concept Center Network**

- 6 sites
- 33 institutions

Boston Biomedical Innovation Center

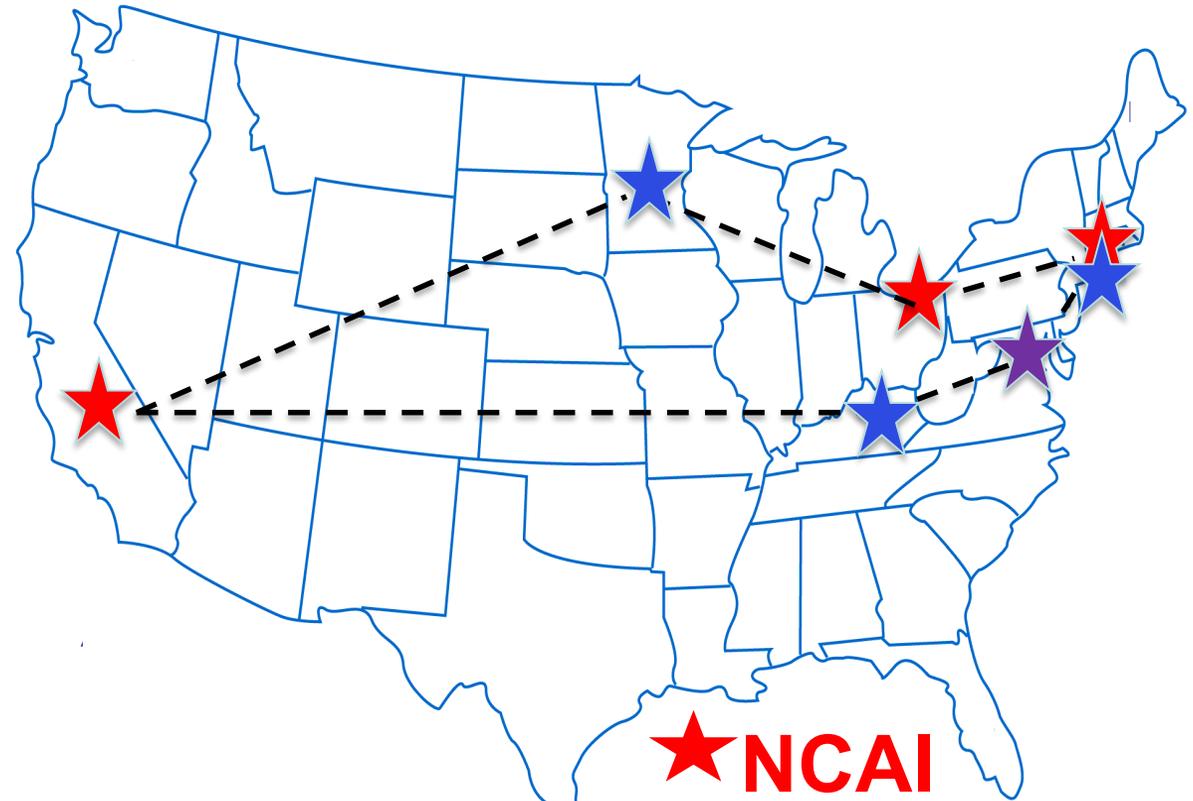
NCAI-CC
Cleveland Clinic

UC CAI
University of California
Center for Accelerated Innovation

ExCITE
an NIH REACH Hub

MN-REACH
University of Minnesota
Coaching to Success

Long Island Bioscience Hub
CSHL, FIMR, SBU, BNL



★ **NCAI**

★ **REACH**

★ **Program Partners**

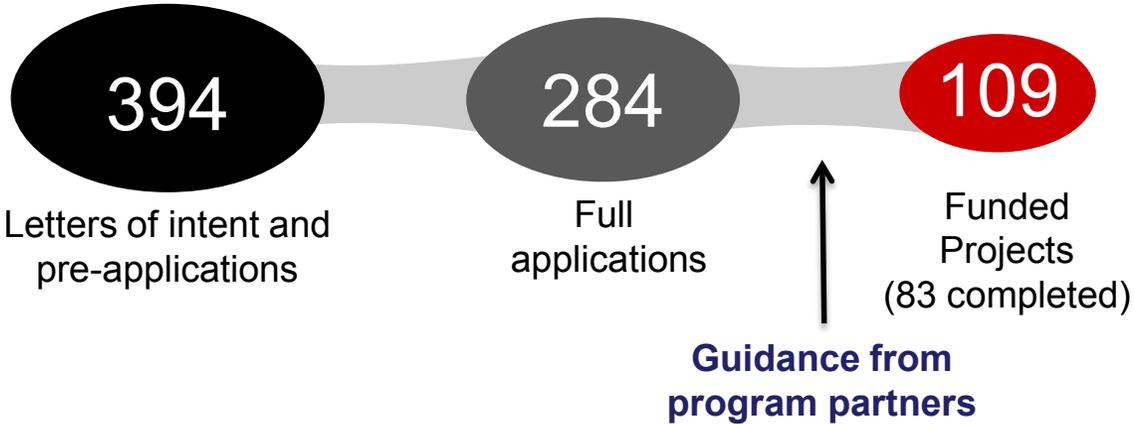
REACH 1.0 Promising Output Indicators

MN-REACH
University of Minnesota
Coaching to Success

Long Island Bioscience Hub

ExCITE
an NIH REACH Hub

Expediting Commercialization,
Innovation, Translation &
Entrepreneurship



New companies

Licensing events

Follow-on Funding (completed projects)

SBIR (1) / STTR (4) Awards



5



22

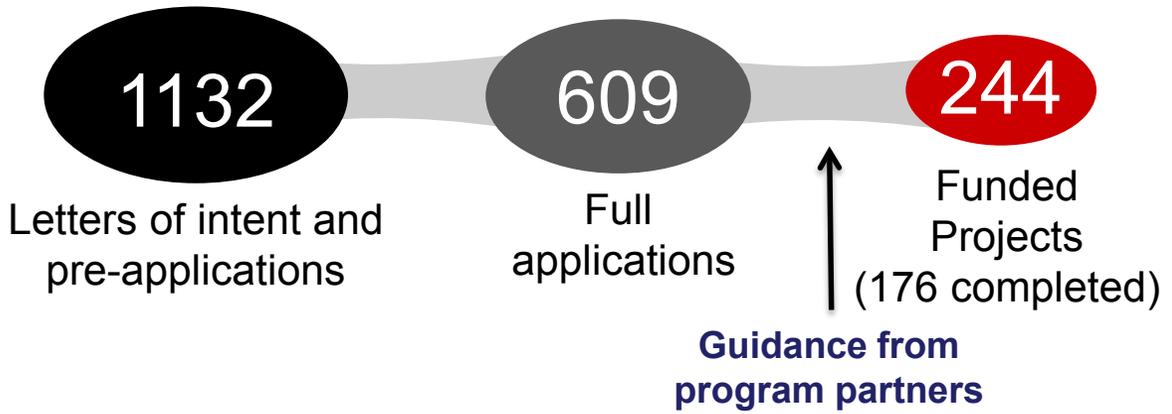
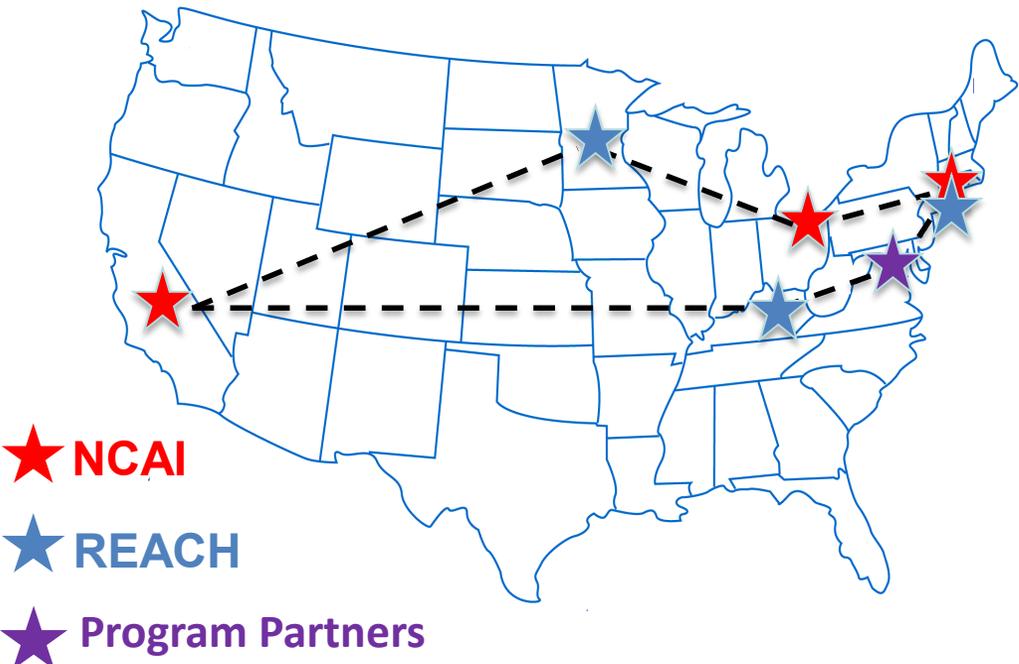


24



\$12.5M

NCAI/REACH Promising Output Indicators



SBIR (14)/STTR (4) Awards



19

New companies



55

Technology licenses and options



49

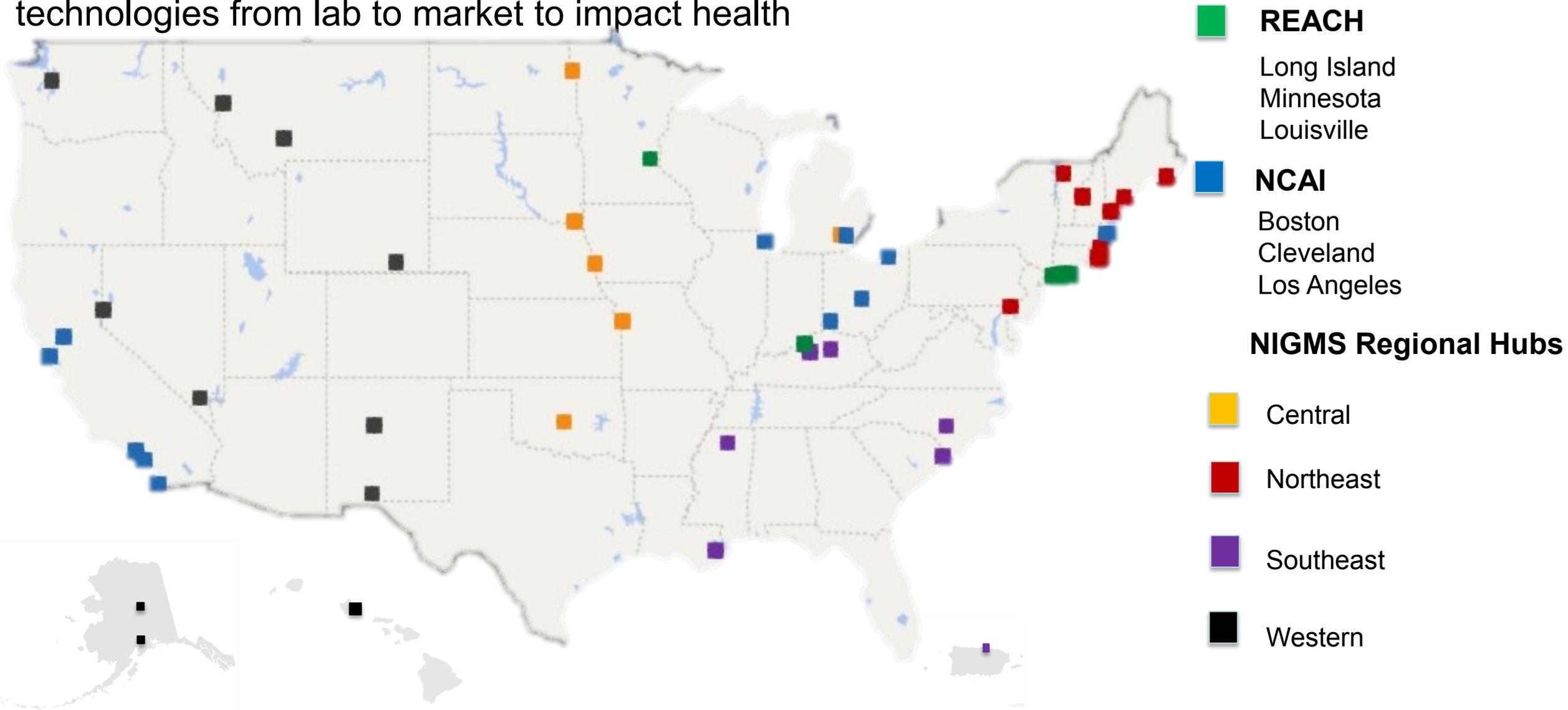
Follow-on Funding (completed projects)



\$548M

REACH/NCAI National Network expansion NIGMS STTR Regional Technology Transfer Accelerator Hubs

Accelerator Hub Goal: Provide entrepreneurial education needed to move discoveries and technologies from lab to market to impact health



- Applicants must be a **university** or other **research institution** that participates, or has participated in, the NIH Small Business Technology Transfer (STTR) program
- Only one application per institution
- **Small businesses are not eligible**
- Current NCAI and REACH awardees not eligible to serve as the primary applicant

- **Types of Eligible Institutions**
 - Higher Education institutions
 - Nonprofits Other Than Institutions of Higher Education
 - Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
 - Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

- Trans-NIH funding opportunity
- Any disease in NIH mission - high burden of disease
- Partnerships encouraged
- Advance promising technologies to next source of independent financing
 - Viable startup company – i.e., SBIR/STTR
 - Licensing opportunities
- Educate a diverse product development proficient workforce

- Anticipate 5 awards
- Up to \$1 million per year (total costs)
 - Includes direct costs and F&A from all components
- Up to 4 years
 - Sunset in 2022

- Leadership and governance
- Collaborations, partnerships, and non-Federal funding
- Technology solicitation and selection
- Funding, resources, and expertise for technology development
- Project management and technology development
- Skills development, education, and mentoring
- Plan for self-sustaining infrastructure

- Demonstrate necessary expertise and track record of transitioning from discovery to market
- Leverage best practices from current pilot programs
- Demonstrate expertise in milestone-driven project management
- Describe plan for collecting and reporting standardized metrics, including tracking progress after project exit the Hub
- Plan to promote information exchanged and dissemination to the research community at large

Collaborations, Partnerships, and non-Federal Funding

- Leveraging/partnering with existing resources encouraged
 - Current REACH/NCAI
 - NIGMS
 - [Regional Technology Transfer Accelerator Hubs for IDEa States](#)
 - Networks of Biomedical Research Excellence ([INBRE](#))
 - Centers of Biomedical Research Excellence ([COBRE](#))
 - NSF Innovation Corps ([I-Corp™](#)) and its National Innovation Network
 - [Small Business Administration Growth Accelerators](#)
 - EDA [i6 Challenge](#)



Collaborations, Partnerships, and non-Federal Funding, cont.

- Leveraging/partnering with existing resources encouraged
 - NCI-designated Cancer Centers
 - NIAID Centers for AIDS Research (CFAR)
 - NCATS Clinical and Translational Science Awards (CTSA)
 - NIBIB Concept to Clinic: Commercializing Innovation Program (C3i)
 - NIBIB Point of Care Technologies Research Network (POCTRN)



Collaborations, Partnerships, and non-Federal Funding, cont.

- Additional partnership examples include:
 - Other research institutions with appropriate technologies
 - Law or business schools
 - State economic development agencies
 - Local incubators or accelerators
- Present a plan to ensure appropriate communication and to facilitate licensing and technology transfer



Collaborations, Partnerships, and non-Federal Funding, cont.

- Expected to obtain non-Federal funding equal to or exceeding the total direct cost funding requested from NIH
 - Examples: foundations, participating institutions, state or local governments, angel investors, venture capital firms, individual benefactors
 - Itemize resources and funding



Collaborations, Partnerships, and non-Federal Funding, cont.

- Include details on non-federal funding that has been secured or anticipated
- Describe plans if fundraising efforts are in progress, or if third-party funding is contingent upon an award
- Include documentation and letters of support
- Provide evidence of access to non-Federal funding that at least equals the direct costs of the year one award

Technology Solicitation and Selection

- Provide infrastructure for soliciting and selecting the most promising technologies that address burden of disease with apparent commercialization potential, or diseases without a broad market that have compelling reasons exist for development
- Describe processes to solicit appropriate technologies
- Describe the diverse expertise of the External Review Board (ERB) including industry, start-up, venture capital, technical, financial, and business experts and university technology transfer officials
- Describe the process for evaluating technologies

Provide details on the ability to maintain robust pipeline of candidate technologies

1. Technology	2. Description of Product Definition Study	3. Technology Type	4. Partner RPI or Affiliate	5. Institutional Official	6. MOU/ MTA
Name of item	Briefly Describe	Diag/Dev/ Thera/Tool	Name	Name, Title	Page #
Adult cardiac stem cells	Intramurally delivered stem cells for cardiac repair	Therapeutic	University of XYZ	John Smith, Director of Technology Transfer	53

Funding, Resources, and Expertise for Technology Development

- Describe plan to provide funding to individual investigators
- Funding amounts for individual technologies may include up to \$100,000 from this award
 - Requires an equal non-federal cash match
 - Matching funds should not be incumbent on the individual innovators to secure
- Describe resources and expertise available to facilitate early technology development



- Describe approach to market-focused project management oversight, with technology development plans that:
 - Involve Tech transfer office to:
 - Enable the best path forward
 - Reduce the burden of licensing
 - Ensure institutional commitment
 - Describe plans to assemble project management teams with appropriate industry expertise
 - Describe processes to assess progress and make milestone-driven go/no-go decisions

Attention to principles of study design and transparency are essential

Follow instructions to address Rigor and Reproducibility

<https://grants.nih.gov/policy/reproducibility/index.htm>



- Provide skills development, hands-on experience, educational and networking activities with linkages to local or virtual resources
 - Describe plans to develop activities or collaborate with existing organizations
 - Detail how mentoring and professional development of the Innovators will be achieved
 - Describe plans to leverage existing or proposed programs such as
 - REACH, NCAI, NSF I-Corps, IDeA States, etc.

- Describe the Hub sustainability plan beyond the end of the 4 year award and include documentation, for example:
 - continued support from partnering institutions or other financial arrangements
 - descriptions of all institutional support, financial arrangements, and agreements for equity positions or royalty payments
 - documentation such as Letters of Support, Agreements, Memoranda of Understanding

- Scored Review Criteria have been modified to include REACH program specific review criteria
- The additional Review Criteria that are not individually scored will contribute to the overall Priority Score
- Review Section V (Application Review Information) carefully before submission

- **Due Date: March 19, 2019**
- Details in [FOA](#)
- All slides, recording, and transcript will be available within 1-2 weeks on sbir.nih.gov
- Enter questions in your webinar chat console or email Kathleen.rousche@nih.gov