

NIH Research Evaluation and Commercialization Hub (REACH) Program

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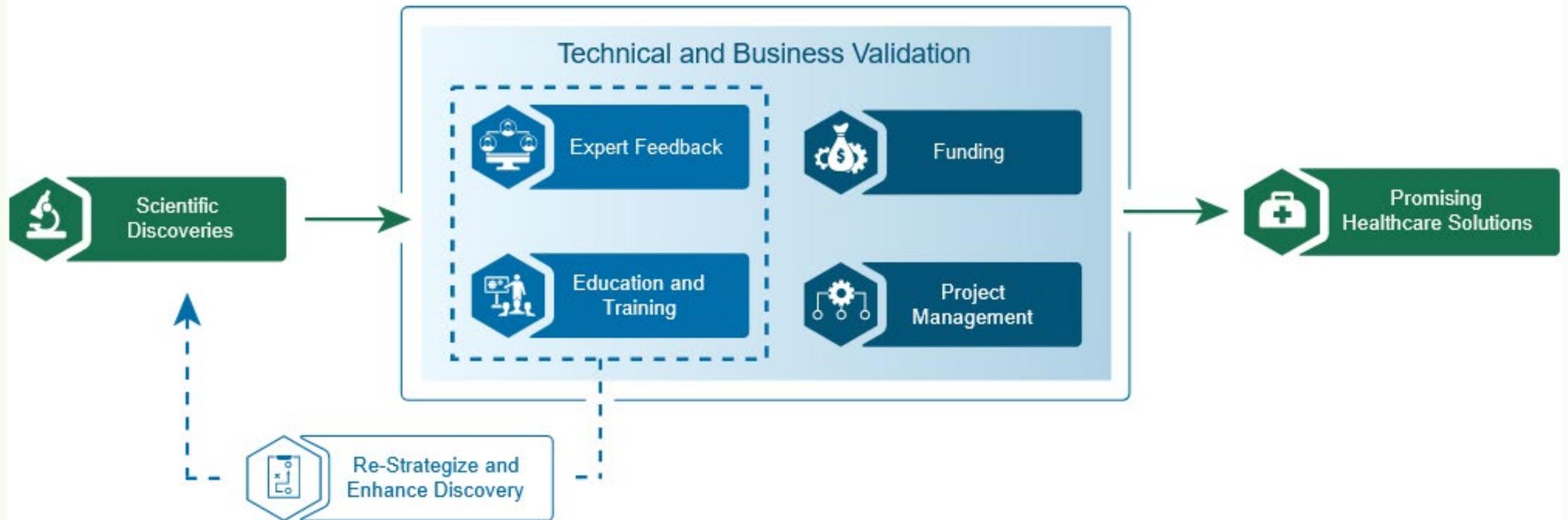
OFFICE OF EXTRAMURAL RESEARCH | OFFICE OF THE DIRECTOR | NATIONAL INSTITUTES OF HEALTH

Agenda

- Welcome/Opening Remarks
- Topics
 - Overview of REACH Program
 - REACH Funding Opportunity Announcement (FOA) overview
 - REACH Grants Management and Highlights of FOA
- Q&A Session

REACH OVERVIEW

Anatomy of a Research Evaluation and Commercialization Hub



NIH Proof-of-Concept Network Outcomes

Data as of November 29th, 2022

Number of Projects	417
Innovators trained	~3,000
Startups Launched	121
SBIR/STTR Awards	63
Total Follow-on Funding Secured	\$2,014 M

Custom Patient-Specific Airway Stents

HemeChip Sickle Cell Disease Diagnostic

Electric Nitric Oxide for Medical Purposes

Gene Therapy for Sickle Cell Disease

First Responder Toolkit

Nutrient Database Research System

Snoring Reduction App

Blood & Transfusion Support System

FUNDING OPPORTUNITY

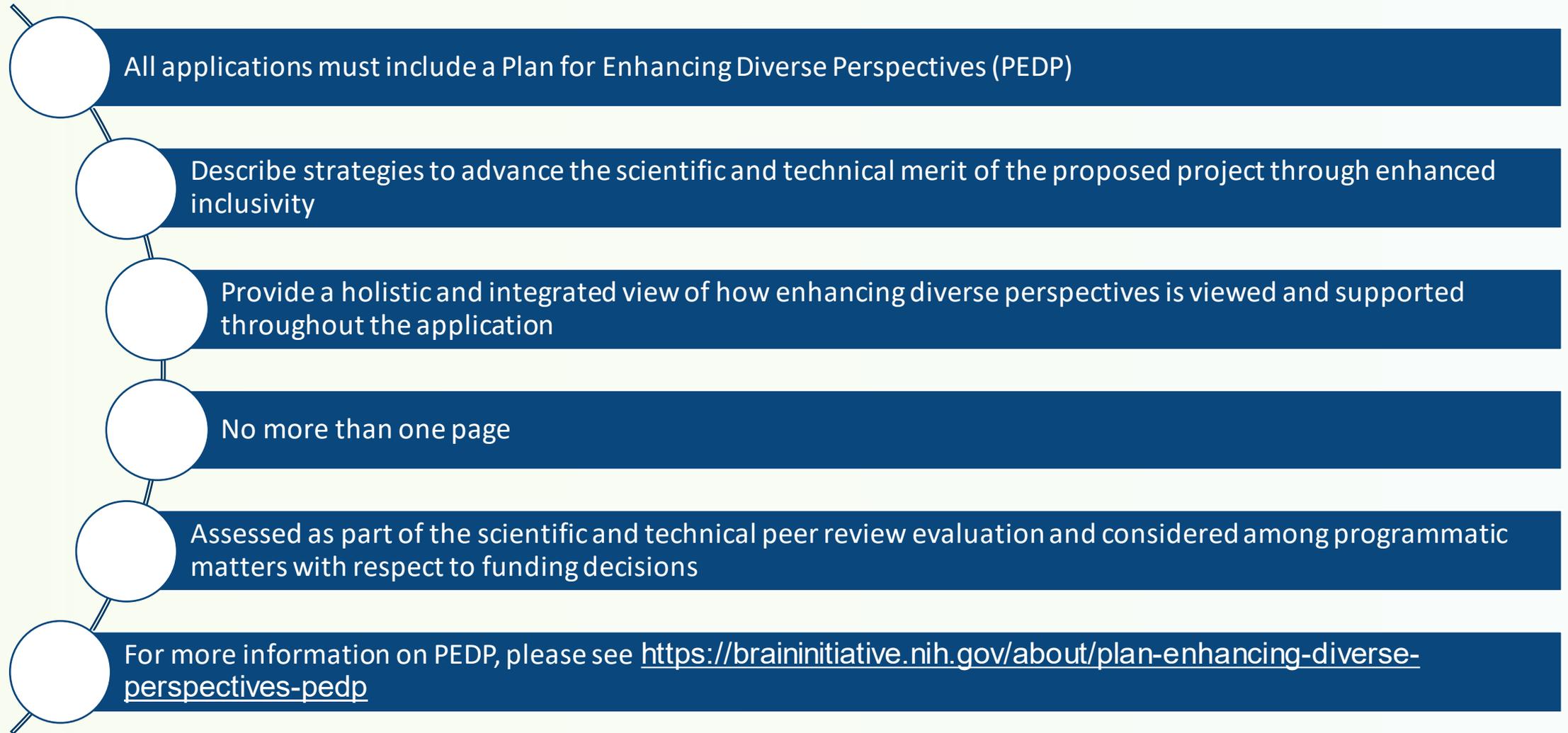
Requirements

Hub leadership	Leadership has documented track record of success in biomedical product development
Collaborations and partnerships	Develop necessary collaborations and partnerships with stakeholders (e.g., academia, non-profits, industry, and existing federal resources)
Regional and local impact	Make an impact on small business development, entrepreneurial culture, workforce diversity, and health disparities
Technology development	Demonstrate the ability to support technology development from early-stage technology feasibility through pre-clinical technologies across the breadth of the NIH mission
Project management	Develop and implement milestone-driven, market focused project management oversight and decision-making processes.
Educational activities	Provide innovators from diverse backgrounds, including innovators from underrepresented groups, access to skills development, hands-on experience and educational and networking activities
Sustainability plan	Develop and implement a plan for ensuring that capacity develop under their REACH award will be sustained at their institution

Guidelines for Project Types

- **Small Molecule Therapeutics:** The compound is at the lead optimization or preclinical stage. The target is known, and/or there is some method or assay to determine its effect.
- **Biologics or Cell Based Therapies:** The biologic or cell population has been identified and some reasonable method of development, sourcing, manufacture, or proliferation is proposed. Mechanism of action has been determined to a sufficient level that there is a reasonable understanding of the product to be developed or tested in the project.
- **Interventional Medical Device:** Includes prototype development and testing, either on the bench or in animals. Physiologic experiments have been conducted or reported in the literature, providing rationale for prototype development.
- **Diagnostic Medical Device/IVD/MDx:** Includes prototype development and some method of testing.
- **Health IT, Software, Apps, and Algorithms:** Should be beyond the concept stage and already have an existing code base. The idea should be grounded in previous experiments or solid peer reviewed evidence. Should include steps to validate the technology by demonstrating its efficacy versus the standard of care or utility in pilot studies or user testing, or, if already validated, to refine the technology to make it appropriate for commercialization.

Key Component: Enhancing Diverse Perspectives



AWARD INFORMATION

Funding instrument

Cooperative agreement

Anticipated number of awards

Up to five awards

Award budget

Maximum budget for a Hub is \$1,000,000 in total costs per year

Award project period

Maximum project period is 4 years

Cost Sharing

Applicants are encouraged to obtain \$250k in non-federal funding each year

ELIGIBILITY

Eligible Institutions

- Public Institutions of higher learning (including Minority Serving Institutions)
- Private institutions of higher learning (including Minority Serving Institutions)
- Nonprofits with or without 501(c)(3) status
- Applicant organization **MUST** be a university or research organization that participates in the NIH STTR program

Non-eligible Institutions

- Non-US entities
- Non-US components of US organizations
- Businesses are not eligible to serve as the primary applicant organization
- Previous recipients of NIH Centers for Accelerated Innovations (NCAI) and REACH awards are not eligible to serve as primary applicant

APPLICATION and SUBMISSION

Application Due Date: February 9, 2023



READ RFA-OD-23-005 CAREFULLY!

There are additional instructions for this FOA in addition to the SF 424 (R&R) Application Guide.

Research Strategy

- Provide the overall objectives of the Hub, including short and long-term goals
- Identify challenges facing the Hub's entrepreneurial ecosystem and how the award will mitigate obstacles
- Describe how the Hub's expertise, capabilities, partnerships and resources will enable it to have significant influence on discoveries and innovations being developed into products that will have health, economic and societal impact.

Research strategy should address the following seven components (details in [RFA-OD-23-005](#)):

- Hub leadership
- Collaborations and partnerships
- Regional and local impact
- Technology development
- Project management
- Educational activities
- Sustainability plan

Other documentation

Letters of support

Applicants must include documentation of support indicating:

- Support from sources of non-federal resources
- Institutional commitment to the program
- Participation of the technology transfer or commercialization offices

Applicants are encouraged to include letters supporting the sustainability plan

Resource Sharing Plan:

All applications, regardless of the amount of direct costs requested for any one year, should address how relevant resources (e.g., training presentation slides or videos, template documents, best practice handouts, how and why go/no-go decisions are made, etc.) resulting from the award will be freely shared with the public.

Other Attachments

Plan for Enhancing Diverse Perspectives (PEDP)

Appendix

Template or Sample Agreements

Template or sample institutional agreements to streamline interactions and decrease barriers to technology transfer and commercialization may be included in the Appendix.

Non-Federal Matching Funds

Hubs are encouraged to obtain \$250,000 of non-federal funding each year of the award to support technology development projects. Sources of non-federal funding could include (but are not necessarily limited to):

- Foundations
- Participating institutions
- A state or local governmental body
- Angel investors
- Venture capital firms
- Individual benefactors

Applicants should include details on non-federal resources that have been secured or anticipated during project period. Documentation of planned non-federal funding may include a term sheet and/or letter of commitment from funding source.

GRANTS MANAGEMENT

Grants Management Points of Interest

- Mechanism of Support: Cooperative Agreement
- Substantial Federal scientific or programmatic involvement. NIH scientific or program staff will assist, guide, coordinate or participate in project activities
- Cooperative agreement purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities
- The dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH
- NIH Project Coordinator vs. NIH Program Officer
- Specific Cooperative Agreements Terms of Award on NoA

Requirements and Registrations

- The maximum budget for a Hub is \$1,000,000 total costs per year (including applicable F&A).
- Foreign institutions, foreign applicants and foreign components, as defined by the NIH Grants Policy Statement, are not allowed
- Follow FOA instructions for detailed (i.e. non modular budget) elements and justifications
- SAM, eRA Commons, UEI, grants.gov registrations

Additional Requirements

- Human/animal subjects research, clinical trials registration, other support
- JIT procedures
- Annual submission of RPPR
- Closeout Documents

Award Process

- Peer review process and generation of summary statement
- Submission of JIT materials
- Communication with NIH staff regarding potential funding
- Review by NIH Program Staff and NIH Grants Management Staff
- Receipt of Notice of Award
- Compliance with terms and conditions of Notice of Award

Q&A Session

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The NIH Guide for Grants and Contracts:

<http://grants.nih.gov/grants/guide/listserv.htm>