RFA-OD-14-005: NIH Research Evaluation and Commercialization Hub (REACH) Awards (U01)

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Questions

• Please enter your questions into the webinar chat console
• If we do not address your question during the webinar or you have further questions, you can email kurt.marek@nih.gov
Purpose

To support proof-of-concept centers (Hubs) that facilitate and accelerate the translation of biomedical innovations into commercial products that improve patient care and enhance health.

- infrastructure for identifying the most promising technologies
- funding for product definition studies (e.g. feasibility studies, prototype development, or proof-of-concept studies)
- coordinated access to expertise in areas required for early stage technology development (including scientific, regulatory, reimbursement, business, legal, and project management)
- skills development and hands-on experience in entrepreneurship
Background

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.

This program implements Section 5127 of the SBIR/STTR Reauthorization Act of 2011
Applicants must be a university or other research institution that participates in the NIH Small Business Technology Transfer (STTR) program.

- Participation means a formal partner to a small business on an NIH STTR grant
- Only one application per institution
- **Small businesses are not eligible.**

See also [NOT-OD-14-087](#)
• Trans-NIH funding opportunity
• Therapeutics, preventatives, diagnostics, devices, and tools
• Does not have to be a consortium, but if necessary to meet the goals of the RFA, partnerships are encouraged
• Applications from, or consortia that include, institutions from IDeA states are encouraged
Applications from, or consortia that include, institutions from IDeA states are encouraged.
• Up to $1 million per year (total costs): includes direct costs and F&A from all components
• Up to 3 years
1. Leadership and governance
2. Collaborations, partnerships, and non-Federal funding
3. Technology solicitation and selection (External Review Board)
4. Funding, resources and expertise for technology development
5. Project management for technology development
6. Skills development, education, and mentoring
7. Plan for self-sustaining infrastructure
Leadership and governance

- Hub leadership should demonstrate the necessary operational, business, and scientific expertise
- Leadership should have a documented track record of success in transitioning technologies from the discovery phase to commercialization
- Define appropriate metrics, including tracking the progress of technologies after exit from the Hub
- Describe a plan to promote information exchange and the dissemination of research outcomes to the research community at large
Hubs should establish and manage necessary collaborations and partnerships. Examples of partnerships include:

- other research institutions with appropriate technologies
- law schools or business schools
- state economic development agencies
- local incubators or accelerators
- clinical research organizations
- clinical trials networks

The applicant must present a plan to ensure appropriate communication and to facilitate licensing and technology transfer.
REACH Hubs are expected to obtain non-federal funding equal to or exceeding the funding requested from NIH.

- Examples include foundations, participating institutions, state or local governments, angel investors, venture capital firms, individual benefactors
- Applicants may value in-kind support if it represents a substantial resource available to the Hub
- Applicants should clearly itemize the resources and funding that will be secured and indicate the total value (can include additional budget pages in the Appendix)
- If the fundraising efforts are in progress or if the third-party funding is contingent upon an award, then such plans should be clearly described
- Include documentation in the Appendix and letters of support
A REACH Hub must provide infrastructure for soliciting and selecting the most promising technologies predicated on medical need, scientific merit, and commercial potential.

External Review Board (ERB):

- 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 describe the process for establishing the ERB, the expertise that will be represented on the board, and the processes by which the Hub will solicit appropriate technologies and the ERB will use to evaluate them
- Applicants should not contact potential ERB members or name them in the application
Each Hub must provide appropriate funding, resources and expertise required for early stage technology development.

- Applicants should describe a plan to provide funding to individual investigators to conduct product definition studies
- Funding amounts may include up to $100,000 from this award
- Funding can be subsidized by other sources
- Applicants should describe the resources and expertise available to the Hub to facilitate early technology development [scientific, business plan development, market research, intellectual property (IP) protection, regulatory submission, reimbursement, legal, project management, etc.].
Each Hub must develop a market-focused project management oversight process to enable early stage technology development.

- The technology transfer or commercialization office should enable the best path forward for technologies. Agreements designed to reduce the burden of licensing should be described (examples may be included in the Appendix). Applicants should demonstrate institutional commitment to this effort.

- Describe applicant’s ability to assemble project management boards comprised of industry, start-up, venture capital, technical, financial, and business experts.

- Describe processes to assess progress and make milestone-driven go/no-go decisions to terminate development of projects and reallocate resources when necessary.
A Hub must provide skills development, hands-on experience, educational and networking activities with linkages to local or virtual resources.

- Applicants should describe plans to develop these activities or collaborate with existing.
- Applicants should provide a detailed discussion of how mentoring and the professional development of the technology Innovators will be achieved.
- Leveraging existing or proposed NSF I-Corps programs is encouraged.
It is expected that a REACH Hub will become self-sustaining and a suitable sustainability plan must be presented.

- Sustainability may include support from partnering institutions or other financial arrangements.
- Include descriptions of all institutional support, financial arrangements, and agreements for equity positions or royalty payments that the Hub will receive from successfully commercialized technologies.
- Appropriate documentation (Letters of Support from institutional leaders and others, Agreements, and Memoranda of Understanding) should be included in the application.
• The Scored Review Criteria have been modified
• There are Additional Review Criteria that contribute to the overall Priority Score
• Review Section V (Application Review Information) carefully
• Details in the FOA (RFA-OD-14-005). Read it carefully.
• Slides and FAQs: http://grants.nih.gov/grants/webinar_docs/webinar_20140514.htm
• http://sbir.nih.gov
• Please enter questions in your webinar chat console
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