Introduction/Overview

The Clinical and Translational Science Institute (CTSI) at the University of Pittsburgh in partnership with the office of the Chief Scientific Officer (CSO) of UPMC seek applications for the Commercialization-Innovations Phase II Pilot Awards. These awards are part of a series of funding opportunities to stimulate research for which implementation may involve inventions or commercialization.

This specific opportunity will support established stages of work, derived from the first phase of these pilot awards as well as new applications from University projects which have a current industry partnership and minimal concurrent funding. Awards being offered are up to $75,000 for one year of work.

Description:

Many basic discoveries are more likely to benefit individuals and populations if they are embodied into sustainable products or practices. Multiple funding strategies can support translation or implementation of innovations including support from large companies, start-up company funding from venture capital, and SBIR / STTR grants from NIH or other federal agencies.

This Pilot will support teams in the secondary stage of their path towards competitive proposals for these extramural sources of funding. As such, teams are expected to have already filed an invention disclosure.

This funding opportunity intends to support work leading to new drugs, new therapeutics, or new technology. **Applications must focus on a clearly identified invention or product that has potential for commercialization.** While we will not exclude applications addressing other areas, there are other programs on campus planned or designed to support digital health, develop new medical devices, and to atract commercial partners.

In addition to product development milestones, this Pilot award may also include the following:

- Completing a market analysis for an invention

- Initial prototyping or design of a product that embodies the IP

- Stakeholder evaluation of usability of a proposed new product

- Comparing different design options for a product as part of down selection

- Completing key experiments to support claims about IP or to de-risk IP

- Completing a related project with a commercial entity to show partnership

Eligibility: To be eligible for this funding, teams must either:

(1) Have previously been awarded funds from Phase I of this pilot, or
(2) Have an existing industry partnership and minimal concurrent funding.

For previously funded awardees, this stage of funding is meant to provide additional funding from Phase I of these awards. The progress of Phase I awardees will be taken into consideration. This additional funding can be used in the development of a device to create the initial prototype. A team that already has an invention might use this Pilot to refine the invention for a market or de-risk the invention to atract extramural funding.

This funding opportunity is not intended for projects that have already secured external investment or other grant funding. If the investigators or members of the team have had prior commercialization experience or SBIR/STTR funding, the application must make clear that this is a new project or invention.

This funding opportunity is intended to support early innovation from within the University similar to the STTR awards (https://www.sbir.gov/tutorials/preparing-proposal/). The majority of work must be conducted on campus, and the majority of funds must be expended within the University of Pitsburgh.

We expect and encourage partnerships with external businesses that can accelerate commercial translation of research. University investigators also may be on a path to start their own business as part of the translation. While we value efforts that may help investigators set up companies or partner with external companies, funding of those external entities will not be the focus of this opportunity. Nevertheless, some teams may find that efforts within this Pilot program facilitate those partnerships. Other funding mechanisms on campus are planned and designed for projects in which commercial partners assume a larger role (https://www.oiep.pit.edu/faculty).

Commercialization Training through I-CORPS: As part of the Phase II awards and in conjunction with the Innovation Institute, awardees will be offered the opportunity to enroll in a series of courses offered through the Interior Northeast regional hub of I-CORPS. The goal of this program is to understand the market need and fit and path to commercialization. https://www.innovation.pit.edu/pit-ventures-first-gear/. Please contact John Inserra (jinserra@innovation.pit.edu) Program Manager at the Pit Innovation Institute, with your questions regarding how you can apply for I-CORPS.

Intellectual Property: All teams should have an Invention Disclosure on-file prior to the final round to be eligible for funding. University faculty should follow the procedures for protecting IP as outlined by OIE and the Innovation Institute (https://www.oiep.pit.edu/faculty/commercializing-your-idea). While this Pilot is jointly supported by CTSI and the UPMC CSO Office, participation will not imply any changes in usual policies and procedures related to inventions nor will it require intention to partner with UPMC for subsequent funding. However, CTSI and the CSO will provide the option and opportunity for interested investigators to present projects to UPMC Enterprise or other potential partners who might provide follow-on funding.

CTSI Assistance (Optional)

CTSI Innovation provides consultation and resources for investigators working on projects with potential for implementation in the marketplace.

Research facilitators at CTSI are available to assist investigators at any stage of a project. Facilitators can advise on finding collaborators, regulatory issues, human research protection, other required approvals, and research design or conduct.

Limited statistical consulting on projects is available from [CTSI's Biostatistics, Epidemiology, and Research Design (BERD) Core](#).

Key Dates

Round 1 LOI Submission Deadline:
October 6, 2023 by 11:59:59 p.m. EDT

Round 1 Notification:
October 20, 2023

Round 2 Full Proposal Submission Deadline:
November 17, 2023 by 11:59:59 p.m. EDT (by invitation)

Award Notification:
December 15, 2023

Earliest Anticipated Start Date:
February 15, 2024
(award must start within three months of notification)

Funding Information

Applicants for Phase 2 can request up to **$75,000** in direct costs, with a maximum funding period of one year.

The funding cycle will be for 12 months after the start date; no extensions of this award period will be made. Funding cannot start until any necessary regulatory approvals have been received (IRB, hSCRO, IBC, CORID, IACUC). **Projects must start within 3 months of Notification of Award. Projects that do not start within 3 months will be forfeited.**

CTSI pilots do not have any mechanism for no-cost extensions; any funds that are not used during the award period will be forfeited.

This award is eligible for CTSI Bonus Awards as described on the separate [Bonus Award page](#). For bonuses requested in this award, "community partners" should be representative groups and does not include corporate partners.

Progress Reports

Unique to this Pilot Award, CTSI requests milestone-driven progress reports for funded projects.

Given the focus of this Pilot Award, progress reports may have novel formats and should include a presentation or pitch for any invention. CTSI will offer assistance developing progress reports and presentations that may help teams to compete for other follow-on funding.

Eligibility

The Principal Investigator (PI) must be a faculty member in the University of Pittsburgh Schools of Health Sciences. Postdoctoral trainees and trainees in clinical training programs are not eligible to serve as PI. Faculty members on early-career training awards or clinical research scholars (i.e. recipients of K-series

or similar career development grants) are eligible. New PIs are strongly encouraged, but submissions from established investigators will be accepted if they meet other eligibility criteria.

This funding opportunity is intended to support early innovation from within the University similar to the STTR awards (https://www.sbir.gov/tutorials/preparing-proposal/). The Pilot does not exclude projects that involve partnerships with commercial entities, but the majority of work must be conducted and the majority of funds must be expended within the University of Pitsburgh. If the PI already has developed a commercial venture (e.g. a licensed start-up company), that venture cannot be the recipient of the Pilot award. The PI must receive and administer this award in their role as a member of the University faculty, following established policies and procedures for Conflict of Interest, disclosure and licensing (https://www.coi.pit.edu/outside-activities/licensed-start-companies).

Study teams that involve cross-disciplinary collaborations are strongly encouraged. Co-investigators may be from other universities. However, CTSI's primary mission is to promote research at the University of Pitsburgh, and applicants should justify any extensive off-campus collaboration. Partnerships with non-academic community partners are also acceptable.

Questions? Contact the CTSI Pilot Core at ctsipilots@pit.edu.

Submission and Review Information

Round 1: Leter of Intent (LOI)

Applications will be evaluated in two rounds: (1) a brief leter of intent, and (2) a full application.

Round 1: Leter of Intent (LOI)

Submit a leter of intent that summarizes the proposed research. Each submission must include the following sections:

1. Study Title: Include the title of the proposal at the top of the page, with the PI name and contact email.

2. Abstract/Scope of Work (500 word limit): Provide a high-level overview of the project and the proposed work. **Clearly identify the IP, product or topic of commercial interest.** Clearly identify plans for follow-on funding (SBIR/STTR, startup funding, internal Pit awards, etc.) and the existing industry partnership (if applicable).

3. Existing funding for this project: List all current support (grants, venture capital, etc.)

4. Study Team: Provide the names and affiliations of all members of the study team and a brief description of their roles (25-50 words per person)

5. Suggested Reviewers: To facilitate the second round of review, please suggest two or more Pit/UPMC faculty members to potentially serve as non-conflicted scientific reviewers. For each suggested reviewer, list their name, title, department, and contact email.

Leters of Intent should be in the form of a single PDF document. The font should not be smaller than Arial 11; margins must be no smaller than 0.5 inches. All materials must be uploaded to the InfoReady web site by 11:59:59 PM on **October 6, 2023**. Additional or supplemental materials cannot be accepted after the deadline and will not be reviewed.

Round 1: Review Criteria

The review of leters of intent will be conducted by the faculty and staff of CTSI and the office of the CSO of UPMC. Proposals will primarily be evaluated based on responsiveness to the funding opportunity announcement, as well as potential impact of the proposed work. The results of this evaluation will determine which investigators will be invited to submit a full proposal for the second round.

Applications for this funding opportunity must clearly identify the intellectual property (IP) that the team is advancing or developing.

Round 2: Full Application

Applications should be in the form of a single PDF document; please use Arial size 11 font, with margins of 0.5 inches. All materials must be submited before 11:59 p.m. on **November 17, 2023.** Additional or supplemental materials cannot be accepted after the deadline and will not be reviewed.

Applications must include the following sections. Please start each new section on a new page.

- Cover Sheet (one page): Include the following details:

    o Project Title

    o Names, titles, affiliations and preferred contact email for the Co-Principal Investigators (faculty members)

    o Scientific Abstract (maximum 250 words): Summarize your proposal

- Research Plan (maximum five pages including tables/figures): Please address the components in typical NIH proposals including the following:

    o **Specific Aims:** What will this project accomplish?

    o **Significance:** What need or problem will this project solve?

    o **Innovation:** What is the new IP or approach?

    o **Approach:** How will the team achieve the Specific Aims? What milestones can objectively define when the Aims have been achieved?

    o **Commercialization plan:** Clearly identify the IP, product or topic of commercial interest and/or existing industry partnership. Describe a well-defined path from the pilot to future funding, licensing, or efforts that will lead to widespread availability and implementation. Clearly identify plans for follow-on funding (SBIR/STTR, startup funding, internal Pit awards, etc.)

Applications for this Pilot should address the unique requirements identified in the review criteria SBIR/STTR grants. Specifically, teams must demonstrate Innovation, Potential for Commercialization, and Capabilities of the Team (https://www.sbir.gov/tutorials/preparing-proposal/).

Round 2: Review Criteria

Review of the pilot proposals will use the NIH review criteria and Program-specific criteria to evaluate the scientific merit and transdisciplinary nature of the project. Reviewers will score final applications on an NIH scale (1-9) in the domains of Significance, Investigators, Innovation, Approach, and Environment. Special emphasis will be given to a rating of the overall impact of the proposed project. Note that the review (based on the criteria below) will be adjusted to the pilot nature of the award.

NIH Review Criteria: Scientific Merit

1. Overall Impact: The likelihood for the project to exert a sustained, powerful influence on the research field?

2. Significance: Does the project address an important problem or a critical barrier to progress in the field?

3. Investigators: Are the PD/PIs, collaborators, and other researchers well suited, sufficient, and able to conduct the project? Is the Team appropriate for developing the product or invention?

4. Innovation: Does the project use novel theoretical concepts, approaches, methodologies, instrumentation, or interventions? Is there a clearly new invention at the center of this project?

5. Approach: Are the strategies, methods, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

6. Environment: Are the personnel, equipment, and other physical resources available to the investigators to perform the proposed research within the time frame alloted?

Program-Specific Criteria:

7. Commercialization Potential: Does this project lead to or have potential for a product that will be sustainable and marketable?

8. Intellectual Property (IP): Does the project have defined IP? Has the team considered and appropriately address the protection of IP?

9. Commercialization Plan: Does the team have a defined plan for follow-on funding or for licensing that will move the product towards implementation?