Overview

The Clinical and Translational Science Institute (CTSI) at the University of Pittsburgh's Implementation Lab is now seeking applications for the Implementation Lab Pilot Awards (ILPA). The lab aims to facilitate connections between Pitt researchers and organizational Health Operations Partners (HOP) that enable them to conduct Dissemination and Implementation research aimed at getting priority evidence-based practices into clinics and communities*.*

Dissemination research is defined as "the scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to understand how best to communicate and integrate knowledge and the associated evidence-based interventions." (National Institutes of Health (NIH) 2021)

Implementation research is defined as "the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve individual outcomes and benefit population health." (NIH 2021)

The goal of dissemination and implementation (D&I) research is to shorten the often-stated 17-year evidence to practice gap. D&I research aims to translate evidence to positively impact individuals and communities, healthcare delivery and financing, or policy. D&I research engages essential partners with relevant experience such as patients, the public (e.g., families, informal caregivers), providers, payers, and policy makers. Inherent in D&I research is ensuring equitable dissemination and implementation of evidence-based practices to all who would benefit.

A Health Operations Partner (or HOP) is defined here as a health system, provider network, payor, public health agency, health-focused community organization, etc.

Purpose

These pilot awards will support:

1) D&I research projects co-designed by researchers and around the HOP's priorities that examine some aspect of disseminating, adopting, implementing, or maintaining an evidence-based practice or program.

2) Other types of research co-designed projects (e.g., hybrid effectiveness-implementation studies).

Investigators should consider their work in the context of health equity. This could include expanding healthcare access for vulnerable populations or addressing equity as an outcome.

Examples of projects that might fit this opportunity include:

• Evaluating barriers to, and facilitators of, an evidence-based practice or program prioritized by the HOP

• Designing and testing strategies, tools, or resources tailored for dissemination or implementation in the HOP

• Engaging a HOP's patients or clients to collaboratively develop and test/evaluate dissemination strategies for study findings

• Testing strategies to support equitable implementation of evidence-based practices or programs throughout the HOP

• Testing the use of an implementation team that is constructed in a novel way tailored to the HOP's structure

Examples of projects not responsive to the RFA:

- Efficacy trials
- Early-stage intervention or product development studies
- Exploratory studies

Key Dates

Letter of Intent Deadline:
Wednesday, July 31, 2024, by 11:59:59 p.m. EDT

Notification to Advancing Teams:
Tuesday, August 13, 2024

Round 2 Submission Deadline:
Monday, September 30, 2024, by 11:59:59 p.m. EDT

Notification to Awardees:
Friday, November 15, 2024

Anticipated Start Date:
January 1, 2025

Funding Information

Award funding of $50,000 is available to cover direct costs; no indirect support will be provided. The award period is 12 months. The ILPA pilots do not have any mechanism for no-cost extensions; any funds that are not spent during the award period will be forfeited.

Before the start of the award period, awardees must provide documentation of all necessary regulatory approvals. Once regulatory documentation is provided, awarded projects will undergo an administrative review from the National Center for Advancing Translational Sciences (NCATS) which is the National Institutes of Health (NIH) Institute that funds the University of Pittsburgh CTSI. Funding cannot begin until projects have been approved by NCATS. Because the NCATS review may take up to 30 days, applicants are strongly encouraged to have the necessary regulatory documents ready for submission.

Eligibility

Postdoctoral and clinical trainees are not eligible to serve as PI.

The Principal Investigator (PI) must be a University of Pittsburgh faculty member who specifies an HOP. 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 to apply, but submissions from established

investigators will be accepted if there is clear evidence that the pilot project represents a distinctly new direction from their previously funded work.

Study teams that involve cross-disciplinary collaborations are also strongly encouraged. Co-investigators may be from other universities; however, CTSI's primary mission is to promote research at the University of Pittsburgh, so applicants should justify extensive off-campus collaboration besides that with the HOP.

Questions about eligibility? Contact the CTSI Pilot Core at ctsipilots@pitt.edu

Submission Format and Requirements

CTSI uses the InfoReady system to collect and review all pilot project submissions. The ILPA program will utilize a two-tier submission and review system. Round 1 requires submission of a letter of intent (LOI). Round two requires submission of a full application by invitation only. If you have any questions while using the system or encounter any errors while submitting, please contact CTSI Pilot Funding Core at ctsipilots@pitt.edu.

Round 1: Letter of Intent (LOI)

The LOI should be formatted to use Arial size 11 font with margins of 0.5 inches and submitted as a single PDF document. All materials must be submitted before 11:59 p.m. on Wednesday, July 21, 2024. Additional or supplemental materials cannot be accepted after the deadline and will not be reviewed.

The LOI <u>must be signed by both the PI and HOP representative</u> and should include the following sections:

1. <u>Study Title:</u> Include the title of the proposal at the top of the page, along with the PI name, title and department and contact email.

2. <u>Structured Abstract (500-word limit)</u>: Please provide an overview of the study including, as applicable:
• Background and rationale for the study, including why the evidence-based program or practice of interest is a priority for the HOP
• Objectives
• Approach
• Study Design
• Setting (should be the HOP)
• Participants (should be the HOP's personnel/patients/clientele)
• Outcomes

3. <u>Path to Impact Plan (250-word limit):</u> Please describe the steps you will take to ensure that your work impacts the target population. We define impact as the positive influence this research will have on a) the health and well-being of individuals, communities, and populations; and b) the organization, delivery, and financing of healthcare and health policy. When writing this section, consider the following questions:

• What is the problem that your research addresses from all relevant points of view (e.g. patients, caregivers, community members, providers, administrators, policy makers, and payers)?

• Who are the target audiences that would be interested in this work, and why should they be interested? Please include:
- Those who would benefit directly
- Those who could benefit indirectly from longer term effects on communities/populations, research institutions, policy, or the HOP itself

• What steps will your research team take to engage HOP leadership, providers/staff, and patients/clientele in this project and/or future work?

• What will be your next steps to ensure the impact of your work?

• What steps do you envision further "down the road?"

[Click here to view Path to Impact examples](#)

[Click here for a consultation with the CTSI IMPACT core about the Path to Impact](#)

[Click here to view a 10-slide module on Research Impact and the Path to Impact](#)

4. <u>Study Team</u>: Please provide:
      1. the names and affiliations of all members of the study team and a
      brief description of their roles (25-50 words per person)
      2. the name of the HOP, the lead collaborator, and a brief description of the HOP's role within the community.

For more senior PIs, please indicate how the proposal represents a new direction. If including constituents/community members, please describe them within your study team description.

5. <u>Suggested Reviewers:</u> To facilitate the final round of review, please suggest three Pitt faculty members, not from your department, who may be qualified to serve as scientific reviewers. Include the person's name, title, department, and email address.

Round 1: Review Criteria

The review of letters of intent will be conducted by the faculty and staff of CTSI. Proposals will be evaluated based on:

1. Alignment with the RFA, including alignment of proposed project with an HOP-defined need that could be overcome through implementation of an evidence-based practice or program

2. Potential for impact on population health and/or health and healthcare disparities

3. Clarity and depth of the Path to Impact Plan

4. Innovation or contribution to meeting the aims of the HOP

5. Strength of the study team

The results of this evaluation will determine which investigators will be invited to submit a full proposal for Round 2.

Round 2: Full Packet Submission

Applications should be formatted use Arial size 11 font with margins of 0.5 inches and submitted in the form of a single PDF document. All materials must be submitted before 11:59 p.m. on Monday, September 30, 2024. Additional or supplemental materials cannot be accepted after the deadline and will not be
reviewed.

Include the following sections, beginning each section on a new page:

1. **Project Overview** (one page): The first page should include the following:
   - o Project Title
   - o PI Name and contact email
   - o HOP, principal liaison, and contact email
   - o Scientific Abstract (250-word limit): Briefly summarize the proposed work and how you will work with the HOP to address an HOP-defined need that could be overcome through implementation of an evidence-based practice or program.

2. **Research Plan** (no more than five pages, including tables and figures): This section should include the following elements from a traditional NIH proposal to best allow reviewers to address the review criteria:

   - o Specific Aims (1 page)
   - o Significance (~1/2 page)
   - o Innovation (~1/2 page)
   - o Approach (~2 pages)
   - o Key constituents (e.g. patients, caregivers, community members, providers, administrators, policy makers, and payers) and plan for integration
   - o Path to Impact Plan (~1/2 page; please refer to description and resources under LOI section of the RFA)

3. **References** (no page limit): Literature cited does not count toward the Research Plan's three-page limit.

4. **Budget with Budget Justification** (no page limit): Use PHS 398 Form Page 4 and Page 5. The budget justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested.

o Grant funds may NOT be budgeted for:
   - ▪ Salary support for the PI or faculty collaborators*
   - ▪ Effort for post-doctoral trainees or fellows
   - ▪ Routine office supplies or communication costs, including printing
   - ▪ Meals or travel, including to conferences, except as required to collect data

- Professional education or training
- Computers or audiovisual equipment (exceptions require clear justification)
- Manuscript preparation and submission
- Indirect costs

*Effort is required of the principal investigator and must be reflected on the budget page. This effort should be cost shared by the department or other entity that will support such effort. Reviewers understand that this may be a very small proportion of effort given the size of this award but will be cautious if investigators do not appear to have sufficient time to complete a project.

Any salary support requested in a submitted budget should reflect federal fringe benefit rates. If an award is made, a budget meeting will be held between principal investigators, their respective research administrators, and financial administrators from the CTSI. If necessary, adjustments to the requested budget will be made at that meeting.

5. **Proposal Timeline** (up to half a page): Describe milestones and timeline for completion of the project. These milestones are critical for the pilot program because all awards must be expended during the one-year award period. The CTSI Pilot program does not have mechanisms to allow no-cost extensions. In the event an award is made, investigators should immediately confer with CTSI staff if any delay in initiation or completion of the project is anticipated.

6. **Human Subjects** (no page limit): NIH supported pilot awards must address Protection of Human Subjects, Adequacy of Protection Against Risks, Data and Safety Monitoring Plans, Inclusion of Women and Minorities, and Inclusion of Children.

o   Human Research Protection Office (HRPO) approval is not required prior to submission. However, HRPO approval is required for all projects involving human subjects before NCATS will approve project funding.

o   Applicants must describe any human subject issues, as well as the sources of materials that will be obtained from human subjects. If human subjects are involved, provide a description of their involvement and characteristics, specific risks to subjects who participate, and protection against those risks. Reviewers may consider whether significant delays in approval are an anticipated barrier for project completion when selecting projects. Evidence of prior or ongoing HRPO review is encouraged. Similarly, this section should discuss if other special regulatory approval is required.

7. **NIH Biosketches** (no page limit): Include biosketches for the Principal Investigator and key members of the research team. Use new NIH biosketch format as of September 2020.

8. **Letters of Support** (optional): Letters of support are not required, but are encouraged (e.g., advisory committee members and health system partners/organization collaborators).

Round 2: Review Criteria

It is a requirement that review of CTSI pilot proposals should address the NIH review criteria. 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:

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?

4. Innovation: Does the project shift current research or clinical practice paradigms, use novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

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 allotted?

Program-Specific Criteria:
- Does the project indicate a clear path to impact plan?
- Does the project reflect true collaboration with partners?
- Does the project have potential for sustainment?