1. **Introduction/Overview**

CTSI requests applications for the Engage Pilot Award program. The Engage program seeks projects that will test new ways to involve individuals in maintenance of their own health. In particular, we are looking for solutions that give agency and responsibility primarily to the non-medical individual. In this way, Engage applications will be distinct from other initiatives that develop treatments or interventions that will be pushed from medical providers to patients.

Because of the focus on individuals in the community, this program will emphasize and require community-engaged methodology. The structure of this award will include support from the CTSI Community PARTners Core, and we intend that built-in support will encourage applications from investigators who may not have prior experience with community-engaged methodology.

Examples of projects that might be responsive to this request include

- A strategy to improve diet in persons at risk of metabolic syndrome
- Self-monitoring of weight or edema in persons with heart failure
- Awareness of lifestyle changes to affect blood pressure
- Modification of substance use, including alcohol or tobacco

Program Requirements

 Projects are required to conduct at least one Community Engagement Studio (https://ctsi.pitt.edu/research-services/core-services/community-partners/stakeholder-engagement-studios/) and to establish a meaningful partnership with a community group or organization. Budgets must include direct costs for studios and equitable compensation for community partners with whom the research is being co-created. Examples of ways to budget for community partners are stipends for attending meetings, yearly honoraria for community-based organizations, or hourly budgeting for involvement in the research project.

Applicants are strongly encouraged to work with the Community PARTners Core at CTSI during the development and planning of the projects. The Community PARTners Core is made up of Community Engagement Coordinators and Core Directors that are experts in community-partnered research methodologies. The PARTners core can also assist teams in how to budget for community partnerships in research.

Proposals should also describe how they will disseminate results to the community in engaging and accessible ways; support is available from the Community PARTners Core for applicants who need assistance with community-level dissemination. Applicants should also create a plan for maintaining these relationships and committing to ongoing community-engaged research.

CTSI Assistance (Optional)

If you would like to request a consultation, please fill out this form. Select "Community Engagement Support" and make note of your intention to apply for the Engage Pilot Awards in the additional information section.

2. Key Dates

Round 1 LOI Submission Deadline:
November 8, 2023, by 11:59:59 p.m. EDT

Round 1 Notification:
November 17, 2023

Round 2 Full Proposal Submission Deadline:
December 8, 2023, by 11:59:59 p.m. EDT (by invitation)

Round 2 Notification:
December 21, 2023

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

3. Funding Information

This Pilot offers University-affiliated investigators up to $45,000 in funding. Projects are required to conduct at least one Community Engagement Studio (CES) or to establish a meaningful partnership with a community organization.

Special consideration is given to applications that develop and describe plans for the following:

- Maintaining and enriching relationships established during the award period.
- Disseminating findings in unique and creative ways (e.g.., use of infographics)

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 the 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 program is eligible for the Training Bonus Award (https://ctsi.pitt.edu/funding/funding-opportunities/bonus-funding-for-ctsi-pilot-awards/). Because community engagement is a core requirement of this program, this program is not eligible for the Community Engagement Bonus. Applications that intend to apply for a Bonus Award should state that intent in the application according to the instructions for the Bonus.

4. **Eligibility**

The Principal Investigator (PI) must be a University of Pittsburgh faculty member; 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 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 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.

5. **Submission and Review Information**

How to Submit

Round 1: Letter of Intent

Please submit a letter of intent that summarizes the proposed research. Each submission must include the following sections:

A. <u>Study Title:</u> Include the title of the proposal at the top of the page, along with the PI name and contact email.
B. <u>Abstract and Scope of Work (500-word limit):</u> Please provide a high-level overview of the study and the proposed work. Be sure to indicate how the study will focus on engaging individuals in their own health and how the proposal represents a new direction for the PI.
C. <u>Study Team:</u> Please provide the names and affiliations of all members of the study team and a brief description of their roles (25-50 words per person).
D. <u>Suggested Reviewers:</u> To facilitate the final round of review, please suggest two to three faculty members, not from your department, who may be qualified to serve as scientific reviewers. Include email addresses for each suggested reviewer.

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 submitted before 11:59 p.m. on **November 8, 2023.** Additional or supplemental materials cannot be accepted after the deadline and will not be reviewed.

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 the thematic emphasis individual health agency, the utilization of community engagement methodology, and perceived impact. The results of this evaluation will

determine which investigators will be invited to submit a full proposal for the second round of Engage.

Round 2: Full Packet Submission

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 submitted before 11:59 p.m. on **December 8, 2023.** 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:

A. Project Overview (one page): The first page should include the following:

1. Scientific Abstract (250-word limit): Briefly summarize the proposed work.
2. Focus on Community Engagement (100-word limit): Indicate how community participation will be used in the proposed work and how the proposed work represents a new direction for the investigators.

B. Research Plan (three-page limit, 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:

1. Specific Aims
2. Significance
3. Innovation
4. Approach

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

D. 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. We encourage budgeting for community member participation in the science. Budget should include costs associated with the required Community Engagement Studio. Applicants should work with the CTSI Community Engagement Core to estimate these costs. Additional considerations around language equity and accessibility are also highly encouraged.

　　　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

E. 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. 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.

F. Human and/or Animal 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.

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. Likewise, the Institutional Animal Care and Use Committee (IACUC) must approve any projects involving animal subjects prior to final funding approval.

Applicants must describe any human and/or animal 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 / IACUC review is encouraged. Similarly, this section should discuss if other special regulatory approval is required prior to funding: Human Stem Cell Research Oversight (hSCRO), Institutional Biosafety Committee (IBC), Committee for Oversight of Research Involving the Dead (CORID), Radiation Safety Office (RSO), etc.

G. NIH Biosketches (no page limit)**:** Include biosketches for the Principal Investigator and key members of the research team. Use new as of September 2017.

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:

7. Emphasis on individual health agency and engagement: Does the project focus on evaluating approaches to helping people gain agency in their health?

8. Utilization of Community Engagement Methodology: Does the project have a clear plan to use community engagement studios and community partnerships?