CTSI's Re-Impact Pilot Program Awards: Improving the lives of older adults

1. Introduction/Overview

The Re-Impact pilot awards are designed to stimulate new translational research across the lifespan. This year's focus, co-sponsored by the Clinical and Translational Science Institute (CTSI) and Department of Bioengineering, is on the translation of research into devices and/or interventions that can have a positive impact on older populations. This funding opportunity is designed to encourage new translational research addressing clinical needs, biological processes, or therapeutics to improve the lives of older adults. In addition to funding, specialized support and consulting from experts across the university will be made available. The Human Factors Laboratory, housed within the Department of Bioengineering, can provide expertise in designing for older populations, prototyping, and testbed capabilities for device development and evaluation. The Alzheimer's Disease Research Center (ADRC) will offer advice on projects addressing cognitive issues. Pitt's Pepper Older Americans Independence Center will offer guidance for those projects involved in mobility improvement.

The Re-Impact program encourages a broad spectrum of approaches, including biological, physiological, technological, therapeutic and psychosocial mechanisms to improve health. This RFA is specifically focused on the needs of older adults. To be responsive to this opportunity applications should address a focused need or scientific question that has the potential to be developed into an intervention or device that will improve the health and quality of life for older populations.

Because this funding opportunity is for pilot studies, applications should include an explicit discussion of how the intended aims can lead to larger funding in the future, whether through the NIH National Institute on Aging, or other extramural opportunities.

Examples of projects that would fit this opportunity include:

- Robotic assistance for mobility
- Wearables for real-world health monitoring
- Cognitive assistance devices or apps.
- Medication management systems
- Devices to reduce osteoporosis risk
- Therapeutic virtual reality for pain relief, strength training, memory exercises

2. CTSI Assistance (Optional)

If you would like to request a consultation, please email Aleks Zivic abz17@pitt.edu. Make note of your intention to apply for the RE-Impact Pilot Awards in the subject line, and we are happy to provide feedback about the program or your application.

3. Key Dates

Round 1 Applications Open: Wednesday, December 11
Round 1 Letter of Intent Deadline: Friday, January 24 by 11:59 p.m. EDT

Notification to Advancing Teams: Monday, February 3

Round 2 Full Proposal Submission Date: Friday, February 21 by 11:59 p.m. EDT (by invitation)
Notification to Awardees: Monday, March 10

Anticipated Earliest Start Date: May 15

All projects must start by June 1, 2025

4. Funding Information

Award funding of up to $25,000 is available to cover direct costs; no indirect support will be provided. The award period will last for 12 months, beginning when all regulatory and administrative approvals have been received. ***Under no circumstances, do the Re-Impact pilots have any mechanism for no-cost extensions****; any funds that are not spent during the award period will be forfeited.*

*Before any funding can begin, awardees must provide documentation of all necessary regulatory approvals (IRB, IACUC, hSCRO, IBC, CORID, etc.). Once regulatory documentation is provided, awarded projects will undergo an administrative review from NCATS, which may take up to 30 days. Funding cannot begin until projects have been approved by *NCATS.*

When submitting your new IRB application for this project, please add Susan Sandusky (SLS127@pitt.edu) as Key Personnel under the Study Team Members with her qualifications as "CTSI Regulatory Support for CTSI Pilot Grants."

5. Eligibility

The Principal Investigator must be a University of Pittsburgh faculty member; postdoctoral trainees and trainees in clinical training programs are not eligible to serve as PI. Faculty member 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. Partnerships with non-academic community partners are also acceptable.

6. 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. Study Title: Include the title of the proposal at the top of the page, along with the PI name and contact email.
B. Abstract and Scope of Work (500 word limit): Please provide a high-level overview of the study and the proposed work.
C. Study Team: 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. Suggested Reviewers: 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 **Friday, January 24, 2025.** 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 primarily be evaluated based on the inclusion of specified populations and the impact for those populations, as well as the overall scientific 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 of RE-Impact.

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 **Friday, February 21, 2025.** 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.

B. Research Plan (five-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
5. Path to Impact Plan (250-word limit): 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. Path to Impact Examples

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.

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.

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.
8.