

Health Innovation in Translational Science (HITS)

Overview

Translational Science is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public. According to the National Center for Advancing Translational Sciences (NCATS), one of the guiding principles that underpin this definition is the emphasis on creativity and innovation, particularly as it applies to research design, conduct and facilitating factors, with the goal of increasing impact of the research.

As a function of CTSI's commitment to biomedical health innovation, the aim of this funding opportunity is to stimulate health innovation via translational science, with Graduate Students leading product development as Co-PIs. Examples of relevant health innovations can be:

- **Therapeutic** - applied biological product, either chemically synthesized or naturally occurring, whose novel action can be used to diagnose or treat a specific health ailment.
- **Device** - instrument, wearable, consumable, or other tool used for the diagnosis, monitoring, treatment, or prevention of a specific health ailment.
- **App** - novel software application or digital tool used to assist decision-making workflow of clinicians, or in the self-management of a user's health via smartphone or browser.
- **Clinical Workflow** - novel clinical process modification that improves patient outcomes.
- **Public Health / Social Impact Program** - community-based solution to improve the well-being of a larger segment of the population.

**This funding opportunity will not consider proposals which will involve clinical trials.*

2. CTSI Assistance (Optional)

For CTSI pilot program related questions, please email Aleks Zivic (abz17@pitt.edu). To request a consultation on whether your proposal fits the scope of health innovation, please email Aneesh Ramaswamy (akr40@pitt.edu).

Key Dates

Round 1 LOI Submission Deadline: Wednesday February 5, 2025 by 11:59:59pm EST

Round 1 Notification: Friday February 14

Round 2 Full Proposal Submission Deadline: Monday March 10, 2025 by 11:59:59 pm EST

Funding Notification: Thursday March 27, 2025

Award 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.

Please be aware, under no circumstances, do the HITS 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. Because of this, all applicants are strongly encouraged to have the necessary regulatory documents ready for submission.

5. Eligibility

The HITS Pilot Awards competition is focused on supporting the work of graduate student researchers (master's or doctoral) at Pitt working with a formal mentor. As such, each project should have at least two investigators:

- Principal Investigator (PI): the PI must be a faculty member at Pitt.
- Co-Principal Investigator: the Co-PI must be a graduate student currently enrolled in either a master's or doctoral degree program at Pitt.
- Other Co-Investigators (Co-Is) may be included but are not required.

The PI should serve as a mentor to the Co-PI, as either the academic mentor or academic adviser to the Co-PI. Submissions should describe clearly the role of each investigator, with sufficient detail for reviewers to identify that all listed team members will have an active role in the research.

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 nonacademic community partners are also acceptable.

6. Submission 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 and Co-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. Please include how this proposal represents a new direction for the PI.
- 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 **Wednesday, February 5, 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 Responsiveness to the RFA, Overall Impact of the proposed work as well as the Overall Scientific Merit 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.

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 **Monday, March 10, 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:
Cover Sheet (Include following details)
 - Project Title
 - Study Team (Please include the name and preferred contact email for the:
 - Principal Investigator (faculty member)
 - Co-Principal Investigator (mentored graduate student)
 - Scientific Abstract (maximum 250 words): summarize your proposal

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](#): (250-word limit): Please describe the impact of your work and the steps you will take to realize it. 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. Please click [here for specific 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:

