



**Clinical and Translational Science Institute (CTSI)
Bridges to Translation RFA
Pilot Project Funding Available**

Release Date: February 6, 2017

REQUIRED Letter of Intent (LOI) Due Date: March 24, 2017

Application Due Date (Invited Applicants Only): May 1, 2017

Anticipated Award Date: July 1, 2017

I. INTRODUCTION

The Penn State Clinical and Translational Science Institute (CTSI) invites applications for pilot projects designed to break down roadblocks across the translational spectrum. The long-range goal of the Penn State CTSI is to develop, implement, and make available to the community at large new methods to promote health and to predict, prevent, and effectively treat human disease. The translation of biomedical and health discoveries to application is a long and complex process with high costs and substantial failure rates. The CTSI seeks to fund pilot projects that address roadblocks at any stage in the translational process, including but not limited to:

- Projects that move research from one translational phase to the next (e.g., T1 to T2)*
*Translational Spectrum of Research:
T1 Translation to Humans; T2 Translation to Patients;
T3 Translation to Practice; T4 Translation to Population Health
- Projects that seek to develop a novel technology, tool, or methodology including new collaborations with industry
- Projects focused on multidisciplinary collaboration between basic science researchers and clinical investigators, across departments and campuses
- Projects focused on dissemination and implementation
- Projects that develop novel statistical methods or models to analyze data, including population health
- Operations-focused projects designed to speed up the process of translation including training for clinical research staff, team science/mentoring programs, patient recruitment initiatives, and regulatory and ethics training
- Projects focused on integration of translational science across its multiple phases and disciplines within vulnerable populations and across the lifespan
- Projects that focus on the ethical challenges involved with translational research
- Projects that focus on the training or education of research teams involved in translational

research

- **Special consideration** will be given to projects that focus on development or applications of:
 1. Telemedicine
 2. Investigator-initiated clinical trials, including new trials or augmentation of ongoing trials
 3. Community engagement to involve primary healthcare providers and/or other community organizations/advocacy groups, in research

The CTSI will provide up to \$300,000 to support between 5-10 multi-investigator projects. Typical awards are in the \$35,000-65,000 range. Projects should be completed in 12 months. Successful applications will describe how the project will advance clinical and translational science. Also, given the enabling capacity of engaged communities to be a part of the translation process, applications not focused on Priority # 3 above should specify plans for community connections, with “community” being defined broadly (e.g., patients, health care providers, community organizations, industry, educators, researchers, other groups within the university). Community connections might include plans for outreach and dissemination beyond the scientific community.

II. ELIGIBILITY CRITERIA AND CRITERIA FOR REVIEW.

A. Eligibility

The Principal Investigator (PI) must hold a Pennsylvania State University faculty appointment. This includes faculty members at all Pennsylvania State University campuses. Proposals from multi-disciplinary, cross-campus teams will be most competitive.

In addition, to be eligible, each project must include:

1. Compelling statement of the project’s translational potential and a description of the community(ies) the project will serve.
2. A research plan with defined “next steps” beyond the pilot funding. We are particularly interested in plans for seeking external funding; consideration of potential product development, and dissemination would also be relevant here.
3. A detailed budget with justification. Limited salary support is available for faculty, and no more than \$10,000 (fringe is not included in the \$10,000 limit) annually may be allocated to faculty salaries for a given project. (Additional funds may be budgeted for research coordinators, research techs, nurses, graduate student salaries, etc.)
4. A detailed project timeline of 12 months. (Note that progress reports are required at regular intervals throughout the course of the project.)

Funds may **not** be used to support:

- Student or postdoctoral fellow independent research (note that portions of stipends are permitted for postdocs and graduate students working directly on the pilot project)

- Tuition
- Publication costs
- Funding for activities typically supported by departments and colleges (e.g., travel to conferences, basic software purchase)
- Summer salary (where applicable)

B. Criteria for Review:

Reviewers will consider each of the five review criteria (below) to assess merit.

- **Significance:** Does the project address an important problem or critical barrier to improving health and/or healthcare? Is the project's translational potential clear and compelling? Does the project involve any special emphasis topics (i.e., telemedicine, clinical trial proposal, community engagement of primary care physicians or organizations in research)?
- **Innovation:** Does the project challenge or shift current research or practice paradigms, advance novel concepts, approaches/methods, instrumentation, interventions, or apply these in novel ways?
- **Approach/Scientific Rigor and Reproducibility:** Are the procedures and analysis plans justified and appropriate to accomplish the specific aims? Will the project provide the foundation for a competitive proposal for external funding and dissemination? Was the community connection for the project well described? How does the proposed project address these concepts per the NIH definition, <https://www.nih.gov/research-training/rigor-reproducibility>?
- **Investigators:** Do the PI and collaborators have the expertise needed to conduct the project? Do the investigators capitalize on differing disciplinary perspectives?
- **Collaboration:** How does the proposed project benefit from the collaboration of investigators? Is there a new member of the investigative team? Are the disciplines represented complementary, and does the research plan appear to build on the expertise of the entire team? Does the team leverage expertise from multiple disciplines and across the University?

III. APPLICATION PROCESS

The application for pilot study funding is a two-step process: 1) Letter of Intent (LOI), and 2) Full proposal (upon invitation) based on review of the LOIs.

A. Letter of Intent (2-page limit)

Page 1: Proposal title and names/degrees and institutional affiliations of all investigators involved in the project

Page 2: Specific Aims stating concisely: (1) the goals and expected outcomes of the proposed research; (2) a statement of the translational significance of the project and how that scientific knowledge will translate into health impact; and (3) how the pilot study will lead to substantive

extramural funding (e.g., a NIH R01, R21, or comparable grant).

Due Date: March 24, 2017, 12 pm EST. The Letter of Intent must be submitted to be considered for funding.

Applicants will be notified by **April 1, 2017** with a decision as to whether or not their proposals have been chosen to move forward to the second tier of the application process.

Submit Letter of Intent as a **single PDF file** titled as follows: Last name of the PI-LetterofIntent-B2T3 - Receipt Date (e.g., Sauder-LetterofIntent-B2T3-03242017) to CTSI@hmc.psu.edu.

B. Full Application (if invited to submit; see page limitations for each section)

Remember that reviewers may not have specific expertise in your area. Therefore, proposals should be written for a broad academic audience.

1. Proposal Format

a. Cover Page (1 page)

1) Title of Proposal

2) Names of Principal Investigator, Co-Investigators and Collaborators (include degree, departments, and college);

3) Lay abstract (300 word max) – provide a succinct overview of the proposal, including how the proposal will address the translational roadblock. Assume that reviewers do not have technical knowledge in a specific field. Avoid or explain technical jargon, field-specific terminology, and acronyms.

b. Body of Application (limit 5 pages)

1) Specific Aims: List the specific aims and the rationale for each;

2) Significance/Innovation: Describe how addressing the study aims will promote the translation of scientific knowledge into health impact; describe how the concept, strategies, etc. are innovative;

3) Approach/Scientific Rigor and Reproducibility: Describe the activities that will be undertaken to address the study aims; include description of how scientific rigor and reproducibility will be ensured;

4) Community Engagement: Specify plans for community connections, with “community” being defined broadly (e.g., patients, health care providers, community organizations, industry, educators, researchers, other groups within the university);

5) Investigators and Environment: Describe the qualifications of the investigative team, the role each team member will perform, and resources in the environment that will support the conduct of the study. Indicate if this is a new team or if there is a new member of the team. Describe multidisciplinary and, if included, the cross campus collaborations within the team;

6) Timeline, Anticipated Outcomes and Future Plans: Describe the project timeline over the 12-month period of requested funding. Plans for specific products and outcomes should be specified, including dissemination of results. Examples include: presentations at CTSI events, grant submissions, papers submitted, or the development of a new interdisciplinary team for future grant submissions. For external funding, please include potential sponsor(s) (e.g., specific NIH institute) and the expected date for submitting the first application.

c. Literature Cited

d. CTSI Resources to be used

The following services are available through the CTSI:

Clinical Research Center (UP and/or Hershey); BERD (Biostatistics); REDCap; i2b2; EMR Data; Ethics Consultation; Community Engagement Consultation; Other (specify)

Please indicate which services would be useful for this project in your application. Please utilize the CTSI consultation services found at: <http://ctsi.psu.edu/ctsi-consultation-services/>

e. Budget and Justification

Provide an itemized budget and budget justification including salaries, fringes, and other expenses, etc., (IAFs will not be used). No more than \$10,000 (direct salary) may be allocated to **faculty** salaries in any project year. Fringe is not included in the \$10,000 limit. (Funds may be budgeted for research coordinators, research techs, nurses, graduate student salaries, etc.) Use of the SIMS budget is preferred. An acceptable template is available here: <http://ctsi.psu.edu/research-resources/fundingopportunities/>

As part of the budget justification, describe the roles and experience of the investigators and any other personnel included in the proposal.

F&A costs (indirects) are not provided.

f. Provide the name email address and phone number of your department's budget coordinator.

g. NIH Biosketches for the PI and each co-investigator and/or collaborator.

Format for biosketch available at: <http://www2.med.psu.edu/researchconcierge/new-nih-biosketch/>

Due Date (if invited): May 1, 2017

Submit the full application as a **single PDF file** titled as follows: Last name of the PI-Bridge2Translation3-Receipt Date (e.g., Sauder-Bridge2Translation3-05012017).

IV. FORMAT AND SUBMISSION OF PROPOSALS

Proposals should be single-spaced, in Arial 11 font, left-aligned with half-inch margins. Appendices should not be included. Your proposal must be complete when submitted and include

all items noted above.

Interested investigators are encouraged to consult with the CTSI's Informatics, Biostatistics, Community Engagement, and/or Ethics core areas prior to submission. To request a consultation, [submit a CTSI service request form](#).

Submission for Letter of Intent & Full Application Submission:

Submit both the Letter of Intent & Full Application (if invited) by email to CTSI@hmc.psu.edu on or before the deadlines indicated above.

Send only 1 PDF document for each submission using the appropriate naming scheme described above.

NOTE: For projects that will be funded, additional 'Just-in-Time' information will be required. This will include a signed letter from the department head/chair or vice chair or vice dean for research as well as a note from each collaborator that acknowledges his/her participation (e-mail is acceptable) if not already included in the application. This will also include Institutional Review Board (IRB) and/or IACUC approval as relevant, along with conflict of interest information.

NIH/NCATS has new guidelines regarding a prior approval process for any funded project that includes Human Subjects. This will require additional documentation and time (generally less than 30 days) so please take this into account when planning the timeline of the project. Finally, the CTSI's Community Engagement Research Core (CERC) will review the funded applications and make suggestions to strengthen community engagement within the proposal. The PIs will have a chance to discuss and implement these suggestions offered by the CERC. Additional funds required for implementation will be offered to specific projects as recommended by the CERC.

The PI and/or key personnel of the submitted application must agree, if called upon, to serve as reviewers of CTSI proposals for future rounds of pilot study funding and will be encouraged, where appropriate, to present their work at the annual ACTS Conference or related venues.

Questions about this Pilot Project Funding opportunity should be sent to: CTSI@hmc.psu.edu.