



NCATS Pilot Funding Request for Applications (RFA) Center for Clinical and Translational Sciences

The Center for Clinical and Translational Sciences (CCTS) at UTHealth Houston is now accepting applications for pilot studies. This pilot funding will support novel, unfunded, clinical studies with translational research and translational science scope. The awarded dual-scoped proposals are expected to generate preliminary data for extramural investigator-initiated opportunities. Four pilot grants of **up to \$25,000 each** will be awarded.

The application deadline is Monday, February 17, 2025, at 5 PM (CST).

In alignment with CCTS's goal to reshape the translational landscape to become faster, more efficient, and impactful, the primary goal of this RFA is to promote the scientific knowledge and operation innovations of clinical translation as we address existing roadblocks that have hindered moving research into clinical practice.

The applicant (principal investigator, or PI) must (i) hold a faculty appointment at any of the six CCTS partner institutions: UTHealth Houston, The University of Texas MD Anderson Cancer Center, Rice University, UT Tyler Health Science Center, UT Rio Grande Valley, or Texas Tech Health EI Paso and (ii) not have prior significant research funding (i.e. history of a R01 or large grant). No portion of the funding can be transferred to an institution other than those listed above, and all funds must be used within the project funding cycle (07/01/2025 to 06/30/2026).

The PI must identify a translational research (TR) mentor in the application. A translational science (TS) mentor will be assigned by the pilot research committee (PRC) at the CCTS. Both mentors will provide expertise and assist with the design and execution of the work described in the proposal. Both mentors must be employed by and have a faculty appointment at one of the six CCTS partner institutions. The TR mentor should be an expert in the project's related clinical field (e.g., neurologist, pulmonologist, etc.) The TR and TS mentors are required to provide their PIs with coaching and practical training, foster connections, and support their learning environment.

The proposal must include two specific aims: one related to TR and another related to TS. The TR aim must address a problem with applicable results that may directly benefit human health. The TS aim should address and test an improvement to an impediment of the successful adoption or dissemination of the proposal's TR aim. Thus, the TS aim will address the challenges of moving the clinical research innovation (TR aim) to the bedside or into the community. More information and examples of TS pilot studies can be found on page 4 of this RFA.

Applications will be evaluated by a panel of reviewers convened by the PRC. Reviewers will be invited to identify 4 proposals as most likely to generate a TR and TS significant contribution, and to match themselves as TS mentors of each selected proposal. The selected PIs will be expected to review the proposal aims and content with their TR and TS mentors and submit their revised proposal to the PRC by Monday, March 31, 2025, at 5 PM (CST). Upon PRC acceptance, the awarded proposals will be announced, and PIs will be requested to provide additional documents requested by NCATS.

Applicants must complete the Application Checklist (page 3 of this RFA) and submit the documents listed in the order as indicated. Submissions are required to be typed using single-spaced, Arial, 11-point font, with 0.5" margins and saved in PDF format as one file. Submissions that are not in the correct format (PDF) may not be reviewed.

Key dates and activities related to this RFA are summarized below.

Date	Activity
00/47/0005 (Mass)	Deadling for anyling time submission
02/17/2025 (Mon)	Deadline for application submission
03/03/2025 (Mon)	Panel of reviewers selects 4 proposals and assigns TS mentors to the selected PIs
03/31/2025 (Mon)	Deadline for re-submission of revised proposals to the PRC
04/14/2025 (Mon)	PRC announces awarded proposals and requests PIs to provide NCATS required additional documents
05/12/2025 (Mon)	Deadline for submission of NCATS required additional documents
06/02/2025 (Mon)	Deadline for CCTS submission of proposals to NCATS
07/01/2025 (Tue)	Awarded proposals that are approved by NCATS begin 2025-2026 funding cycle

Applications should be submitted via email to Yuko Yamamura at Yuko.Yamamura@uth.tmc.edu by **Monday**, **February** 17, 2025, at 5 PM (CST). Questions may also be submitted to the same email address.

Collaborative Research Pilot Project Awards Program - Application Checklist 1. ☐ Title of project 2. Does the study involve human subjects? YES □ NO 🗆 (If YES, additional documents will be required if application is awarded.) If you are unsure whether your project qualifies for human subjects research, please refer to this link: https://grants.nih.gov/policy/humansubjects/research.htm 3. Current valid IRB protocol approval letter for the study, OR ☐ Check here if IRB approval has been applied for, but not yet obtained. (Proof of completed IRB submission can be a screenshot as it will be vetted with the IRB. In-progress submissions will not be accepted.) ☐ Check here if an IRB approval is not needed (provide rationale). Important: If the pilot project is an offshoot of a parent study, the pilot study must be novel and have its own IRB submission listing the applicant PI as the main PI for the submitted pilot study. 4. Name of principal investigator (PI), department/school and CCTS partner institution 5. Names of co-investigators (Co-I) if any, department/school and CCTS partner institution 6. Name of the TR mentor, department/school and CCTS partner institution 7. One-page structured proposal with the subheadings: Introduction, Hypothesis, SpecificAims (Specific Aim 1 will be the TR Aim, and Specific Aim 2 will be the TS Aim), Methods, Analysis, and Anticipated Results describing the proposed study. References should be included on a separate page. 8. NIH biosketch and completed NIH Other Support form for the PI, Co-I (s) and TR mentor. Forms and examples available at: http://grants.nih.gov/grants/forms/biosketch.htm and http://grants.nih.gov/grants/funding/phs398/phs398.html 9. One-page budget with a brief explanation of the purpose and necessity of each listed item. Items such as salaries, equipment, supplies, and patient-care costs may be included. Salaries cannot be more than 60% of the budget. This includes PI funding which is capped at no more than 5% of their salary.

<u>Important:</u> The minimum required effort for the PI and Co-I/s is 2% while there is no effort requirement for mentors. No indirect costs will be paid, and the following are not allowed as budget items: faculty salary, travel, or subcontracts.

10. ☐ All items in one, single-spaced PDF, using Arial 11-point font, with ½" margins.

What is Translational Science?

Pilot funding is provided by the National Center of Advancing Translational Sciences (NCATS) via the Center for Clinical and Translational Sciences (CCTS), one of over 60 CTSA Hubs across the country. NCATS defines translational science (TS) as the systematic process of <u>identifying and overcoming barriers</u> that limit or stop the translation of research to interventions that improve the health of people. Examples of translational science include, but are not limited to <u>identifying causes and application of strategies to overcome:</u>

- incorrect predictions of toxicity or efficacy of new drugs
- inefficient clinical study/trial operations
- · barriers to clinical adoption and patient knowledge/engagement
- ineffective clinical study/trial recruitment/retention/diversity
- inefficient clinical research administrative and regulatory processes
- gaps in public health crisis preparedness, health policy changes and dissemination
- lack of data interoperability or the inability of different information systems, applications or devices to access, exchange, integrate and cooperatively use data

Translational barriers can affect all research, regardless of the specific disease or clinical condition. "Through the conduct of pilot projects, investigators also have the important opportunity to <u>identify and test strategies</u> to overcome barriers in the conduct of that research, so these issues can be minimized or eliminated in the subsequent work" (CTSA Hub, University of Alabama at Birmingham, UAB).

Translational Science in Pilots

Three pilot studies performed at the UAB Center for Clinical and Translational Science that exemplify TS projects are listed below, and more information may be viewed at: https://www.uab.edu/ccts/research-commons/funding-opportunities/pilot-program/pilot-toolbox/translational-science-in-pilots.

Translational Barrier: Access to patient information at the point of care.

Health care providers depend on patient information at the point of care to guide treatment plans. Increasingly, providers can utilize genetic information to guide care plans. However, access to relevant genetic information and reports at the point of care presents a barrier. Dr. Courtney Watts Alexander, PharmD, BCPS, BCOP, Assistant Professor in Auburn University's Harrison College of Pharmacy plans to traverse this barrier at the Tuscaloosa VA Medical Center. She seeks to integrate pharmacogenomic screening results into patients' health records to guide health care providers in choosing a drug treatment plan, helping the right patients receive the right drug therapies at the right time.

Translational Barrier: Fidelity of remote data collection.

Remotely delivered health interventions represent a relatively new era of clinical research. However, remotely measuring health benefits represents a barrier to larger utilization and participation, particularly for individuals with disabilities and transportation issues. Dr. Byron Lai, PhD, Assistant Professor in UAB's Department of Pediatrics and Lakeshore Foundation, is addressing this gap by validating a method to remotely measure health outcomes, which is expected to increase the enrollment and retention of healthy and disabled participants in remotely delivered exercise studies as it will minimize or remove the need for participants to report to a clinical laboratory for measurements.

Translational Barrier: Patient Recruitment

Participant and patient recruitment to clinical studies and clinical programs, respectively, are key to health equity. The demographics of patients engaging the Information is Power (IiP) initiative, an inherited risk cancer screening program, did not reflect the area served. To address this gap, Dr. Sara Cooper, PhD, Faculty Investigator at Hudson Alpha Institute for Biotechnology, engaged a new patient recruitment method designed to increase participation by individuals underrepresented in the program and identify drivers towards their participation to inform future programmatic outreach.