Consortium for Translational & Precision Health

Consortium for Translational and Precision Health Pilot Awards

Frequently Asked Questions

I. What is translational science?

Despite innumerable fundamental discoveries in various biomedical fields, only a small number are transformed into a functional output that can be implemented on a population scale. Translation is the process by which these discoveries work their way from bench to bedside and beyond. However, this process is slow and filled with numerous roadblocks that can halt progress to a standstill. Translational science applies scientific principles to the process of translation by developing interventions to overcome common causes of inefficiency and failure in translational research projects. Through scientific and operational innovation, translational scientists develop strategies to improve the efficiency and effectiveness of the translation process for all research.

Examples of roadblocks that can be addressed by translational science can be found below. A more extensive description of translational science can be found on the NCATS website and in the 2021 CTS paper, Opportunities and challenges in translational science. Some examples of how a specific use case could be applied to address a clinical and translational science roadblock can be found in this guidance for a similar pilot program from the Colorado CTSA.

- Understanding of translation and translational science
- Target qualification*
- De-risking undruggable targets/untreatable diseases*
- Predictive efficacy
- Predictive toxicology
- New therapeutic modalities; repurposing*
- Biomarker qualification*
- Data interoperability and transparency*
- Registries and natural history studies*
- Clinical diagnostic and outcome criteria
- Patient/community engagement
- Clinical trial participant recruitment and diversity*
- Single/harmonized IRBs
- Clinical trial operational efficiency
- Clinical trial networks
- Adaptive clinical trial designs
- Electronic Health Records for research
- Shortening time of intervention adoption*
- Access and adherence
- Pharmacoepidemiological studies and comparative effectiveness trials*
- Integration of project management
- Incentives/credit for team science
- Incentives/credit for health improvements
- Education/Training (scientific and cultural)
- Collaborative structures, agreements, IP management

Major rate-limiting translational roadblocks that are the focus of translational science. *Barriers that have been identified as being particularly prone to failure, delay in progression, and/or high cost and therefore high priority for innovation. IP, intellectual property; IRB, institutional review board. From: Opportunities and challenges in translational science, *CTS*, 2021.

II. My project is about a specific disease/therapy/intervention; does that count as translational science?

A pilot can focus on a specific disease, therapy, or intervention if the project is a use case for an application or intervention that can be used to address a translational roadblock. The application or intervention must be generalizable to other translational contexts. How the study addresses a translational roadblock and how the results of the project can be generalized broadly should be clearly explained in the "Discussion of the CTS problem to be addressed" section of the application.

III. Is there a way to check if my idea is translational science?

If you are unsure whether your proposed project is considered translational science, please email a brief description how you believe the proposal will address translational science (up to 30 lines of text) to CTPH@bcm.edu by **October 10, 2024**. Where possible, we will make suggestions to help align the proposed project to the goals of the program.

IV. How many applications can I submit?

The CTPH Grants Management System will allow a PI to submit up to two applications. However, please note that new investigators (those with NIH new Investigator status) are only permitted to be PIs on up to two CTS pilot awards within a 4-year period, and senior faculty can only be PI on one award every 4 years. These requirements will be taken into consideration should both projects be recommended for funding by the review committee.

V. Does my research team have to include members from both partner institutions (BCM and UH)?

The research team is not required to have members from both Baylor College of Medicine and University of Houston. However, the CTPH is strongly committed to facilitating multidisciplinary collaborations between the partner institutions. If there is an investigator at a partner institution with whom you would be interested in starting a conversation about collaboration, please contact us at CTPH@bcm.edu, and we will try to facilitate that meeting.

VI. Can I have a Co-Investigator from outside the partner institution?

No. We cannot fund salary support for individuals outside of Baylor College of Medicine or University of Houston.

VII. Can I have a Co-Investigator from outside the partner institution if they have zero effort?

No, the RFA states that all Co-Investigators must be budgeted for at least 1% effort. Therefore, investigators from institutions outside of the CTPH cannot be included in the application.

VIII. Do I need to include a trainee (i.e., an undergraduate student, a graduate student, or a resident) in the project?

One goal of the CTS Pilot program is to engage learners in mentored research and team science. Thus, including a trainee is not required, but projects with trainees will be given preference in funding decisions.

IX. I have or anticipate getting a Career Development Award based on the proposed topic. Can I still apply?

A Career Development Award will not conflict with the CTPH Pilot award. Early-career investigators are strongly encouraged to apply.

X. Do I need prior IRB/IACUC approval?

Yes. Because these grants use NIH funds, they require NCATS regulatory approval, which can only be applied for after receiving institutional IRB and/or IACUC approval. NCATS regulatory approval can take up to 5 weeks once the correctly completed forms are submitted. Given the short award period, we are requiring that applicants have their institutional approvals in place at the time of submission.

XI. Do I need to have preliminary data?

Pilot proposals do not need to have preliminary data to be competitive for funding.

XII. How many awards will be funded?

The number of awards funded will vary based on the proposed budgets of the projects, the federal funding level, and the institutional distribution of funds.

XIII. For what can the funds be used?

All expenditures must comply with the NIH's grants policy.

XIV. Do I need to budget indirect costs?

The budget should only include direct costs. Indirect costs are claimed by the host institution on these funds for administration of projects.

XV. Will applicants receive reviewer comments?

Scored applicants will receive reviewer comments by email after awarded grants are announced. Proposals that qualify as translational science will be able to revise and resubmit the proposal once in future funding cycles.

XVI. Does my project need to be submitted to NIH for prior approval?

If your projects is selected for funding and uses animals or human subjects, it is subject to review by NCATS. In most cases, the project cannot start until approval has been received. The exact requirements for an NCATS prior approval depend on the nature of the project. We suggest reviewing the NCATS requirements for vertebrate animals and human subjects. In general, we encourage you to complete your paperwork as you would for an NIH proposal, i.e., using the criteria outlined by OLAW for vertebrate animal studies and by the eRA Human Subjects System for human subjects studies. Having these documents prepared in advance will facilitate the release of funds if your project is selected.

XVII. If awarded, when can I start my study?

If the project does not require prior approval by NCATS, funds will be made available January 2025. If the project requires prior approval by NCATS, funds will be made available once approval is given. Delays in completing and submitting the necessary paperwork will delay the start of funding.

XVIII. When must the funds be spent by?

All funds must be spent by July 31, 2025.

XIX. Can I get a carry-forward?

No. The terms of the CTSA parent grant do not allow for carry-forward of pilot grant funds.

XX. How long will you track the progress of my project?

The Pilot Awards are funded by NCATS, and every year, NCATS requires the CTPH to submit an annual progress report. Consequently, awardees will be asked to provide the CTPH with a brief update on the progress of their award no later than May 15, 2025. We will also require a final report submitted by September 30, 2025. We will request yearly updates, primarily related to additional extramural funds, publications, and/or presentations associated with the project. These requests will coincide with the annual progress report for the parent grant and continue for as long as the award is active.