Consortium for Translational & Precision Health

Consortium for Translational and Precision Health Pilot Awards
Request for Applications (RFA)

I. Key Dates

♦ RFA release date	September 23, 2024
♦ Submission portal open	October 1, 2024
♦ Informational webinar	October 10, 2024 10:00–11:00 am CT
♦ Application due date	October 30, 2024
♦ Grant review completed	November 21, 2024
♦ Grant review panel	December 1, 2024
♦ Regulatory/NCATS approval deadline	December 4–30, 2024
♦ Final funding decisions announced	January 2025
♦ Funding period	January–July 31, 2025

Informational Webinar
October 10, 2024
10:00–11:00 am CT
Register in advance for this webinar

II. Purpose

The Consortium for Translational and Precision Health (CTPH) is the academic home of the National Institutes of Health Clinical and Translational Sciences Award (CTSA) co-led by Baylor College of Medicine (BCM) and the University of Houston (UH). The CTPH is a **new** regional and national hub for infrastructure, services, community engagement, and workforce development to advance research across the translational spectrum and drive innovation in clinical and translational science.

The CTS Pilot Award Program supports **clinical and translational science**, the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process. Translational research focuses on the specific case of a target or disease, whereas **translational science** **generates scientific and operational innovations that overcome longstanding challenges and roadblocks along the translational research pipeline.** These include scientific, operational, financial, and administrative innovations that transform the way research is conducted, making it faster, more efficient, and more impactful.

Pilot projects submitted for this mechanism must focus on translational science, i.e., focused on (1) understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research, or (2) addressing a broadly encountered roadblock in the process of translational research.

The types of clinical and translational science (CTS) pilot activities that could be supported include:

- Development of new research methodologies and/or new technologies, tools, and resources that will advance the efficiency and effectiveness of research
- Development of strategies to increase the inclusion of understudied populations
- Early-state development of new therapies and technologies with *generalizable* application to an identified translational roadblock
- Demonstration that a new methodology or technology advances translational science by successfully making one or more steps of the translational process more effective or efficient in a particular use case
- Dissemination of effective tools, methods, processes, and training paradigms

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.

III. Funding and Eligibility

A. PI/Co-I Eligibility

- Principal Investigator applicants should hold a faculty appointment or a permanent non-faculty appointment i.e., "research assistant professor" or other positions typically held by investigators from research institutes and centers who are eligible to apply for investigator-initiated awards from NIH.
- Only eligible individuals from BCM or UH can serve as the project PI.
- Multiple-PI teams are eligible, with the understanding that all MPIs share equal responsibility for the conduct and direction of the project and all MPIs individually fulfill the PI eligibility requirement described above. Only one PI can be designated as the "Contact PI," and this person will serve as the primary contact between the research team and the CTS Pilot Award administration.
- Co-Investigators (Co-Is) must be from BCM or the UH and at the level of a postdoctoral fellow or higher (i.e., Assistant Professor, permanent research staff, or faculty).

B. PI/Co-I Support

- PIs must include between 1–5% salary effort (up to the NIH cap). Other faculty who are contributors to the project must also budget effort commensurate with their role in the project, with a minimum of 1% salary effort per contributor.

C. Award Size, Cost Sharing, and Submission Requirements

- The CTPH Pilot awards offer up to $50,000 in direct costs. Matching funds are not required or allowed.
- Cost sharing is not allowed, except for over the cap salary costs that may be covered by institutional unrestricted funds. Pilot projects must be supported with CTS Pilot Award funds only, and no other external funding sources can be budgeted for these projects.
- New investigators (those with **NIH new Investigator status**) can be PIs on up to two CTS pilot awards within a 4-year period.

- Senior faculty may be PIs on only one CTS award every 4 years.
- Investigators may submit only one application as PI per funding cycle.
- Funds will support preliminary studies that allow researchers to develop hypotheses, collect preliminary data, and establish methods necessary for submission of highly competitive applications to extramural funding sources.
- Funds must be used to support new projects, although the applicant investigators can have existing collaborations.
- Funds will not be awarded to support continuation/renewals of previously funded projects.

IV. Grant Cycle

The CTPH Pilot Grant applications will be accepted once per year.

V. Proposal Submission Process

Applications should be submitted as PDF files using the CTPH Grants Management System. Completed applications are due by **5:00 pm CT on October 30, 2024**. Applicants will be notified by email in early **January 2025** regarding the status of their application. Applications selected for funding will be submitted to the National Center for Advancing Translational Sciences (NCATS) for review and approval.

The applications section are:

- Abstract: Summary of the proposal (**250 words maximum**).

- Lay Summary: Brief overview of the proposed study (**1 paragraph**).

- Discussion of the CTS problem to be addressed: This section of the application should clearly:
  - Outline the CTS problem the work will address and the overarching hypothesis that underlies the proposed CTS project
  - Explain how addressing this problem will have broad applicability
  - Explain the CTS relevance of any Clinical and Translational Research use case proposed (***if applicable***)
  - Detail how, if the project is successful, the results or lessons learned will impact other realms of translational research—provide specific examples if possible
    (*PDF, **2-page limit**, 1.5-line spacing, font no smaller than Arial 11 pt, and 0.5-inch margins*)

- Research Team: Briefly describe the research team, highlighting the skills and experience that speak to the feasibility of the proposed work and what specific role each will play in the project (*PDF, **1-page limit**, 1.5-line spacing, font no smaller than Arial 11 pt, and 0.5-inch margins*).

- Research Plan: The research plan should include Specific Aims, Innovation, and Approach. Include, where applicable, clear evidence of how the proposal meets the review criteria and how the project will be generalizable. (*PDF, **4-page limit**,*

including tables and figures. 1.5-line spacing, font no smaller than Arial 11 pt, and 0.5-inch margins. Cited references do not count towards the 4-page limit).

- Cited References: (PDF, no page limit).

- Plan for Future Funding: Describe in as much detail as possible how the data generated during the pilot project will support subsequent application(s) for external grant support (*PDF, **1-page limit**, 1.5-line spacing, font no smaller than Arial 11 pt., and 0.5-in margins*).

- Study Timeline: Outline the proposed activities for the funding period, including timeline and milestones. (*PDF, **1-page limit***).

- Budget: Use PHS 398 Form Page 4. The total project budget should not exceed $50,000 in direct costs only. The time period for the budget is January 1–July 31, 2025. Cost extensions will not be allowed.

- Budget Justification: Include sufficient detail for reviewers to assess whether appropriate resources were requested. (*PDF, **no page limit**, 1.5-line spacing, font no smaller than Arial 11 pt, and 0.5-inch margins*).

- Protection of Human and/or Animal Subjects: If human or animal subjects are involved in the research, provide a description of their involvement and characteristics, specific risks to subjects who participate, and protection against those risks. **Please begin working on your IRB/IACUC applications during the peer review process**. Because of the short time frame in our first year of funding, an existing protocol must be available and relevant to support the proposed research. Describe the sources of materials that will be obtained from human subjects as part of their study participation.

  Do not use this space to include experimental details that should be described in the research plan. No funds will be dispersed until required NCATS and IRB or IACUC approval is received. (*PDF*, ***No page limit***, *1.5-line spacing, font no smaller than Arial 11 pt, and 0.5-inch margins*).

- Biosketches: NIH-format. Provide for team members at the PI or Co-PI level only. (*Combine in a single PDF, **5-page limit** for each investigator*).

- Letter(s) if applicable: Letters can be included if (i) they outline work that will be done for the project by a consultant (**do not** include letters from co-PIs, co-investigators) or (ii) clearly state a commitment of resources required for the project's success.

Review of Applications

VI. Applications will be reviewed by a panel of peer reviewers from BCM and UH. Proposals will be assigned overall scores based on traditional NIH criteria (e.g., Significance, Investigators, Innovation, Approach, and Environment) and a 1–9 scale (1=outstanding).

In the final selection process, among proposals deemed fundable, preference will be

given to proposals that include NIH-defined early-stage investigators. This preference is intended to advance the goals of the CTS Pilot program to 1) support multidisciplinary research activity that leads to productive and longstanding research collaborations and 2) engage learners in mentored research and team science.

The following criteria will be considered during the proposal review process:

- CTS Significance of the translational work—its likelihood to advance CTS methods and processes
- Innovation
- Multidisciplinary team in place that is integral to the conduct of the research
- Potential for the project to lead to future external funding or to a commercialization opportunity
- Soundness of the proposed methods
- Feasibility of completing the project within the study timeline

VII. Budget Guidelines

- Per NCATS rules for CTS pilot awards, voluntary cost share **is not permitted**. The proposed work must be supported solely by the CTS pilot award. The CTS Pilot Award administration will work with awardees to ensure that their project budget is in accordance with NCATS guidelines.

- Pilot grant funds must be budgeted for (i) PI, co-PI(s), other significant contributor (e.g., co-I) salary support; (ii) research support personnel, including RAs/GRAs, technicians and other research staff; (iii) travel necessary to perform the research; (iv) equipment, research supplies and core lab costs; or (v) other purposes deemed necessary for the successful execution of the proposed project.

- All personnel effort must be included in the budget, and no personnel effort, including faculty, can be listed as “in kind.” Include at least 1% per PI, with no more than a total of 5% salary effort across multiple PIs (at the NIH salary cap). Co-Is who are significant contributors to the project can also budget effort of up to 5% each (at the NIH salary cap). These % FTE guidelines apply only to members of the project leadership (PIs and co-Is) but do not apply to non-faculty technical staff or RAs/GRAs, who should be budgeted with whatever % FTE is required for the project.

- CTS Pilot funds can be expended only in (i) participating institutions (BCM and UH) or (ii) outside commercial entities providing a service unavailable from one of the two institutions. This includes consultants who provide a specific service otherwise unavailable to the research team, for example, producing a video.

- Where the proposed work involves investigators from more than one institution, separate institution-specific budgets and budget justifications should be included. While an equitable distribution of funds between institutions is encouraged, the proposed work will determine the optimal distribution of effort and funds between team members and institutions, and unequal distribution of funds between institutions is acceptable if adequately justified. While an equitable distribution of

funds between institutions is encouraged, the proposed work will determine the optimal distribution of effort and funds between team members and institutions, and unequal distribution of funds between institutions is acceptable if adequately justified.

- The following items **cannot be budgeted** for in a Pilot grant application: (i) office supplies or communication costs, (ii) meals, (iii) travel, including to conferences, except as required to collect data, (iv) conference registration or attendance, (v) professional education or training, (vi) manuscript preparation and submission, or (vii) costs outside of the U.S. (e.g., foreign individuals, foreign entities).

VIII. Other Guidelines

CTPH is funded through a CTSA grant from the NCATS. NCATS reviews and approves all CTPH grants involving human and animal subjects research prior to release of funds. If a funded application involves human or animal subjects research, CTPH will require additional documentation to send to NCATS.

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. CTPH will manage and disseminate scientific data in accordance with the approved plan. Additional information will be included in the Pilot Award if funded. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

IX. Final Report: Funded PIs must provide an interim project update no later than May 15, 2025 and a final report (max 2 pages) within 60 days of completion of the project, along with a final financial report in standard NIH format.

X. Publications

Publications resulting from work **supported by these funds must acknowledge** the Consortium of Translational Precision Health at Baylor College of Medicine and the University of Houston (UM1TR004539) from the National Institutes of Health, National Center for Advancing Translational Science.