Clinical and Translational Science Pilot Program

Overview

The NIH's National Center for Advancing Translational Science (NCATS) has the unique charge of examining research at a systems level to determine where common pitfalls exist in the translational process and developing innovative solutions that will ultimately benefit research across a range of diseases and conditions. A key tenant of translational science is to understand common causes of inefficiency and failure in translational research projects. NCATS stance is that many of the causes are the same across targets, diseases and therapeutic areas. Therefore, advances in translational science will increase the efficiency and effectiveness of translational research to improve health.

Program Objective

In alignment with NCATS mission, the CCTS supports translational science pilot projects surrounded by a framework that incorporates translational science principles, such as cross-disciplinary team science and boundary crossing partnerships.

Key Dates

NOFO Released:	August 24, 2026
Pre-Applications Due:	October 19, 2026
Full Applications Due:	December 18, 2026
Notice of Selection:	February 2027
Award Period:	May 1, 2027 – April 30, 2028

Proposals

Pilot projects must be focused on translational science (i.e. generation of generalizable innovations that address translational barriers). Therefore, a project's focus **must be addressing a roadblock in science and/or operations that limits the efficiency of translation**. The expectation is development of innovations that address persistent challenges to advancing translational science found across multiple initiatives and/or projects, or span research on multiple diseases or conditions. For instance, innovations that address:

- Lack of patient/participant/community involvement in the advancement of health interventions
- Ineffective clinical trial recruitment
- Failure/inability to retain participants
- Lack of novel clinical trial design (e.g. adaptive designs)
- Lack of novel endpoints for clinical studies/trials (e.g. behavioral endpoints)
- Complexity of study protocols
- Complexity in management of multi-site studies
- Clinical trials not completed on time or budget
- Translation of evidence-based interventions between populations (e.g. adult to pediatric)
- Lack of rigor, transparency, and reproducibility (e.g. clinical to real-world settings)
- Lack of data interoperability and transparency
- Challenges to data acquisition, integrity, and analysis
- Failure to utilize existing data for research (e.g. electronic health records, national cohorts)
- Challenges in testing new therapeutic modalities and drug repurposing
- Failure to correctly predict drug toxicology or efficacy
- Failure to technically execute complex mechanistic studies
- Lack of access to biospecimens
- Lack of common solutions across research on a range of diseases and conditions
- Lack of incentivization for collaboration
- Lack of training research teams
- Lengthy regulatory approval processes (e.g. participant consent content/process)
- Failure to disseminate evidence-based interventions, health practice or system updates
- Failure to implement evidence-based interventions, health practice or system updates

Projects may focus on the advancement of innovations aimed at addressing gaps in clinical translation (see above) at any of the following stages:

- **Developing** new research methodology, technology, tool, resource, therapy, or training paradigm that will advance clinical translational science (CTS) (i.e. has generalizable application to an identified translational roadblock).
- **Demonstrating** that the developed innovation (see above) improves the effectiveness or efficiency of the translational process (including assessment of feasibility/proof of concept studies to support future CTS projects).
- **Disseminating** effective innovations (see above) towards becoming a standard of scientific, healthcare or public routine.

Pilot project support is intended to support the generation of preliminary data, refine research strategies, demonstrate study feasibility, establish proof of concept, and exploration of new leads/directions to support subsequent extramural grant applications of translational science projects. Pilot projects are intended to answer, "Can this be done?", not "Is this effective?". Projects must be feasible within the proposed timeframe. Projects written as a clinical trial (i.e. measuring the effect of an intervention on a health-related biomedical or behavioral outcome) will be highly scrutinized and are generally discouraged for this funding mechanism, as pilots are intended to assess feasibility (e.g. outcomes/measures that are preparatory to a trial). If your project falls into this category, consider how to use research to enhance the design of a future clinical trial, rather than evaluating an effect on health-related outcomes.

Ineligible projects include those that: Exclusively focus on or are only applicable to one target or disease; Quality improvement and evaluation projects; Generation of large-scale human or non-human genomic data studies (learn more); Development or exclusive use of animal models; Involvement of a Foreign Component; Greater than Minimal Risk projects that require a Single IRB for Multi-Site Research; Supplement to a parent project supported by another funding source; or do not comply with current federal priorities or NIH policies, as **the NIH supports this pilot program**.

Investigator Eligibility

Full-time assistant or associate professors (or institutional equivalents) employed at CCTS Partner Network institutions are eligible to apply. Full professors may only serve as co-investigators or mentors. One proposal may be submitted per faculty member. Faculty members with a current grant containing overlapping aims are not eligible. Postdoctoral fellows, staff scientists, clinical fellows, residents, research professionals, health system administrators and trainees are not allowed to serve as PIs (or MPIs). While resubmissions are allowed, they cannot refer to prior applications or reviews and will be competitively reviewed in the same manner as all other applications. Submissions from award winners in the prior four years are not allowed.

Application Process

Before applying, applicants are highly encouraged to:

- Carefully read the CCTS' Translational Science website
- Carefully read the CCTS Pilot website, including examples of current and past projects
- Carefully read this NOFO
- Consult with CCTS Research Resources
- Connect with the CCTS pilot program administrator regarding application responsiveness

This program utilizes a two-stage application process. **Pre-applications are due October 19, 2026 by 5PM.** From the pool of pre-applications, a subset will be invited to submit a full application. Our program strives to send invites and declines in early November 2026. During the "Consultation Period" between receiving an invitation to submit a full application and its due date, the CCTS may recommend applicants meet with one or more CCTS Research Resources, where applicable. **Full applications are due December 18, 2026 by 5PM**. Applications selected for funding will be notified of selection and a mandatory meeting with program administrators to review regulatory aspects of the project.

Funding

The CCTS has committed $240,000 (Direct) of its NIH support to this program during the planned project period of May 1, 2027 – April 30, 2028. Applicants may request up to $30,000 (Direct). Funding to CCTS Partner Network sites will be conveyed through the existing subaward to that institution c/o the designated site

lead. The number of awards is contingent upon a sufficient number of meritorious applications. Projects must be fully supported with NIH funds awarded through this funding announcement. Cost sharing is not allowed. No cost extensions (NCE) or carryover requests will not be supported by this funding mechanism.

Pre-Application Instructions

Prepare pre-applications as a single, flattened, PDF containing the sections below. Follow NIH formatting.

A. **Project Narrative** (200 characters or less). Communicate a problem (i.e. the translational barrier), an innovation that will address the barrier, and the impact of the proposed work.
   - Throughout your application(s), when describing "impact", kindly utilize The Translational Science Benefits Model (TSBM) domains of clinical, community, economic and/or operating standards and relevant indicators (https://doi.org/10.1111/cts.12495).

B. **Research Plan** (2-page maximum)
   1. **Significance.** Describe a critical ***translational barrier***. Address the importance of the barrier. Describe strengths and weaknesses of prior research.
   2. **Approach.** Describe the overall strategy, methodology and analyses to be used to systematically address (as specific aims) a ***translational barrier***. While a detailed budget and timeline are not part of the pre-application, applicants must describe a study that can be done well within these confines.
   3. **Impact.** Describe the potential impact of the proposed work (see TSBM above).
   4. **References Cited.** Provide a bibliography of all references cited (no page limit).

C. **Human Subjects** (if applicable, 1-page maximum)
   If your study involves prospective enrollment of human subjects, describe the study populations(s), if/how participants will be grouped, anticipated enrollment numbers, inclusion/exclusion criteria, study sites, recruitment and retention activities, and study procedures (e.g. focus groups, acquisition of human research materials, whether data or specimens can be linked to living individuals, if private identifiable information will be obtained).

D. **Biographical Sketch Common Form** SciENcv generated biographical sketch of PI only.

Submit pre-applications via RED-ASSIST (https://redcap.dom.uab.edu/surveys/?s=XKRYLHKE34).

Consultation Period

During the "Consultation Period" between receiving an invitation to submit a full application and its due date, the CCTS may recommend applicants to meet with one or more CCTS Research Resources, such as the following, and as applicable to the research project:

- CTS Pilot Contact(s)
- CCTS Biostatistics, Epidemiology and Research Design (BERD) unit supports a multidisciplinary team of biostatisticians, epidemiologists, and methodologists to assist investigators on study design, data collection and analysis.
- CCTS Dissemination & Implementation Section Consultation Unit offers expert consultations and research advising to guide investigators through the complexities of dissemination and implementation
- Informatics can help investigators assess cohort sizes, access to summary, limited (de-identified), and fully identified data sets to assess everything from cohort size, biospecimen inventory, to clinical outcomes.
- CCTS Community Scientific Action Board (CSAB) provides guidance on community engaged research activities and program development.
- CCTS Clinical Research Support and Facilities including:
  - Clinical Research Support Enterprise (CReSt) can discuss, provide resources and/or assist investigators with clinical study feasibility, regulatory requirements (e.g. human subjects research protocol development, good clinical practice, IND/IDE submissions, clinicaltrials.gov registration and reporting), budgeting, research nurses and study coordination, recruitment and data collection.
  - Bionutrition Unit enables nutrition-related research, inclusive of a Metabolic Kitchen supporting nutritional requirements for outpatient studies, facilities and equipment to support onsite nourishment and metabolic analyses, study planning and nutritional education.

- Specimen Processing and Biorepository Unit (SPAN) works closely with the CRU, Phase I Clinical Trials Unit and other UAB Health System clinics to rapidly process, aliquot, store and/or ship research specimens.
- Clinical Research Unit Nursing (CRU Nursing) provides investigators with clinical space (outpatient and limited inpatient), equipment and nursing capacities frequently needed to execute clinical studies.
- Child Health Research Unit (CHRU) provides investigators with clinical space (outpatient) and equipment essential to support pediatric clinical studies.

- **Other Vendors –** Applicants should connect with vendors early and often for guidance/quotes.

Full Application Instructions

Prepare pre-applications as a single, flattened, PDF containing the sections below. Follow NIH formatting. Your invitation to submit a full application will contain a unique RED-ASSIST hyperlink, which must be used to submit your full application.

A. Research Strategy (4-page maximum)

1. **Significance.** Describe a critical ***translational barrier***. Address the importance of the barrier. Describe strengths and weaknesses of prior research.
2. **Approach.** Describe the overall strategy, methodology and analyses to be used to systematically address (as specific aims) a ***translational barrier***. .
3. **Impact.** Describe the potential impact of the proposed work in terms of its influence on clinical, community, economic, and/or operating standards (see TSBM above).
4. **References Cited.** Provide a bibliography of all references cited (free from page limit).

B. Data Management and Sharing Plan (1-page maximum)
Utilize the NIH's 2026 DMS Plan Format Page

C. Human Subjects (no page limit)
If planning to conduct research involving human subjects, please detail study activities based on how you anticipate your IRB will review the risk of your study activities:

- Not Human Subject Research: If you anticipate that your IRB will determine that your study is "Not Human Subject Research", describe how the proposed activities do not involve living human participants, their identifiable private data, or their biological specimens.
- Exempt Studies: If you anticipate that your IRB will determine that your study falls under any exemptions (1-8), justify why the study meets the criteria for the exemption(s) that you have claimed. The justification should explain how the proposed research meets the exemption claimed. Do not merely repeat the criteria or definitions of exempt studies.
- Non-Exempt Studies (i.e. Expedited/Minimal Risk, or Greater Than Minimal Risk studies): If you anticipate your IRB will determine that your study is non-exempt, provide the following two sections:

1. **Risks to Human Subjects:**
   a. Human Subjects Involvement, Characteristics and Design. Briefly describe the overall study design. Describe the subject population(s), if/how participants will be grouped, anticipated enrollment numbers for each study group, inclusion/exclusion criteria, and study sites where human subject research will be performed, role(s) of those sites, and collaborating investigators in performing the proposed research, as applicable.
   b. Study Procedures, Materials and Potential Risks. Describe planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data and/or records, will be obtained and whether private identifiable information will be collected. Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects. If applicable, describe alternative treatments and procedures and rationalize the proposed approach.
2. **Adequacy of Protection Against Risks:**

a. Informed Consent and Assent. Describe the process for obtaining informed consent (e.g. who seeks it, the environment under which it is sought and method of documentation). When appropriate, describe how potential adult subjects' capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent. Provide justification if a waiver for some or all of the consent is planned.
b. Potential Benefits of the Proposed Research to Research Participants and Others. Discuss the potential benefits of the research to participants and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

D. Recruitment and Retention Plan (if applicable, no page limit)
If you plan to prospectively enroll human subjects, provide the following information.
1. **Recruitment.** Describe how you will recruit participants (including planned recruitment activities)
2. **Retention.** Describe how you plan to retain participants (e.g. engagement strategies) or justify why retention is not needed (e.g. only one interaction).

E. Biographical Sketch Common Form SciENcv generated biographical sketch of PI(s) and key personnel listed on the budget.

F. Budget (1-page maximum)
Applicants may request up to $30,000 Direct Costs. Awards are limited to 12 months in duration. Applicants should utilize the PHS398 Form Page 4: Detailed Budget for Initial Budget Period to submit their budget (note: commas/placeholders are not allowed in this form).
- Allowable costs: ≤10% faculty and key personnel salary and fringe, ≤100% other personnel salary and fringe, supplies, other expenses (e.g. services, participant incentive).
- Unallowable costs: Travel ancillary to study activities (e.g. attending a conference), administrative support, office supplies, books, subscriptions, publications, capital equipment ≥$10,000, alterations, renovations, space to conduct research, subawards to institutions beyond the CCTS Partner Network. Tuition and consultant costs are generally unallowable.

G. Budget Justification (no limit)
All expenses must be well justified. Applicants may use this Budget Justification Template.

H. Project Timeline (1-page maximum)
Please download and use this Project Timeline Template or create your own to define project milestones according to experimental plan**.** Projects are expected to be completed in one year. Do not include IRB or other regulatory-related approvals or registrations in your timeline, as these must be completed before regulated study activities may begin and release of funds.

I. Letter(s) of Support/Collaboration (optional, no page limit)
While not required, Letter(s) of Support/Collaboration and related agreements may be included in the application to substantiate a collaboration, utilization of a resource, etc.

Submit full applications via the unique RED-ASSIST link provided in your invitation letter.

After submission of your full application and during the review of your full proposal in January 2027, applicants are highly encouraged to draft (but not submit) regulatory protocols (e.g. draft a new IRB protocol, but do not submit to your Office of IRB).

Review Criteria

Pre-Application Review Criteria
Pre-applications will be checked for factors like completion, eligibility, responsiveness, merit, and regulatory preparedness. Select applications will be invited to submit a full application and recommended/scheduled to meet with CCTS units.

Full Application Review Criteria
Reviewers will assess the proposed innovation addressing persistent challenges in advancing translational science based on the NIH's Simplified Review Framework factors of (1) Importance of the Research, (2) Rigor and Feasibility, and (3) Expertise and Resources. Reviewers are also empowered to consider the study timeline, budget, protection of human subjects, data management and sharing plan. Finally, reviewers will

assign a single overall impact score (NIH 9-point scale) and provide comments, which may be considered by the CCTS Pilot Directors and Office of the Director in final review of applications and summary statements.

Notice of Selection

Applicants referred for award will receive a Notice of Selection (NoS) letter, akin to the NIH's "Just-in-Time" notification, and a request for your availability to attend a mandatory meeting with pilot administrators. The goal of this meeting is to review regulatory aspects of your project, our NIH sponsor's requirements and offer support towards refining your draft IRB protocol, as applicable. (Reminder: Institutional regulatory offices, such as the Office of the IRB, are responsible for determining the level of risk associated with research projects, not investigators.). After reviewing drafts of regulatory protocols, applicants are expected to submit their regulatory protocol(s) to their respective institutional offices. Once regulatory protocols are approved, applicants are expected to complete a dynamic "Just-in-Time" RED-ASSIST survey (example PDF) that requests information based on institutional office(s) risk determination(s) of your project. Your JIT information will be reviewed by the CCTS QA/QC specialist to help ensure compliance with our NIH sponsor's requirements. Then, the CCTS will submit JIT information to our NIH sponsor via the Human Subject System module associated with the CCTS grant in eRA Commons. The CCTS will provide a "Notice of Pilot Award" after our NIH sponsor's requirements have been met. Please note, CCTS Pilot awards are contingent on NIH approval.

Notice of Pilot Award and Award Administration

Notice of Pilot Award - Upon NIH approval of JIT information, the CCTS will send awardees a Notice of Pilot Award (NPA) that outlines terms and expectations of awardees. If the selected project's budget includes CReSt, Specimen Processing and Biorepository, and/or CRU costs, investigators must establish these services by completing a CCTS Clinical Support Registration Form.

Project Teams - The CCTS will work with you to set up a Project Team. These teams will bring together content experts and methodologists to meet with you and to assist with project troubleshooting and progress. Teams meet approximately quarterly.

Enrichment - The CCTS is committed to fostering translation principles and community of scholarship through CCTS Events. Events span the career arc and address a wide variety of Clinical and Translational Science topics, including clinical research trainings, assets, and practices. We request that awardees participate in two events throughout the year.

Progress Reports - In addition to meeting with Project Teams, you will be asked to provide scientific progress reports and, if applicable, enrollment information. Templates and deadline(s) will be provided.

Citing the CCTS - All grantees publications (including research manuscripts, press releases and other publications or documents about research) that are funded by NIH must include a specific acknowledgment of grant support.

Compliance with the NIH Public Access Policy – Awardees must comply with the NIH Public Access Policy.

Contacts

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