# Clinical and Translational Science Research Program

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## 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. In alignment with NCATS's mission, the focus of the **CCTS Partner Network Clinical and Translation Science Research Program** is to identify, develop and test novel approaches to address significant roadblocks in clinical translational science, generating new insights that can be generalized to other institutions and disciplines. The CCTS has committed resources to support one (1) project from May 1, 2026 – April 30, 2028. Applicants may request up to $200,000 (Direct costs) annually, for a 2-year project period.

**Program Objective**
This program is interested in projects that address barriers to translation of evidence-based knowledge ("innovations") into real world practice settings. Evidence-based innovations include diagnostics, therapeutics, interventions, and programs with proven efficacy being delivered in clinical, community, and public health practice whose potential implementation on a wider scale is limited by a rectifiable roadblock(s).

**Key Dates**

- **Pre-Applications Due:** **September 19th, 2025**
- **Full Applications Due:** **January 7th, 2025**
- **Notice of Selection:** **February 2nd, 2026**
- **Award Period:** **May 1st, 2026 – April 30th, 2028**

**Proposals**
Projects must be focused on translational science aligned with the Program Objective, i.e. generation of generalizable innovations that address translational roadblocks to the translation of knowledge to practice. Barriers of interest include, but are not limited to:

- Implementation of innovations into the clinical workflow at the point-of-care
- Patient mistrust and distrust as a barrier to uptake of novel innovations within or outside of clinical settings
- Modifications to the electronic health record; new data capture, clinical decision support
- Decentralized ambulatory trial enrollment; drug/device, behavioral, pragmatic, Implementation Science, etc.
- Accessibility of remote patient monitoring and innovation delivery (e.g., self-testing kits)
- Communication and delivery of results for innovative diagnostics to guide medical care (e.g., genetic testing)

**Current Projects**

1. Utilizing risk stratification and social determinants of health to identify and link high-risk patients to social interventions to improve hospital readmissions and length of stay
    - Roadblock: While social risks are associated with poor health outcomes and are prevalent at the point of care, screening and linking patients to appropriate services via the health system are fragmented.
2. Developing a Contextual Assessment-Implementation Strategy Linkage Process
    - Roadblock: Delivery of multicomponent evidence-based programs (Enhanced Recovery Program as use case) in under-resourced health systems with limited scalable tools for implementation in "real world" (i.e., non-research) settings.

- Link to more information regarding current projects: Clinical & Translational Science Research Program - Center for Clinical and Translational Science

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

- **Developing a** 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 approach overcomes a barrier and improves the effectiveness or efficiency of the translational process (including assessment of feasibility/proof of concept studies to support future CTS projects).
- **Disseminating** effective approaches to overcoming barriers towards becoming a standard of scientific, healthcare or community routines in a broadly applicable manner.

Research projects should be framed as addressing a roadblock to translational sciences and not as pilot project. Projects are encouraged to focus on roadblocks aligned with Translational Science Principles (see Figure). Projects must be feasible within the proposed timeframe. Projects exclusively focused and applicable to a particular target or disease and not potentially generalizable to other targets and diseases are not allowed. Projects involving a foreign component are not allowed.


Translational Science Principles | National Center for Advancing Translational Sciences

**Investigator Eligibility**
Investigators from any of the CCTS Partner Network institutions are eligible to apply. Clinical research staff professionals, health system administrators and trainees may play essential roles on project teams, including as a Multiple PD/PI (MPI), provided that an investigator is allowed by their employer to lead a research study and serve as the communicating MPI. All projects should directly represent the ideas of the PI/MPIs. Researchers at all levels are encouraged to apply.

**Application Process**
Prior to applying, applicants are highly encouraged to consult with CCTS Capacities for quotes/feedback. Questions about the program and its timeline can be directed to Reid Eagleson (rmeagle@uab.edu).

This program utilizes a two-stage application process. **Pre-applications are due September 19th, 2025, by 11:59 PM.** From the pool of pre-applications, a subset will be invited to submit a full application.

During the ~6-week "Consultation Period" between receiving an invitation to submit a full application and its due date, the CCTS will coordinate a meeting between applicants and one or more of the Program Leaders (see "Contacts"), followed by a consult with a Biostatistics, Epidemiology and Research Design (BERD) team member. When applicable, the CCTS will refer the applicants to consult with CCTS Dissemination & Implementation Science methodologists. Applications will also be reviewed by the CCTS Community Scientific Action Board (CSAB) with feedback provided.

**Full applications are due December 19th, 2025 by 11:59 PM.** Application recommended for funding will be notified in February, 2026, triggering a "Just-in-Time" request for information subject to QA/QC review and NIH approval of the information before funding is formally approved.

**Funding**
The CCTS has committed resources to support one (1) project from May 1, 2026 – April 30, 2028. Applicants may request up to $200,000 (Direct costs) annually, for a 2-year project period. Total cost awards to Partner Network institutions outside of UAB will include up to $200,000 direct costs/year plus the corresponding indirect costs at the site's established F&A rate; Funding to Partners will be conveyed through the existing subaward to that institution c/o the designated site lead. Projects cannot be supplementary to parent projects supported by another funding source. 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 cannot be supported by this funding mechanism.

## Pre-Application Instructions

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

A. **Lay Summary** (250 words or less). Please communicate a translational barrier, describe a long-term goal towards reducing/removing/resolving the barrier, describe the project investigation (i.e. short-term goal) and how the results will inform the long-term goal. This summary will be used to garner feedback from the CCTS Community Scientific Action Board (CSAB), c/o the Partner Network Community Coalition, to identify reviewers for full applications, and promote of awarded projects; therefore, avoid jargon.
B. **Research Plan** (2-page maximum)
   1. **Significance.** Describe a critical roadblock. Address strengths and weaknesses of prior research.
   2. **Innovation.** Describe the advantage of the proposed innovation in shifting the conduct of research to overcome this ***translational barrier***.
   3. **Approach.** Describe the overall strategy, methodology and analyses to be used to systematically address (via specific aims) the ***translational barrier*** via a "use case" project that could be generalized to other settings or diseases facing this shared roadblock**.** Please see past example of funded projects (Clinical & Translational Science Research Program - Center for Clinical and Translational Science)
   4. **References Cited.** Provide a bibliography of all references cited. This section is not included in the 2-page maximum.

C. **NIH Biosketch (**From project lead and co-leads only, 5-page maximum each)
D. **Budget** (1-page maximum)
Applicants may request up to $200,000 Direct Costs per year. The awards is limited to 24 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). Requests for funding travel, equipment, renovations are not permitted under this mechanism. Awards to Partner Network institutions outside of UAB will be distributed through the existing subaward to that institution c/o the designated site lead.
E. **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 two years.

Submit pre-applications via RED-ASSIST

## Consultation Period

If invited to submit a full application, applicants are **required to meet** with:

1. A CCTS Program Leader(s) to discuss alignment of the project with this funding opportunity, feasibility in two years with $200,000 per year, and/or careful review of projects involving NIH-defined clinical trials or multi-site research.

If not completed prior to the consultation period, applicants are **encouraged to engage CCTS capacities** (listed below, CCTSclinical@uab.edu, 205-934-7442) or institutional equivalents for feedback and/or quotes before submitting full applications, as relevant:

- **Biostatistics, Epidemiology and Research (BERD)**
The CCTS Biostatistics, Epidemiology & Research Design (BERD) unit comprises a multidisciplinary team of expert biostatisticians, epidemiologists, and methodologists that supports the education, design and implementation of clinical and translational studies.
- **Clinical Research Support Program (CRSP)**
CRSP 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.
- **Specimen Processing & Biorepository Unit**
The Specimen Processing & Biorepository Unit 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.
- **Bionutrition Unit**
The 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.
- **Clinical Research Unit (CRU)**
The CRU provides investigators with clinical space (outpatient and limited inpatient), equipment and nursing capacities frequently needed to execute clinical studies.
- **Child Health Research Unit (CHRU)**
The CHRU provides investigators with clinical space (outpatient) and equipment essential to support pediatric clinical studies.
- **Dissemination & Implementation Science Section (Dissem & Implement Sci)**
Consult with experts to align rigorous methodologic standards to bolster awareness, adoption and integration of evidence-based practices, interventions, and policies into routine health care and public health settings to improve the impact on population health.
- **Informatics**
Informatics expertise and resources 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 Panel**
  A Panel, specifically a "Panel Done Quickly", involves assembling a group of peer experts that asynchronously assess study plans and then meet as group with the applicant to provide feedback to help develop a highly compelling application. Please be aware that panels have significant lead time.
- **Other Vendors –** Applicants should connect with vendors early and often for feedback/quotes

## Full Application Instructions

**Full Application Proposal**
Prepare full 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. **Aims Page** (1- page maximum)
B. **Full Application Research Strategy** (4-page maximum)
   1. **Significance.** Describe a critical ***roadblock***. Address strengths and weaknesses of prior research.
   2. **Innovation.** Describe the advantage of the proposed innovation over existing strategies to overcome the ***roadblock***. Address how the proposed innovation is applicable in a broad, generalizable manner.
   3. **Approach.** Describe the overall strategy, methodology and analyses to be used to systematically address (via specific aims) the ***roadblock*** via a "use case" project that could be generalized to other settings or diseases facing this shared roadblock and that is achievable in two years. See webpage for more details: Clinical & Translational Science Research Program - Center for Clinical and Translational Science
   4. **References Cited**. Provide a bibliography of all references cited. This section is not included in the 4-page maximum.

C. **Data Management and Sharing Plan** (1-page maximum)
   If a category is not applicable to the planned research, indicate "N/A".
   1. **Data Type.** Identify the type of data/resource(s) you plan to generate as part of the research. Describe which aspects of the resource(s) (e.g. raw or processed data; whole organism or vectors) and any other relevant information (e.g. metadata, study protocols, data collection instruments) will be preserved and shared.
   2. **Related Tools, Software and/or Code.** Identify specialized tools are needed to support access and manipulation.
   3. **Standards.** Describe what common data standards will be applied to the scientific data to enable interoperability of datasets and resources, and how they will be applied. If applicable, indicate that no consensus standard exists.
   4. **Preservation, Access, and Associated Timelines.** Describe how the resource(s) and related tools, software and/or code will be archived, findable and accessible, and timeframe of availability (start to end).
   5. **Access, Distribution, or Reuse Considerations.** Describe how the resource(s) may be accessed. Describe any anticipated limitation on the use of the resource(s) (e.g. restrictions imposed by the informed consent; applicable laws, regulations, policies, or existing or anticipated agreements; controlled access). State whether access to data will be controlled. Describe how privacy, rights, and confidentiality of human research participants will be protected.
   6. **Oversight.** Describe how compliance with the proposed plan(s) will be monitored and managed.

D. **Protection of Human Subjects** (if applicable, no page limit)
   If you plan to enroll human subjects, provide the following information as organized below.
   1. **Risks to Human Subjects:**
      a. Human Subjects Involvement, Characteristics and Design. Briefly describe the overall study design. Describe the study population(s) to be included in the study and the anticipated numbers of subjects for each study group. List any collaborating sites where human subjects

research will be performed and describe the role(s) of those sites and collaborating investigators in performing the proposed research.

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 any private identifiable information will be collected in the proposed research project. 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.

**E. Recruitment and Retention Plan** (if applicable, no page limit)
If you plan to enroll human subjects, provide the following information.

1. **Recruitment.** Describe how you will recruit participants in your study (including planned recruitment activities)
2. **Retention.** Describe how you plan to retain participants in your study (e.g. engagement strategies) or justify why retention is not needed (e.g. only one interaction).

**F. NIH Biosketch** (From project lead and co-leads only, 5-page maximum each)

**G. Budget** (1-page maximum)
Applicants may request up to $200,000 Direct Costs per year. The awards are limited to 24 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). Requests for funding travel, equipment, renovations are not permitted under this mechanism. Awards to Partner Network institutions outside of UAB will be conveyed through the existing subaward to that institution c/o the designated site lead.

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

**I. 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.

**J. Letter(s) of Support** (if applicable, no page limit)
Letter(s) of Support 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.

## Review Criteria

**Pre-Application Review Criteria**
Reviewers will assess alignment between the project and the funding opportunity's intent to address a barrier to translation of evidence-based knowledge ("innovations") into real world practice settings. Reviewers will assess scientific merit of the proposal based on significance, innovation, approach, investigator(s) and environment. Beyond scientific merit, reviewers will also consider additional criteria such as the protection of human subjects and budget/timeline. Finally, reviewers will assign a single overall impact score (NIH 9-point scale).

**Full Application Review Criteria**
Reviewers will assess alignment between the project and the funding opportunity's intent to address a barrier to translation of evidence-based knowledge ("innovations") into real world practice settings. Reviewers will score the scientific merit of the proposal in terms of significance, innovation, approach, investigator(s) and overall impact, providing a score (NIH 9-point scale) for each of these considerations. Reviewers are empowered to consider the study timeline, budget, protection of human subjects, data management and sharing plan, and extramural competitiveness as part of the overall impact score. Comments on all sections are welcome, as they are collected to provide applicants feedback and may be considered by the Scientific Review Group (SRG) when the merit of applications are evaluated.

## Notice of Selection

**Notice of Selection –** Applicants referred for award will receive a Notice of Selection (NoS) letter, akin to the NIH's "Just in Time" (JIT) notification, which serves to inform applicants of possible funding selection and its contingency on NIH / NCATS approval of relevant regulatory approvals/registrations (e.g. IRB, IACUC, clinicaltrials.gov). The NoS provides access to a dynamic "Just-in-Time" RED-ASSIST survey (example) that guides applicants through regulatory and related documentation requirements. The information that applicants supply will be reviewed via a CCTS QA/QC specialist to ensure compliance with the NIH's requirements and submission. Since there are only ~8 weeks between award selection and award start, and NIH approval is a contingency of award, applicants are highly encouraged to draft (but not submit) regulatory submissions during review of Full Applications.

## Notice of Project Award and Award Administration

**Notice of Award** - Upon NIH approval of JIT information, the CCTS will send awardees a Notice of Project Award (NPA) that outlines the expectations of awardees (e.g. timelines, milestones, reporting, dissemination, public access, enrichment, regulatory compliance). If the selected project's budget includes CRSP, Specimen Processing and Biorepository, and/or CRU costs, investigators can establish these services by completing the CCTS Clinical Support Registration process (i.e the CBR-CCTS-OCS Submission Form).

**Enrichment -** The CCTS is committed to fostering an appreciation for translation principles and a community of scholarship through CCTS events, which can be identified through the CCTS' Weekly Email Digest, CCTS Events, and navigating the CCTS website. Events span the career arc, addressing topics from LinkedIn accounts to learning health systems. We request that awardees participate in two Training Academy activities throughout the year as either content consumers or contributors.

**Progress Reports -** In addition to meeting with Project Teams, regular presentations to the CCTS Executive Committee and involvement in annual Center advisory meetings, you will be asked to provide written scientific progress reports and, if applicable, enrollment information. Templates and deadline(s) will be provided.

**Citing the CCTS** - All grantees publications (including abstracts, 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** - Award recipients are required to comply with the NIH Public Access Policy.

## Contacts

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