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.

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 limit 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/community engagement in the development and implementation 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 policy updates
- Failure to implement evidence-based interventions, health practice or policy updates

Projects may focus on the generation 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 biomedical or behavioral intervention) will be highly scrutinized, as pilots are intended to assess feasibility (e.g. outcomes/measures that are preparatory to a trial). Ineligible projects include those that: Exclusively focus or are only applicable to a particular target or disease; Develop or exclusively use vertebrate animal/cell models of humans; Involve a Foreign Component; Greater than Minimal Risk projects that require a Single IRB for Multi-Site Research.

Before submission, our program strongly recommends applicants read the CCTS' Translational Science and CTS Pilot websites, and connect with CTS Pilot Contacts to discuss questions not address in this NOFO, responsiveness, and eligibility. Applicants are also encouraged to preemptively explore CCTS Research Resources.

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
This program utilizes a two-stage application process.

Pre-applications are due October 25, 2025 by 5PM. NOTE: Due dates falling on a weekend or federal holiday are due the following business day (i.e. October 27th, 2025 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 by November 7th, 2025.

During the ~6-week "Consultation Period" between receiving an invitation to submit a full application and its due date, the CCTS will recommend applicants to meet with one or more CCTS Research Resources.

Full applications are due December 19, 2025 by 5PM. Applications selected for funding will be notified of selection, triggering a "Just-in-Time" request for information subject to QA/QC review and NIH approval of the information before funding is provided.

Funding
The CCTS has committed $240,000 (Direct) to this program during the planned project period of May 1, 2026 – April 30, 2027. Applicants may request up to $30,000 (Direct). Funding to Partners 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 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. **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 (e.g. influence clinic, community, economic, or policy).
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 in terms of its influence on clinical, community, economic, and/or policy practices.
   4. **References Cited.** Provide a bibliography of all references cited (free from page limit).
C. **Human Subjects** (if applicable, no page limit)
   If this research study involves human subjects, provide the following information as organized below.
      a. Human Subjects Involvement, Characteristics and Design. Briefly describe the overall study. Describe the subject population(s), anticipated enrollment numbers and study sites.
      b. Study Procedures, Materials and Potential Risks. Describe planned research procedures. For instance: planned recruitment and retention activities; enrollment/consent process; participant interactions; acquisition of human research materials (biospecimens, data and/or records) and if they can be linked to living individuals. Describe if private identifiable information will be obtained. Describe risks to participants, alternatives (if available), and potential benefits to participants (if any).
D. **NIH Biosketch** Only the PI (or communicating MPI) needs to submit their NIH biosketch.

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

Consultation Period

During the ~6-week "Consultation Period" between receiving an invitation to submit a full application and its due date, the CCTS will recommend applicants to meet with one or more CCTS Research Resources, such as:

- 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 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.
- 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

Full Application Proposal

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***. 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 in terms of its influence on clinical, community, economic, and/or policy practices.
4. **References Cited.** Provide a bibliography of all references cited (free from page limit).

B. 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), 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.

C. Protection of Human Subjects (if applicable, no page limit)

If this research study involves 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 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. NIH Biosketch PI(s) and key personnel (e.g. co-investigators).

F. NIH Other Support PI(s) and key personnel.

G. 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 salary support and fringe, key and 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 ≥$5,000, alterations, renovations, space to conduct research, subawards to institutions beyond the CCTS Partner Network. Tuition and consultant costs are generally unallowable.

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 (optional, no page limit)
While not required, 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
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 Scientific Review Group (SRC) and used to provide applicants feedback.

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" 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 required for NIH / NCATS approval. 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 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 (i.e the CBR-CCTS-OCS Submission 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, 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.

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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