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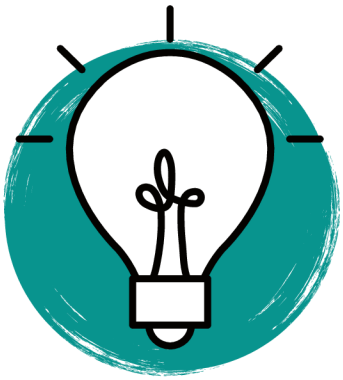

Clinical and Translational Science Pilot Program

Support for **translational science** projects that align with the CCTS' mission of accelerating the translation of research into improvements for human health and healthcare delivery. Investigators spanning the CCTS Partner Network may request up to $30,000.

Key Dates:

NOFO Released.	August 26, 2024
Pre-Application Due.	October 25, 2024
Full-Application Due.	December 23, 2024
Award Period.	May 2025 - April 2026

Learn More: go.uab.edu/CCTSpilots
Questions? Contact Anne Russell, PhD (anneruss@uab.edu)

CCTS
Center for Clinical and Translational Science

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.

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, such as:

- 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 effective health interventions between patient 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 in human or animal models
- Lack of access to biospecimens
- Failure in translation from animal models to human trials
- Lack of common solutions across research on a range of diseases and conditions
- Lack of incentivization for collaboration
- Lack of training research teams (scientific and cultural)
- Lengthy regulatory approval processes (e.g. participant consent content/process, chemical, manufacturing and controls (CMC) criteria))
- Failure to disseminate health practice or policy updates
- Failure to implement 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 community routines in a broadly-applicable, inclusive and equitable manner.

Pilot project support is intended to establish proof of concept or explore new leads/directions. Pilot projects should be framed as foundational work towards informing a larger research goal. Projects must be feasible within the proposed timeframe. Projects exclusively focused and applicable to a particular target or disease are not allowed. Projects involving a foreign component are not allowed.

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 pilot teams, including as a Multiple PD/PI (MPI), provided that an investigator allowed by their employer to lead a research study serves as the communicating MPI. All projects should directly represent the ideas of the PI/MPIs. Established investigators are discouraged from serving as the PI on behalf of others and vice versa. No more than one application will be awarded to an investigator per cycle.

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 Anne Russell (anneruss@uab.edu).

This program utilizes a two-stage application process. **Pre-applications are due October 25, 2024 by 5PM.** 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. Applications will also be reviewed by the CCTS Community Scientific Action Board (CSAB) with feedback provided, as made available.

Full applications are due December 23, 2024 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 to this program during the planned project period of May 1, 2025 – April 30, 2026^. Applicants may request up to $30,000 (Direct). 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. **Lay Summary** (250 words or less). Please communicate a translational barrier, describe a long-term goal towards reducing/removing/resolving the barrier, describe the pilot 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), identify reviewers for full applications, and promotion of awarded projects; therefore, avoid jargon.
B. **Research Plan** (2-page maximum)
   1. **Significance.** Describe a critical ***translational barrier***. Address strengths and weaknesses of prior research.
   2. **Innovation.** Describe the advantage of the proposed innovation in shifting the conduct of research.
   3. **Approach.** Describe the overall strategy, methodology and analyses to be used to systematically address (via specific aims) a ***translational barrier***.
   4. **References Cited.** Provide a bibliography of all references cited. This section is not included in the 2-page maximum.

C. **Human Subjects** (if applicable, no page limit)
If the study involves human subject research, provide the following information as organized below.

1. **Risks to Human Subjects:**
   a. Human Subjects Involvement, Characteristics and Design. Describe the overall study design. Describe the subject population(s) to be included in the study.
   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. If applicable, describe alternative treatments and procedures and rationalize the proposed approach.
2. **Recruitment and Retention** (if applicable, no page limit)
   a. Recruitment. Describe how you will recruit participants in your study (including planned recruitment activities).
   b. 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).

D. **NIH Biosketch**

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

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 one year for $30,000, and/or careful review of projects involving NIH-defined clinical trials or multi-site research.
2. A BERD team member to discuss study design and, if applicable, biostatistics support.

The CCTS will also supply applicants with any feedback garnered from the CCTS Community Scientific Action Board (CSAB) based on the information supplied in the pre-application.

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

- **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.
- **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.
- **Biostatistics, Epidemiology and Research Design (BERD)**
  The 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 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 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. Full Application Research Strategy (4-page maximum)

1. **Significance.** Describe a critical ***translational barrier***. Address strengths and weaknesses of prior research.
2. **Innovation.** Describe the advantage of the proposed innovation over existing innovations. 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) a ***translational barrier*** that are achievable in one year.
4. **References Cited**. Provide a bibliography of all references cited. This section is not included in the 4-page maximum.

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) 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.

C. 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.

D. 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).

E. NIH Biosketch (5-page maximum each)

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). Requests for funding travel, equipment, alternations, renovations are not permitted under this mechanism.

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.

I. 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 translational barrier. 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, vertebrate animals 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 translational barrier. 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 leveraged to provide applicants feedback and may be considered by the Scientific Review Group (SRC) 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" 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 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 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).

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 - Award recipients are required to comply with the NIH Public Access Policy.

Contacts

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