



SCHOOL OF MEDICINE

North Carolina Translational and Clinical Sciences Institute

NC TraCS Institute

Clinical and Translational Science (CTS) Pilot
Grant Program

Information Session: September 29th 2022

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Topics to be covered

- Translational *Research* vs Translational *Science*
- Outline of Program
- Q & A

CTS Pilot Program – language from the [CTSA FOA](#)

“The CTS Pilot Module provides modest research support for new and innovative research projects relevant to CTS.

Pilot projects must be focused on translational science, i.e., focused on *understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research.*

Translational research projects, i.e., projects focused on crossing a particular step of the translational process for a particular target or disease, **are not allowed.**”

Examples of activities that may be supported:

- Development of new research methodology and/or new technologies/tools/resources that will advance CTS and thus increase the efficiency and effectiveness of translation, for example:
 - Early-stage development of new technology with generalizable application to an identified translational roadblock
 - Demonstration in a particular use case(s) that a methodology or technology advances translational science by successfully making one or more steps of the translational process more effective or efficient
 - Novel approaches to secondary analysis of existing data (e.g., the [National COVID Cohort Collaborative \(N3C\)](#) Data Enclave)

Translational *Research* vs Translational *Science*

Translational Research (TR)

The endeavor to traverse a particular step of the translational process for a particular target or disease

An investigator wishes to test whether a particular drug improves outcomes in patients with type 2 diabetes.

The study team proposes to recruit sufficient underserved participants into the trial to ensure that study results are relevant to populations that have greater disease burden.

This is a **Translational Research** problem and will be addressed from the standpoint of effectiveness of the drug and the diabetes community, using established recruitment methods.

Translational Science (TS)

The field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process

Recognizing that underrepresentation of minority populations in clinical studies is a significant and ongoing concern, an investigator wishes to **understand the fundamental underlying barriers to recruitment for clinical trials generally** and test an intervention to address those hypothesized causes and mechanisms.

Because the findings of this work would have application across a broad range of studies, this work would be considered **Translational Science (TS)**. To test the hypothesis and demonstrate the efficacy of the intervention, the TS investigator may use the previously described diabetes drug study as a *use case*.

The primary question is whether the TS innovation accomplishes full recruitment of the desired underserved population more effectively and efficiently.

Some examples of CTS research funded by TraCS

Identifying barriers to participation in prospective autism infant sibling research for Black families: a qualitative and quantitative approach.

1. Explore individual, family, and systems-level barriers to recruitment and retention of Black families in autism infant sibling research,
 2. Identify the most significant factors that predict recruitment and retention of Black families into autism infant sibling research through a novel, data-driven, machine learning algorithm, and
 3. Disseminate recommendations and solutions identified through Aims 1 and 2 to a nationwide network of scientific experts and stakeholders in the autism field.
- *This project has CTS application since the goal is to improve recruitment methods using Autism as the use case.*

Some examples of CTS research funded by TraCS (2)

Non-invasive optoelectronic systems for diabetes health monitoring at the skin interface

- This project describes the development of an advanced wearable glucose sensor, integrating optical polarimetry, near-infrared spectroscopy and advanced data processing in a soft, patchable, and miniaturized construction a novel multi-modality sensing algorithm for enhanced accuracy and stability.
- *While the use care here is specific to diabetes, these technologies may, if successful, be applicable to other use cases.*

Some examples of CTS research funded by TraCS (3)

Validating Claims-based Definitions for Deprescribing Using Electronic Health Records: Bridging the Gap Between Clinical and Administrative Data Sources

- The goal of this study is to better understand and improve claims-based deprescribing definitions by comparing claims with detailed EHR data. It focuses on a clinical scenario in which deprescribing is clearly indicated—benzodiazepine use following a fall-related hospitalization in older adults. Comparing claims data to unstructured EHR data will enable assessment of when a patient's medication was deprescribed, and how well gaps in medication use in claims data can identify intentional deprescribing and distinguish it from stoppages for other reasons (e.g., patient nonadherence).
- *Using benzodiazepine deprescription as a use case, this is designed to be an improvement on an important data tool used in all sorts of research.*

Examples of Translational Roadblocks

Categories	Specific Examples
Infrastructure	<ul style="list-style-type: none"> • Lacking digital and information technology infrastructure to facilitate trials • Inadequate access, transparency, and interoperability of data across clinical care and research
Workforce	<ul style="list-style-type: none"> • Lack of qualified C/T investigators (and team members) • Limited education/training, mentoring (scientific and cultural) for workforce • Lack of education on translational science • Impractical academic reward system and career disincentives
Research Management	<ul style="list-style-type: none"> • Lack of incentives/credit for team science • Limited resources for intellectual property management
Research Methodologies	<ul style="list-style-type: none"> • Inefficient methodologies in preclinical development • Inefficient clinical study designs; underuse of registries and natural history studies, biomarker qualification, pharmacoepidemiological studies, comparative effectiveness trials, adaptive clinical trial designs
Clinical Trial Operational Inefficiencies	<ul style="list-style-type: none"> • Lack of sufficient community and stakeholder engagement and outreach to underrepresented groups • Lack of robust strategies for ongoing patient and community collaborations that are demonstrated to shorten the time and/or improve efficiency

NCATS Translational Science Resources

<https://ncats.nih.gov/training-education/translational-science-principles>

- Scientific and Operational Principles
- Relevant Publications
- Online Courses in Principles of TS
- Case Studies

Remember that this is still a Pilot Program...

- Projects are intended to:
- (1) explore possible innovative new leads or new directions for established investigators.
- (2) stimulate investigators from other areas to lend their expertise in research in CTS.
- (3) provide initial support to establish proof of concept.
- (4) generate preliminary data to support subsequent applications for external funding.

CTS Pilot Program Basics

- 4-8 grants, awarded annually.
- \$25k – \$50k grants. **No match requirement**
- Use of TraCS services is expected/encouraged
- 1 year funding period, extending from April - April.
No budget extensions
- PI from any TraCS partner institution (UNC, NC A&T, NC State)
- PI eligibility essentially same as for NIH “R” funding
- Instructions on [TraCS website](#)
(Funding Opportunities > Pilot Funding > CTS Pilot Program)

Key Dates/Timeline – Cycle 1**

FOA Release Date	August 23, 2022
FAQ Sessions (2)	September 20 & 29
1. Concept Proposal (REQUIRED) Due Date	October 11, 2022
Invitation for Full Proposal	October 25, 2022
Required consultation with NC TraCS*	October 25 - December 7
2. Full Proposal Due Date	January 10, 2023
Anticipated Review Release	February 14, 2023
Anticipated Funding Start	April 3, 2023

*required only for applicants intending to use TraCS services

****This schedule contingent on NCATS funding starting April 2023!!**

Concept Proposal

- Due October 11, 2022 through the NC TraCS [online pilot submission system](#)
- Outline of proposed work, comprising three (3) 1-page PDF sections:
 - NIH-style Specific Aims page outlining the project
 - Description of the Research Team, highlighting skills and experience that support feasibility of the proposed work
 - Outline of CTS problem to be addressed and, if applicable, the CTS relevance of any CTR use case proposed
- Concepts will be reviewed by Program Staff and content experts, and PIs of meritorious projects will be invited to submit Full Proposals.
- Invitations for Full Proposals will be sent out ~October 25, 2022

Full Proposal

- Due January 10, 2023 through the NC TraCS [online pilot submission system](#)
- Application comprises a set of uploaded PDFs describing Research Plan, Timeline, Budget, Biosketches etc
- Applications will be reviewed “NIH-style” – assigned to a small set of reviewers and subsequently discussed in Study Section.
- Funding decisions will be announced ~February 14, 2023, and all applicants will receive written feedback

Program Staff/Contacts

- [David Peden, MD, MS](#) - Module Leader
(for questions re topic suitability)
- [David Carroll, PhD](#) - Lead Navigator
(for questions re topic suitability and application process)
- [Mary Beth Cassely](#) – Director of TraCS Innovation Program
(for questions re applicant eligibility)

Questions/Discussion