



SCHOOL OF MEDICINE

North Carolina Translational and Clinical Sciences Institute

NC TraCS Innovation to Impact Awards

New funding opportunity for Clinical and Translational Science Research

September 13, 2024

Darren DeWalt, MD, MPH, Deputy Director, Implementation and Integration, NC TraCS

Kaitlin Zalcikova, PhD, Program Manager, CTS Research Program, NC TraCS

David Carroll, PhD, Director, Research Funding Development, NC TraCS

Leah Gardner, MIS, Project Manager, CTS Research Program, NC TraCS



SCHOOL OF MEDICINE
North Carolina
Translational and
Clinical Sciences
Institute

Today's info session

- Meet the CTS Research Program team
- Overview of the CTS Research Program
- The *new* Innovation to Impact Awards!
- Currently supported projects
- Navigating the application and submission process
- Collaborating with TraCS resources and services
- What happens after you submit?
- Key upcoming dates
- Questions for us?



Who are we?

The CTS Research Program Team



Darren DeWalt, MD, MPH

Deputy Director,
Implementation and
Integration, CTS-RP



Kaitlin Zalcikova, PhD

Program Manager, CTS-RP



David Carroll, PhD

Director, Research Funding
Development, NC TraCS



Leah Gardner, MIS

Project Manager, CTS-RP

The Clinical and Translational Science (CTS) Research Program

- A new NC TraCS program for supporting translational science and translational research
- CTS Program Goal: support the development of innovative solutions to scientific and operational **roadblocks** in translational research
- Opportunity for Investigators: we are looking for ideas for projects that will enhance translational research effectiveness and efficiency, integrate translational science with translational research, and address critical translational science questions with the potential for rapid implementation at UNC Health and beyond

The Opportunity: Innovation to Impact (i2i) Awards

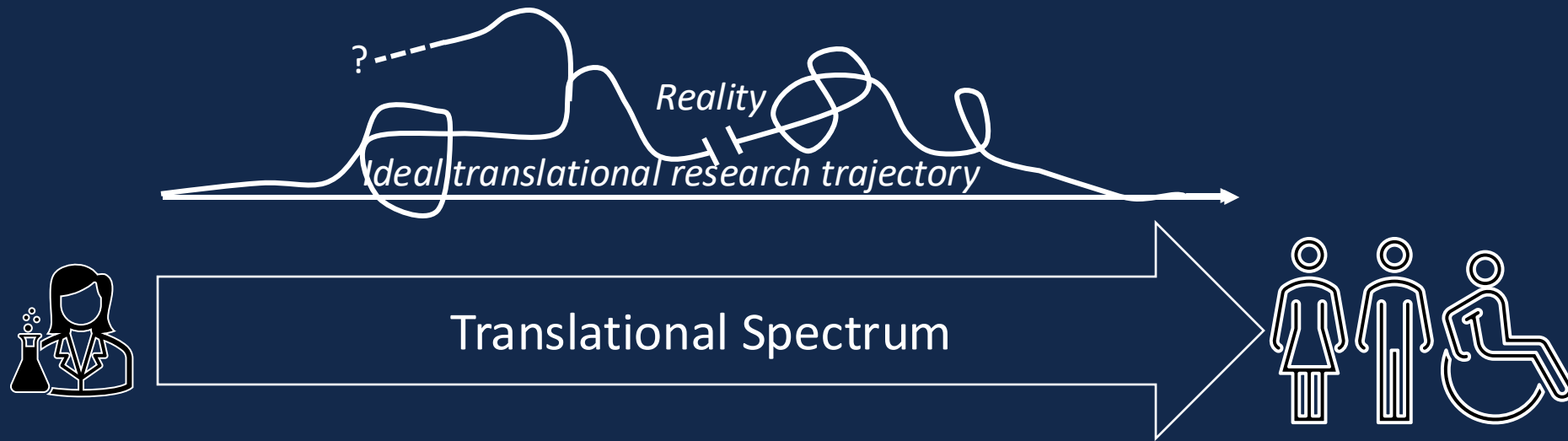
- Proposals must apply a translational science aim to a translational research question
- \$125,000-\$250,000 per year in direct costs over a period of 2-3 years
- Collaboration with NC TraCS resources and services is strongly encouraged
- Awards operate as Cooperative Agreements, with NC TraCS providing substantial involvement and oversight
 - TraCS CTS-RP Project Manager assigned to each research team who will liaise between team and TraCS services
 - Ongoing CTS-RP program input and support, regular meetings with the teams for updates

What types of projects are we seeking to support?

- **Translational Research (TR):** aims to move discoveries in specific diseases from lab to patient
- **Translational Science (TS):** aims to find broadly applicable innovations and methods that speed up the research process and are relevant across multiple diseases or research questions
- Projects support by the i2i Award must include a TS aim applied to a TR question
- If your project focuses only on translational research – *it is not responsive to this RFA*

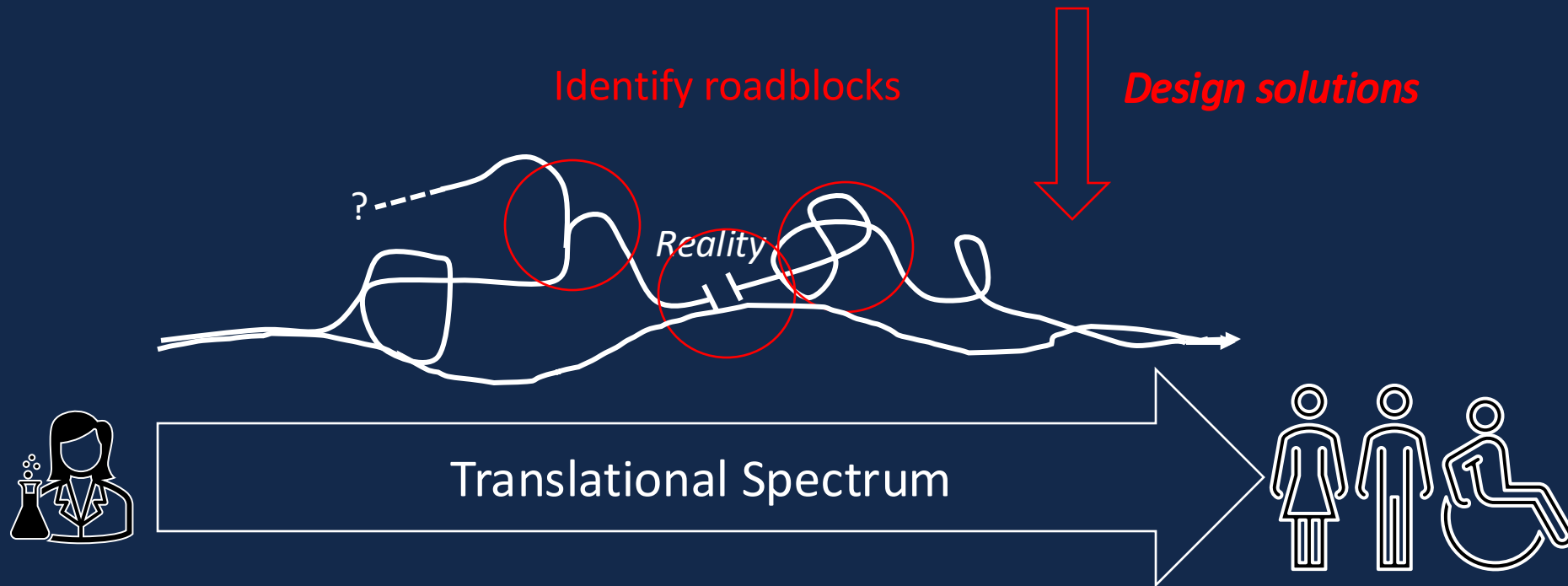
Translational *Science* vs Translational *Research*

Translational Research. Turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and communities – from diagnostics, preventions and treatments, to medical procedures and behavioral changes



Translational *Science* vs Translational *Research*

Translational Science aims to **accelerate** the process of translational research by **identifying** and **addressing** frequently encountered roadblocks, thereby making the process of translational research faster, more efficient and more predictable.



Translational Research as Translational Science Use Case

Innovation to Impact Awards

TS Barrier. *Minority communities are underrepresented in clinical trials*

TS goal. *Understand the barriers to equitable recruitment to trials*

TS approach. *Design a recruitment approach that captures truly representative study population*

TR Project. *Test whether a new drug improves outcomes T2D patients*

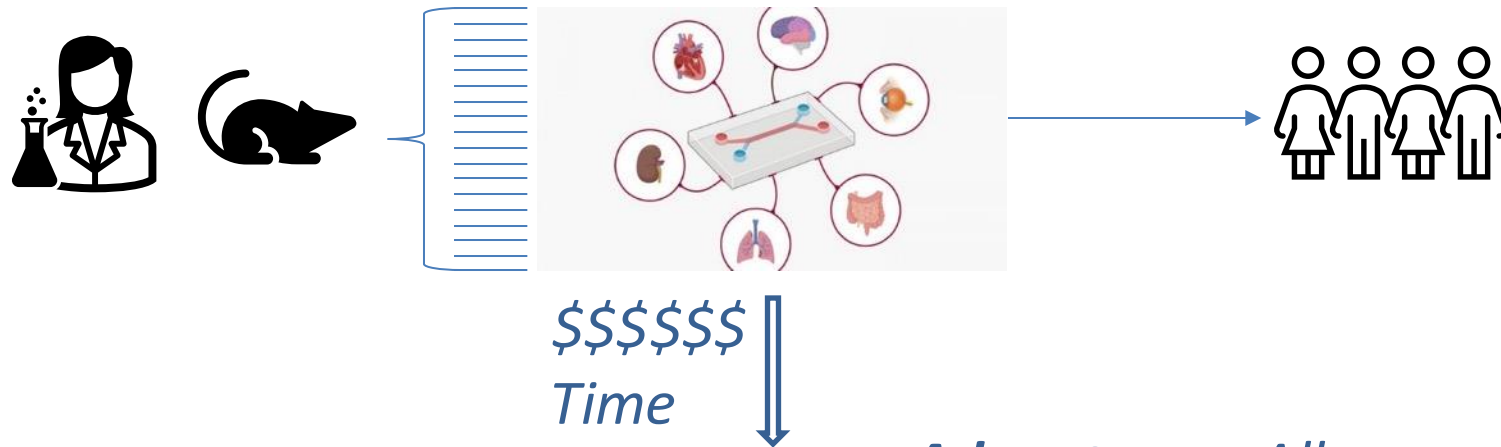
Use Case. *Test the new recruitment approach in the T2D study*

Result. *The insights gained during the course of the T2D study recruitment address the overarching TS question: "Is the new recruitment strategy effective?"*



TS Barriers and TS Approaches

- **Barrier.** Many/most new drugs fail the transition from cell/animal model to human trials



TS Solution. *Human organ on a chip*, replicating human physiology and 3d structure

Advantages. Allows prescreening of larger numbers of candidate drugs faster and cheaper

TS Barriers and TS Approaches

- **Barrier.** (i) Very low adherence to wearable monitors for PA/Sleep studies, (ii) Participant access to data through apps can bias results
- **TS approach.** Evaluate compact user-friendly and researcher-manageable PA/sleep tracker (Oura Ring) and compare with “gold standard” ActiGraph
- **Advantage.** Enables collection of non-biased PA/HRV/sleep data while reducing need to participants to travel to central lab setting. Applicable to a variety of PA-based studies and interventions





What is the project?



- This project involves a collaboration with the U.S. Census Bureau and **integrates** and **compares** social determinants of health (SDoH) data across a variety of sources.

The project seeks to understand:



- The reliability of and biases within the data (Translational Science)
- The association between SDoH responses and diabetes outcomes (Type 2 Diabetes Mellitus) (Translational Research Use-Case)
- How SDoH data is collected from the patient and provider perspective (Translational Research)

Goals and Deliverables:

- **Develop a set of guidelines** to inform researchers of the features/caveats of the sources of SDoH data (Translational Science)
- **Develop an analytical toolkit** to assist researchers in using these data appropriately in their research (Translational Science)
- **Develop recommendations** to healthcare systems about how SDoH questions are asked (Translational Science)



What is the project?

- Uses factors routinely available in medical records, combined with clinician judgement, statistical analyses, model verification, and risk-targeted care plan development in a **wayfinding process** to create an Oncology Risk-Stratified Intervention System (OR-SIS)

The project seeks to:



- Develop the OR-SIS for oncology patients receiving systemic therapy (Translational Research Use-Case)
- Test the efficacy of the OR-SIS in reducing unplanned acute care events (ACEs) among patients initiating systemic therapy (TR)
- Determine acceptability and feasibility of the wayfinding process, identify facilitators/barriers to its use (TS)

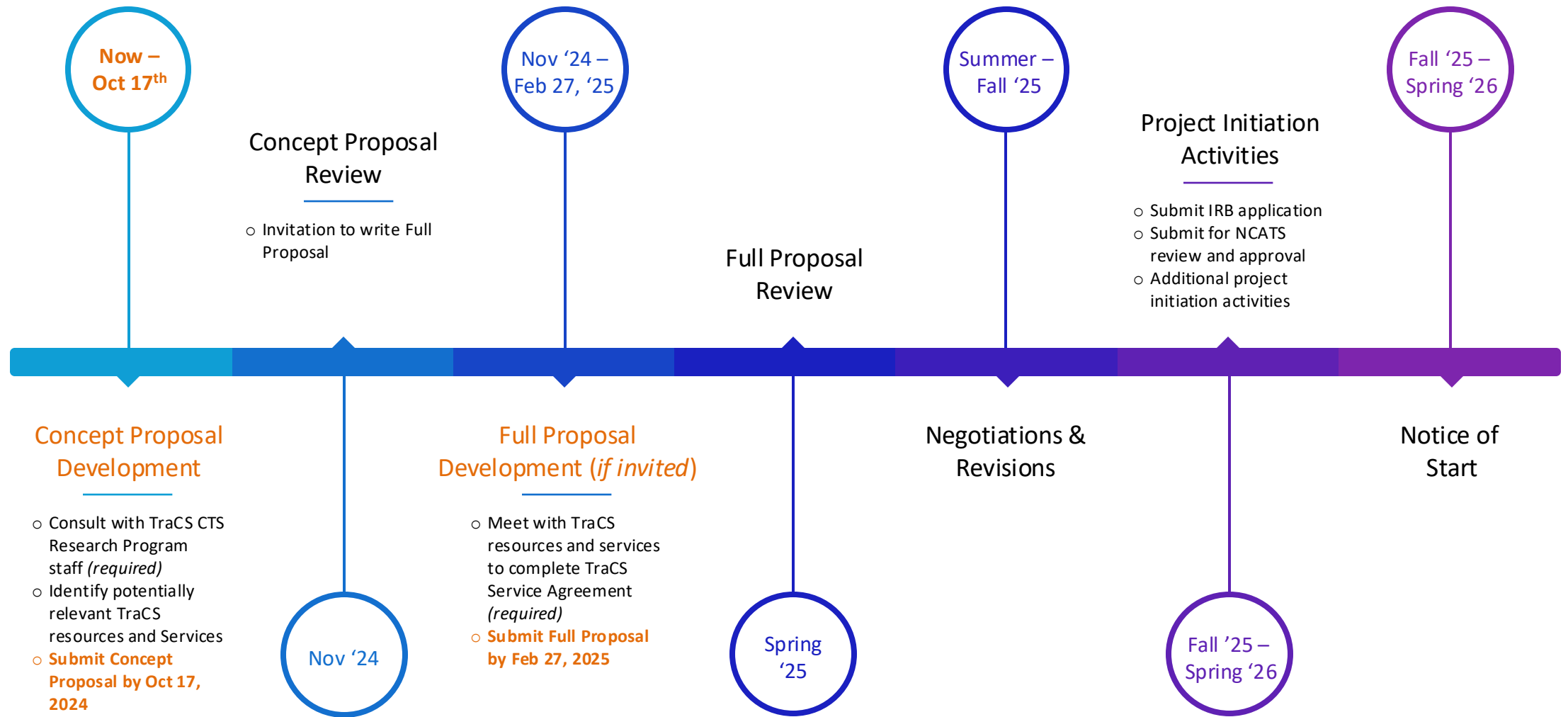
Goals and Deliverables:

- **Identify risk factors** associated with unplanned ACEs and demonstrate reduction of ACEs (Translational Research)
- **Demonstrate** that OR-SIS is acceptable to both clinician and patient users (Translational Research)
- **Develop a generalizable process** that serves as a TS process prototype for prognostic modeling in other clinical contexts (Translational Science)
- **Validate the new wayfinding TS process** for OR-SIS, demonstrate acceptability and feasibility for implementation (Translational Science)

Where can I learn more about these projects (and TS vs TR)?

- Review the [RFA](#)
- Review the [CTS Research Program webpage](#) for info on these projects, on TS vs TR, and on CTS roadblocks
- Stay tuned for upcoming stories on these projects in the TraCS Newsletter
- Request a sample application from [TraCSTAR](#)

How do I navigate the application process?



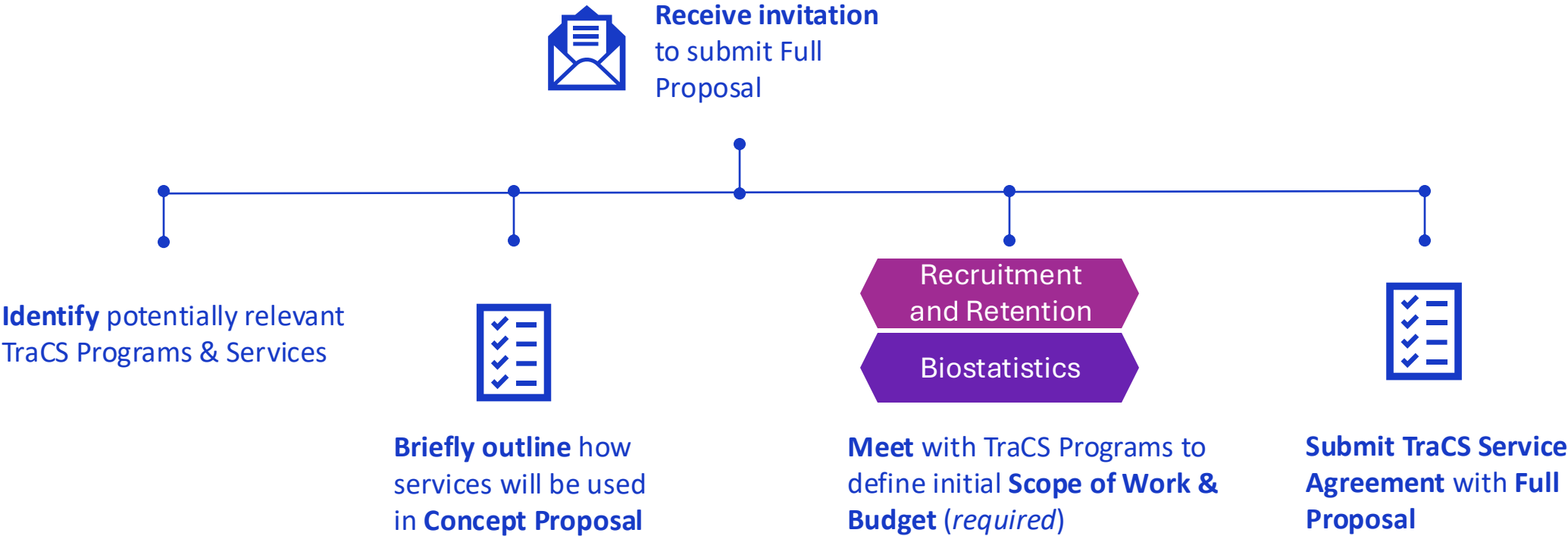
Should I reach out to TraCS for a consult?

- Yes, a consult prior to submitting a Concept Proposal is mandatory!
- What will happen in the consult?
 - When you reach out or submit a request through TraCS Central, we'll schedule a 30-min call with you (and your team)
 - We'll ask you to send a brief description of the translational science challenge and translational research question you hope to address in your proposal *in advance of our call*
 - On the call, we'll discuss your project idea and ask questions to better understand if it is a good fit for the i2i Award
 - We'll provide guidance to inform the development of your Concept Proposal
 - We'll provide guidance on potentially relevant NC TraCS resources and services, if needed

How do I collaborate with TraCS resources and services?

- TraCS services are available at reduced rates to i2i awardees
- Review the services that TraCS provides and determine if you think any might be relevant for your project
- You do not need to schedule a consult with them prior to your concept proposal submission (but you can reach out if you'd like!)
- If you're invited to submit a full proposal, a consult will be mandatory
- Use of TraCS services must be agreed upon with service reps and described in the Service Agreement form submitted with your full proposal (one agreement per service)

How and when do I reach out to TraCS resources and services?



Building Teams

Proposal Development

Team Science

Find Collaborators/Resources

Study Management / Coordination (RCMU)

Patient & Community Engagement

Patient and Community Engagement in Research

Health equity research design and multilingual inclusion

Qualitative Research Services

Equity in Research Community & Patient Advisory Board (CPAB)

Practice-based Research

Latine Community Review Board

Conducting Clinical Research

Data and Safety Monitoring Board (DSMB)

Regulatory Support

Biostatistics

Research Recruitment and Retention

Comparative Effectiveness Research

Clinical Research Ethics

Study Management / Coordination (RCMU)

Multicenter trial assistance

Study Design, Data & Analysis

Informatics and Data Science (IDSci)

Biostatistics

Comparative Effectiveness Research

Health equity research design and multilingual inclusion

Librarian Services

Qualitative Research Services

Integrated Methods & Research Design

Implementation Science

Implementation Science Methods Unit

Education & Training

Training and Career Development

K12 – faculty development award

Biostatistics Training

Protocol Development

UNC Network for Research Professionals (NRP)

Supplement Grants

Entrepreneurship & Commercialization

FastTraCS (R&D/Commercialization)

Office of Technology Commercialization (OTC)

Funding

Pilot Funding

Proposal Development

Advancing Collaborative Team Research

Supplement Grants

Engagement Voucher Program

Clinical & Translational Science (CTS) Research Program

Recruitment & Retention

Research Recruitment and Retention

Study Management / Coordination (RCMU)

Research Space

Clinical & Translational Research Center (CTRC)

Core Lab Facilities & Resources

FastTraCS Design Lab

Resource Sharing

ShareHub

Services Overview



Want to read about all of our services at a glance? Download our services overview brochure (pdf).

Where can I learn more about the services that TraCS offers?

Example: Collaboration with TraCS Resources & Services

Innovation to Impact Award Team



Biostatistics

Collaborator/Co-Investigator on project



Inclusive Science Program

To advise on options for enhancing multilingual engagement and review translated Spanish language study materials



Research and Coordination Management Unit (RCMU)

To screen for and recruit study participants



Recruitment and Retention

To create an evidence-based recruitment and retention plan from scratch, monitor recruitment and retention trends



Regulatory Support

To provide protocol development support and IRB guidance

What are the three sections of the Concept Proposal?

1. **Proposed Work (1-page)** - *NIH-style Specific Aims*

- Define the TS problem (TS challenge/barrier) and the TR question (TR use-case)
- Highlight the project impact (addressing how you'll ensure successful new discoveries are put into practice)
- Define the project deliverables (e.g., toolbox, guidelines, technique or process)

2. **Research Team (1-page)** – *Share the skills and experience of the team members*

3. **Identify which TraCS services might be relevant to your project** – *Provide a brief 1-2 sentences on the potential collaboration*

Have an idea for a Concept Proposal?

- Review the RFA, FAQs, and application portal
- Review NCATS Translational Science Resources ([NCATS Translational Science Principles, What is Translational Science?](#))
- Develop a draft project and question
- **ASAP** – reach out to schedule a consult with CTS-RP staff
- Review [TraCS resources and services](#) to determine which (if any) might be relevant to your proposal – you'll need to briefly indicate how when you submit
- Submit your proposal by 10/17!

Okay, I've submitted my Concept Proposal. Now what?

- Review of Concept Proposals will take place in November
- CTS-RP staff will reach out to select applicants with invitations to submit a Full Proposal
- Applicants will receive instructions on next steps and a checklist for the full proposal
- Applicants can meet with CTS-RP staff to develop and refine their full proposal
- Applicants will be required to meet with TraCS resources and services they plan to engage
- Full Proposals must be submitted via the application system by **February 27th, 2025**

Key upcoming dates

- **October 17, 2024:** Concept Proposals Due
- November 2024: Invitations for Full Proposals
- February 27, 2025: Full Proposals Due
- Spring 2025: Review of Full Proposals
- Summer-Fall 2025: Anticipated Negotiations and Revisions
- Fall 2025-Spring 2026: Anticipated Project Initiation Activities
- Fall 2025-Spring 2026: Anticipated Funding/Project Start



What questions do you have for us?

- *Questions you ask will be tracked and added to our FAQ section on the webpage*
- *A recording of this info session and slides will be uploaded to the CTS Research Program webpage*



Resources & Links (here they are, all in one place!)

- [CTS Research Program & FAQs](#)
- [RFA](#)
- [Submit a request](#) for a consult via TraCS Central to the CTS Innovation to Impact Award Program
- [TraCSTAR](#) sample applications
- What is [translational science](#)?
- [NCATS Translational Science Principles](#)
- List of [common CTS Roadblocks](#)
- [Services](#) offered by TraCS
- [Application submission system](#)

contact: tracs_cts_research@med.unc.edu