NC TraCS Clinical and Translational Science (CTS) Pilot Grant Program

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David Carroll, PhD – Director, Research Funding Development
Mary Beth Cassely – Director of TraCS Innovation Program
Laura Cowan – QA/QC Manager, Pilot Program
Topics to be covered

• Translational Research vs Translational Science

• Outline of CTS Pilot Program

• Q & A
What is Translational Science?

- Identifies barriers to the advancement of research across the translational spectrum
- Works toward a product or approach that overcomes or mitigates that barrier
- Generalizable across multiple diseases/conditions
MORE TREATMENTS, MORE QUICKLY.

That’s the goal of translational science.

95% of rare diseases have no approved treatments.

THOUSANDS OF DISEASES

ONLY

HUNDREDS OF TREATMENTS

New treatments take far too long to develop:

require an average of 10–15 years

fail 95% of the time

CTS
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 turning biomedical research discoveries into real-world applications that improve people’s health, such as diagnostics, treatments and cures.

![Diagram showing the translational spectrum with stages of identifying barriers and designing solutions]

Translational Spectrum
“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 Translational Barriers

<table>
<thead>
<tr>
<th>Categories</th>
<th>Specific Examples</th>
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<tbody>
<tr>
<td><strong>Infrastructure</strong></td>
<td>• Lacking digital and information technology infrastructure to facilitate trials&lt;br&gt;• Inadequate access, transparency, and interoperability of data across clinical care and research</td>
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<td><strong>Workforce</strong></td>
<td>• Lack of qualified C/T investigators (and team members)&lt;br&gt;• Limited education/training, mentoring (scientific and cultural) for workforce&lt;br&gt;• Lack of education on translational science&lt;br&gt;• Impractical academic reward system and career disincentives</td>
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<td><strong>Research Management</strong></td>
<td>• Lack of incentives/credit for team science&lt;br&gt;• Limited resources for intellectual property management</td>
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<td><strong>Research Methodologies</strong></td>
<td>• Inefficient methodologies in preclinical development&lt;br&gt;• Inefficient clinical study designs; underuse of registries and natural history studies, biomarker qualification, pharmacoepidemiological studies, comparative effectiveness trials, adaptive clinical trial designs</td>
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<td><strong>Clinical Trial Operational Inefficiencies</strong></td>
<td>• Lack of sufficient community and stakeholder engagement and outreach to underrepresented groups&lt;br&gt;• Lack of robust strategies for ongoing patient and community collaborations that are demonstrated to shorten the time and/or improve efficiency</td>
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**TS Barriers and TS Approaches**

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

\[ \text{\$\$\$\$\$} \]

\( \text{Time} \)
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.** Structured assessment windows in randomized trials disproportionately exclude those with barriers to participation (childcare, travel, work limitations)

- **TS approach.** New Statistical method allowing irregularly timed data to be used in analysis.

- **Advantage.** Clinical trials can be conducted with more flexible assessment timelines, improving inclusiveness while maintaining rigorous analytical plans
**Barrier.** Patients die from metastasis, not the primary cancer

**TS approach.** Rather than targeting individual cancer types, identify cellular features common to most/all cancer cells prone to metastasis

**Advantage.** Allows drug screening, limits disease progression across cancer types.
TS Barriers and TS Approaches

• **Barrier.** Rural patients must drive far to undergo necessary regular research phlebotomy at university – impedes participation in studies

• **TS approach.** Rural research phlebotomy collective, based in local clinics

• **Advantage.** Reduces effort for rural population research engagement – participation generalizable across multiple studies
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
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.”

**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?”
Translational Research as CTS Use Case

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.**

In this instance, the T2D study (Translational Research) acted as a “use case” to test the TS recruitment approach and address the TS barrier.

This is acceptable **as long as the TR use case is placed in the context of the overarching TS question**
Barrier. Poor engagement of African-American families in pediatric research.

Use Case Study. 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 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 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 to engage African-American families, using Autism as the use case.
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; and
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 October - October. **No budget extensions**
• PI eligibility essentially the same as that for NIH “R” funding
• PI from any TraCS partnership institution (UNC, NC A&T, NC State)
Using TraCS Services for Pilot Projects

- **For example:**
  - Biostatistics
  - Clinical and Translational Research Center (CTRC)
  - Community and Stakeholder Engagement (CaSE)
  - FastTraCS
  - Informatics and Data Science (IDSci)
  - Inclusive Science Program (ISP)
  - Recruitment and Retention
  - Regulatory
  - Team Science

- **Visit NC TraCS website, see what TraCS offers**
- **Consult with Pilot Program staff**
- **Consult with individual service reps**
- **“Reasonable” level of TraCS service assistance free to pilot awardees**
“Cooperative Agreement” vs Grant

• Ongoing Pilot Program input and support:
  • Navigator assigned to research team
    • Advise on CTS aspects of research
    • Liaise between team and TraCS services
    • Future plans and funding opportunities

• Regular meetings

• 6- and 12-month progress reports
## Key Dates/Timeline – Cycle 2

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<tr>
<td>FOA Release Date</td>
<td>March 20, 2023</td>
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<td>FAQ Sessions (2)</td>
<td>April 5 &amp; 14, 2023</td>
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<td>Concept Proposal (REQUIRED) Due Date</td>
<td>April 25, 2023</td>
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<td>Invitation for Full Proposal</td>
<td>May 9, 2023</td>
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<td>Required consultation with NC TraCS*</td>
<td>May 9 – June 30, 2023</td>
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<tr>
<td>Full Proposal Due Date</td>
<td>July 11, 2023</td>
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<td>Anticipated Funding Announcement</td>
<td>~August 8, 2023</td>
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<td>Anticipated Funding Start</td>
<td>~October 1, 2023</td>
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*required only for applicants intending to use TraCS services
Concept Proposal

• Due April 25, 2023 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 (The “Barrier – TS Approach – Advantages” structure is helpful)

• 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 ~May 9, 2023
Full Proposal

- **Due July 11, 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 ~August 8, 2023, and all applicants will receive written feedback**
Program Staff/Contacts/Information

• **David Peden, MD, MS** - Module Leader

• **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)

• **Laura Cowan** – QA/QC Manager, Pilot Program

Funding Announcement, FAQs, Application Portal:
[https://tracs.unc.edu/index.php/services/pilot-program/cts](https://tracs.unc.edu/index.php/services/pilot-program/cts)
Questions/Discussion