Leveraging the Trial Innovation Network (TIN) for Streamlining Multicenter Study Conduct

April W. Armstrong, MD MPH
Professor of Dermatology
Associate Dean for Clinical Research
Director of Clinical Research Support, SC CTSI
Keck School of Medicine
University of Southern California
The NCATS Trial Innovation Network (TIN)

- Collaborative national network that focuses on operational innovation, operational excellence and collaboration and leverages the expertise and resources of the CTSA Program.
3 Key Partners of Trial Innovation Network (TIN)

The CTSA Trial Innovation Network
Connecting: NIH Institutes, Industry, Researchers, and Participants

Investigators at CTSA Hubs across the U.S.

- Trial Innovation Centers (TICs)
- Recruitment Innovation Centers (RICs)

Request Support and Advice for Success
3 Key Partners of Trial Innovation Network (TIN)

- **CTSA Program Hubs** (e.g. SC CTSI is a Liaison Team)

- **Trial Innovation Centers** (TICs)
  - Focus on operational excellence and innovation, and quality by design.
  - Coordinates and provides innovative, high quality operational support for Trial Innovation Network clinical trials.
  - TICs: Duke/Vanderbilt, University of Utah, Johns Hopkins/Tufts

- **Recruitment Innovation Centers** (RICs)
  - Evidence-based center in innovative trial recruitment and retention methods, tools and strategies.
  - Work with researchers to develop, test and share innovations in order to improve participant recruitment and retention.
  - Expertise in informatics and the science of engagement.
  - RICs: Columbia University, The Ohio State, Rockefeller University, The Regenstrief Institute and the University of Utah.
What type of studies should be submitted?

- A multi-center trial (3 or more sites)
- Across disciplines
- Priority for studies that test an innovation to improve the clinical trials process, such as an operational innovation or an innovation in design. [“Research about Research”]
Funding sources for TIN studies

- TIN funds proposals from sources such as:
  - NIH Institutes and Centers (ICs) such as NHLBI and NIA
  - PCORI
  - Foundations and other non-profit organizations
  - Existing cooperative disease research networks such as ADCS (Alzheimer’s Disease Cooperative Study)
Submit a proposal for Initial Consultations

<table>
<thead>
<tr>
<th>Initial Consultations</th>
<th>What You Can Expect</th>
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<tbody>
<tr>
<td><strong>Study Design</strong></td>
<td>Discussions may involve the study goals and aims, the methodology, statistical and regulatory considerations, subject recruitment, schedule of assessments, or study interventions. The goal is to identify potential barriers to successful study completion and propose solutions.</td>
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<td><strong>Study Budget</strong></td>
<td>Experts will generate a budget based on the protocol design, including estimates for the overall study, sites/subjects, and recruitment, if applicable.</td>
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<tr>
<td><strong>Projected Timelines</strong></td>
<td>Recommendations on timelines for application submission and for overall study conduct, including planning, study start-up, subject accrual, closeout, and final publication.</td>
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<td><strong>Recruitment</strong></td>
<td>Experts will provide an assessment of study recruitment and strategies.</td>
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<tr>
<td><strong>Study Feasibility</strong></td>
<td>A feasibility assessment and recommendations to optimize successful study completion within the proposed timelines and budget.</td>
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<tr>
<td><strong>Efficacy-to-Effectiveness (E2E)</strong></td>
<td>See description above</td>
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Submit a proposal for Resources (1)

<table>
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<tr>
<td><strong>Standard Agreements</strong></td>
<td>We will recommend how to use either the FDP-CTSA agreement for federally funded studies or the ACTA agreement for industry-funded studies to streamline contract negotiations and expedite study start-up. Each site can potentially use standard agreements, particularly if you submit your proposal prior to contract initiation.</td>
</tr>
<tr>
<td><strong>Single IRB Support</strong></td>
<td>Recent policy changes by the NIH and DHHS require the use of a single IRB of record for multisite research. The Network has established three Single IRBs (SIRBs) to help meet this requirement. We will provide support, resources, tools, and a web-based platform (IREx) to ensure all site investigators understand how to use a SIRB at their institution, from initial submission to study closeout. The SIRBs use the SMART IRB Authorization Agreement as the basis for reliance.</td>
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| **Recruitment and Retention Plan** | An effective recruitment plan includes strategies to identify and engage specific population(s), including how to communicate and engage potential participants and meet realistic enrollment and retention goals. Key features:  
  - Comprehensive review of your study and existing recruitment plan  
  - Identification of stakeholders and recruitment partners (such as providers and community organizations) as well as recruitment locations  
  - Guidance on understanding the unique needs and preferences of potential participants as well as barriers and facilitators to recruitment and retention  
  - Tailored recommendations for engaging participants from your study population |
Submit a proposal for Resources (2)

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| Recruitment Feasibility Assessment           | This process evaluates the possibility of recruiting an adequate number of participants with the appropriate range of characteristics (such as age, gender, race, ethnicity, and health status) to meet enrollment goals on the projected timelines and costs. The assessment considers environmental strengths and weakness (such as location, competition, prior success recruiting, and potential participant pool) as well as logistical, motivational, and behavioral barriers to recruitment and retention. Key features:  
  - Comprehensive review of your study and budget  
  - Assessment of the likelihood your study will meet predefined recruitment and retention goals  
  - Tailored advice on how to enhance feasibility |
| Recruitment Materials                         | Materials may include written or verbal communication delivered through a range of multimedia channels and platforms to increase enrollment. Key features:  
  - Review of materials needs, including dissemination plans  
  - Recommendations and templates that might improve the recruitment of potential participants for specific studies                                                                                           |
| Community Engagement Studio                  | This consultative method allows for meaningful involvement of diverse groups of stakeholders in the planning and implementation of research. Studios can facilitate guidance on identifying and addressing barriers to participation and how to develop or refine recruitment materials and messages. Key features:  
  - Assessment of whether a studio is appropriate for your study and if so, where it has the potential to add the most value  
  - Advice on when and how to conduct studios                                                                                                                     |
Submit a proposal for Resources (3)

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<td>EHR-Based Cohort Assessment</td>
<td>This resource helps investigators consider ways to use Electronic Health Record (EHR) data to inform study design and potential site selection. Expect expert clinical and technical review of a study’s goal recruitment population and high-level assessment of computable phenotyping. Funded projects may also request support to organize the distribution of phenotype algorithms to potential CTSA sites and collate results.</td>
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| Efficacy-to-Effectiveness (E2E) Trial Design (also a focus area for initial consultation) | An E2E or EE2 consultation will review the evidence required by various stakeholders, such as regulators, payers, patients, healthcare providers, and physicians. This information will be incorporated into the design of a prospective study.  

The consultation may include:  
- working with the investigator to design a study that includes both efficacy and effectiveness endpoints,  
- providing advice on suitable populations to include in the effectiveness phase of the trial,  
- creating a statistical analysis plan, and  
- identifying the role of the Data Safety Monitoring Board in moving from the efficacy to the effectiveness phase. |
What makes a good proposal?

- Willing to partner with the Trial Innovation Network *through the life cycle* of the project
- Study an innovative operational approach to improve quality, efficiency, or cost of clinical research
- More than 60 days allotted for consultation prior to planned grant submission with substantial project development
- Fosters collaboration within the CTSA Program and NIH Institutes & Centers
- Includes diverse populations
Submission process

Using the Trial Innovation Network to Plan Your Trial

1. **Submit Study Proposal**
   - Apply to the TIN now for a personalized assessment of what the Network can offer.
   - Hear from us within 5 business days.

2. **Contact Investigator**
   - Assigned TIC/RIC contacts the investigator to assess priorities.
   - ~5 days

3. **Conduct Consultation**
   - In collaboration with the investigator, the assigned TIC/RIC conducts the initial consultation.
   - ~30 days

4. **Approve Discrete Resources**
   - Resource requests will be prioritized based on resource availability and funding status.

5. **Pre-Application Project**

6. **Complete Comprehensive Consultation**
   - Investigators may wish to have one of the TICs act as the data coordination center/clinical coordinating center and utilize all TIN resources for their study. In this situation, the TIC will be included in the grant application to an individual NIH Institute or Center (IC).
   - ~180 days
SC CTSI support for PIs applying to TIN for multi-centered studies

- Streamlined contracts using standard agreements
- Free IRB document preparation and facilitate use of single IRB
- Free biostatistics support
- Budget preparation
- Recruitment assistance: flyer and brochure preparation, translation of recruitment materials
TIN Team at USC & CHLA

**University of Southern California**

**Principal Investigator**

Thomas Buchanan
buchanan@usc.edu

**Medical Director**

April Armstrong
april.armstrong@med.usc.edu

**Administrator/Project Manager**

Nicki Karimipour
Point of Contact
nicki.karimipour@med.usc.edu

**Liaison Team Staff**

Lubaba Helwani
IRB Contact
helwani@usc.edu

Jeri Muniz
FDP-CTSA Standard Agreements Contact
jeri.muniz@research.usc.edu

Shannen Nelson
Liaison Team Member
shnelson@chia.usc.edu

**Trial Innovation Network Agreements**

- SMART IRB Exchange Portal Access
- FDP-CTSA Standard Agreement

**Trial Innovation Network Contracts**

- Confidential Disclosure Agreement (CDA)
  Randolph Hall (signatory)
  vpres@usc.edu
  (323) 442-1280

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**University of Southern California**

**Principal Investigator**

Thomas Buchanan
buchanan@usc.edu

**Medical Director**

April Armstrong
april.armstrong@med.usc.edu

**Administrator/Project Manager**

Nicki Karimipour
Point of Contact
nicki.karimipour@med.usc.edu

**Liaison Team Staff**

Lubaba Helwani
IRB Contact
helwani@usc.edu

Jeri Muniz
FDP-CTSA Standard Agreements Contact
jeri.muniz@research.usc.edu

Shannen Nelson
Liaison Team Member
shnelson@chia.usc.edu

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Do you have questions or are you interested in submitting a proposal?

Please contact Nicki Karimipour, Ph.D.
Program Manager for Clinical Research Support at SC CTSI

- Nicki.Karimipour@med.usc.edu / 323-442-1280