

Trial Innovation Network Hub Liaison Team Meeting

June 6, 2017

CTSA Clinical & Translational[®]
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TRIAL INNOVATION NETWORK



Trial Innovation Network Hub Liaison Team Meeting

JUNE 6, 2017

NCATS

Trial Innovation Network Agenda

- Transition Plan
- Strategy and Goals for Year 2
- Goals of Hub Liaison Team WG

Trial Innovation Network *Transition Plan*

- NCATS Team working collaboratively on a seamless transition
- Monica will be actively engaged and managing Network until June 16, 2017
- Transition Plan
 - Michelle will be Acting Director; Petra will play active role; NCATS Team will continue their key roles
 - Dr. Bernard will co-chair the NEC meetings with Michelle/Petra
 - Dr. Ford will co-chair Hub Liaison Team meetings with Michelle/Petra and will be on CTSA Program Steering Committee as TIN representative
 - Other WG leadership will remain the same

Trial Innovation Network

What Are Our Goals for Year One - Slide from 8.16

- ☑ Establish our strategic niche & mission
- ☑ Communicate Network goals and vision to our stakeholders
- ☑ Organize the Trial Innovation Network at Network, TIC/RIC, and CTSA Hub Level
- ☑ Build the infrastructure of the Network at each level
- ☑ Use Demonstration Projects as a means to build infrastructure and engage stakeholders

Trial Innovation Network

Proposed Goals for Year 2

- Integrate Trial Innovation Network more fully into CTSA Program
- Build Hub Liaison Teams
- Continue to refine workflows, processes, communication
- Operational Innovation Strategic Plan
- Launch pilot studies, submit applications, negotiate with partner NIH ICs about trials, launch trials
- 2017 - First patient in and successful “Instant Start Up”
- Collaboration - between TICs, RIC, and CTSA Program Hubs

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Hub Liaison Team Working Group - Goals

- Bring together Hub Liaison Teams as a collective force to build a national site-based clinical trials system
- Vet processes, procedures, and get feedback on progress of Trial Innovation Network
- Share ideas and approaches to operationalize the Trial Innovation Network at the local level
- Share ideas to optimize communication in the Trial Innovation Network
- Function as ambassadors to other Hub Liaison Teams, disseminate information, “buddy system”

NUCATS TIN Hub Liaison Team: *Intake Form & Process Map*

Keith Herzog

Northwestern University Clinical and Translational Sciences
(NUCATS) Institute



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Overview

- NUCATS Hub Liaison Team (HLT)
- Process Map
 - Project development through TIN application submission
 - Spotlight steps in the process:
 - Local intake form
 - HLT “Studio”
 - Finalizing the TIN application
- Investigator outreach & identifying local investigator contacts

NUCATS Hub Liaison Team: *Synthesizing Expertise*

- Bringing together expertise from across our hub, University partners, and clinical affiliates
 - **NUCATS CTSA Hub:** Center for Clinical Research, Center for Data Science and Informatics, and Administrative Core (Evaluation and Communications)
 - **Northwestern University Partners:** Institutional Review Board and Office for Sponsored Research
 - **Clinical Affiliates:** Ann & Robert H. Lurie Children's Hospital of Chicago and Northwestern Memorial HealthCare System

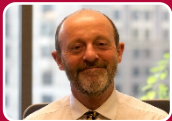
NUCATS Hub Liaison Team: *Team Members*



Donald Lloyd-Jones, MD, ScM
NUCATS CTSA Hub PI



Lewis Smith, MD
Hub Liaison Team Medical Director
Director, Center for Clinical Research



David Johnson, PhD
Hub Liaison Team Faculty Liaison
Associate Dean for Research Operations



Susanna McColley, MD
Hub Liaison Team Faculty Liaison
Associate Director of NUCATS for Child Health



Mara Johnson
Hub Liaison Team Navigator
NUCATS Center for Clinical Research



Keith Herzog
Hub Liaison Team Project Manager
NUCATS Evaluation Team

Domain Experts



Marcella Oliver
Domain expertise: Central Institutional Review Boards
Northwestern University IRB



Peggy Mitchell
Domain expertise: Clinical Research Operations
NUCATS Center for Clinical Research



Dan Schneider
Domain expertise: EHR-based Cohort Assessments
Northwestern Medicine Enterprise Data Warehouse



Ashley Sipocz
Domain expertise: Recruitment & Retention
NUCATS Center for Clinical Research

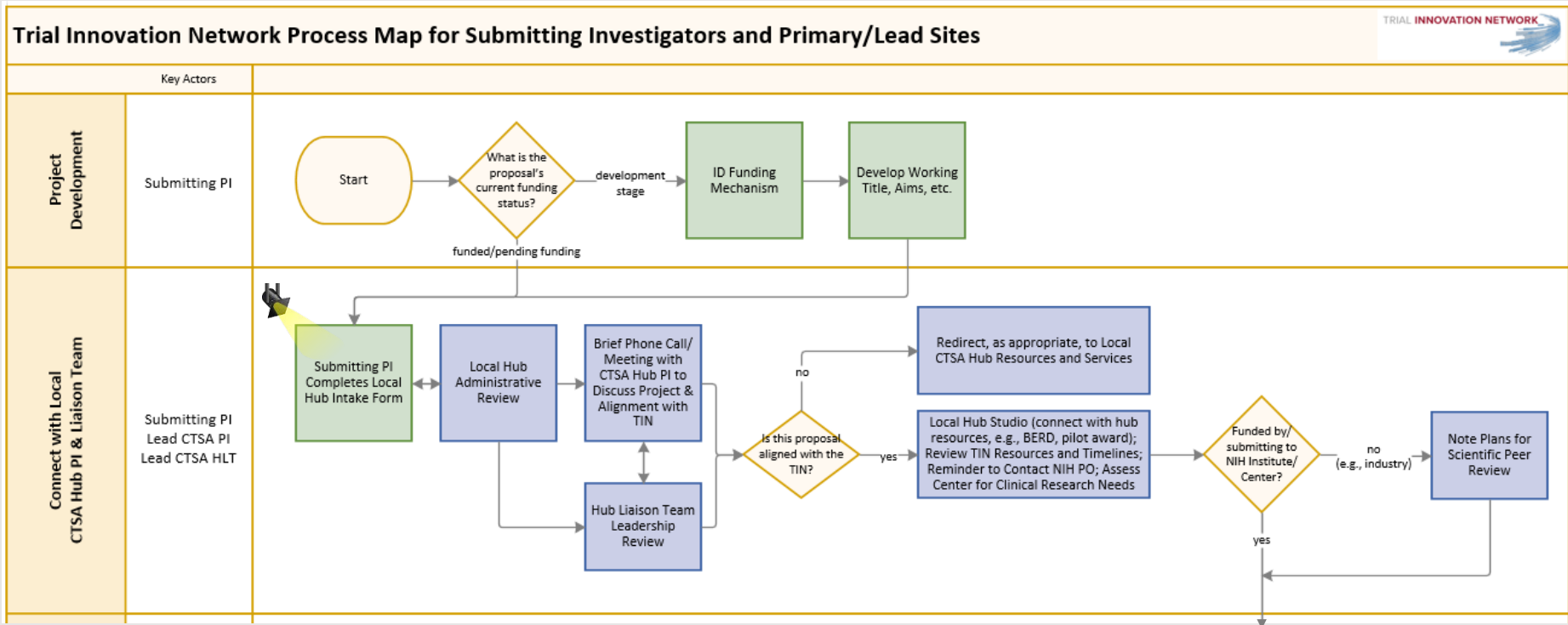


Lynda Wolter
Domain expertise: Standard Agreements
Northwestern University Office for Sponsored Research

Process Map

- Purpose of process map:
 - **Define** the TIN process from start to end
 - Identify critical opportunities to integrate the local HLT throughout the process
 - Understand the process pathways in order to answer investigators' questions
 - **Develop** standardized workflows
 - **Evaluate** workflows and practices over time
- Mapped out the TIN proposal workflow by stage, represented by “swim lanes”
 - Project development
 - Connect with Local CTSA Hub PI & HLT
 - Connect with NIH Program Officer
 - Prepare and submit TIN proposal

Process Map: Project Development & Connecting with Local CTSA Hub PI and HLT



Next step: Connect with Program Officer

Color indicates primary actor:




Green: Submitting PI

Blue: Local Hub Liaison Team

Local HLT Intake Form

- Goals for local intake form
 - **Confirm** eligibility for TIN support (e.g., multi-center trial/study, not requesting support for P01 administrative core)
 - **Collect** basic proposal details in advance of call with local CTSA hub PI (e.g., current funding status, proposal aims, TIN services of interest)
- Guiding principles
 - Short, on-line form
 - Complete in < 5 minutes by submitting PI or study team member
 - Complement TIN application

TRIAL INNOVATION NETWORK INTAKE FORM

Your Name *
First Name Last Name

Email Address *

Phone

School Affiliation

PI *
 Yes
 No

Is this proposal for a multi-center clinical trial or multi-center study with patient-oriented endpoints? *
TIN Innovation Network support is limited to multi-center proposals. For support with other proposals, contact [Center for Clinical Research](#).
 Yes
 No

Proposer's Working Title *

Will this study potentially impact clinical practice and/or operational innovation? *
 Yes
 No
 Unsure

Estimated number of sites *

Estimated number of subjects (all sites) *

Current funding status *
 Funded
 Pending funding or prepared for submission for funding.
 Developmental stage

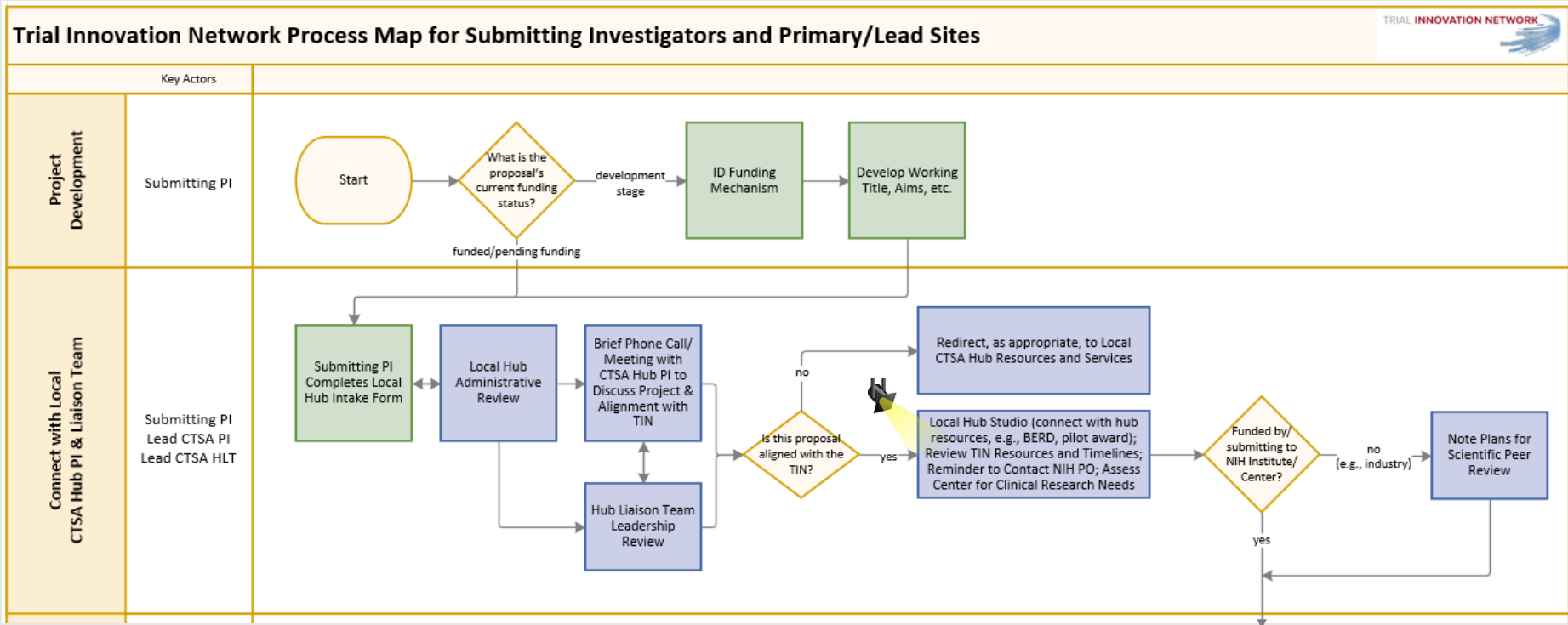
Have you identified a funding agency/ specific funding opportunity announcement (FOA) to target for this proposal? *
 Yes
 No

If your proposal is selected to receive support from the Trial Innovation Network (TIN), please indicate which services you may be interested in utilizing for this study *
 Initial Consultation through to Study Implementation (Developmental stage only)
 Community Engagement Studio
 Operationalize Standard Agreements
 Operationalize Central IRB
 Recruitment Plan
 Recruitment Feasibility Assessment
 Recruitment Materials
 IRB Based Cohort Assessment
 I do not know and need additional information from the NUCATS liaison team.
 Other (please specify)

Please provide a brief working description of your proposed trial or study (e.g., draft aims, subject population(s), etc.) *

You may also email a file to NUCATS@northwestern.edu

Process Map: Project Development & Connecting with Local CTSA Hub PI and HLT



Next step: Connect with Program Officer

Color indicates primary actor:

Green: Submitting PI

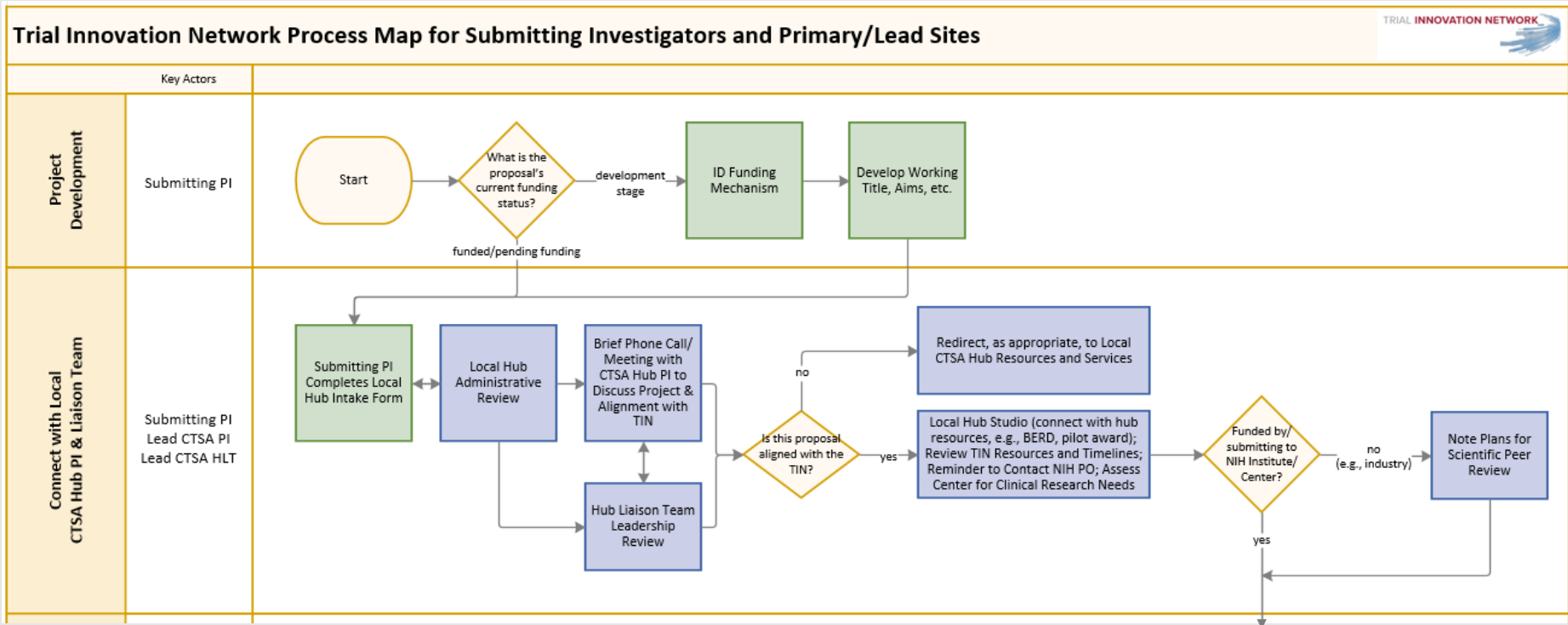
Blue: Local Hub Liaison Team



Local HLT “Studio”

- Based on successful NUCATS hub and Center for Clinical Research studio models
- TIN “Studio” objectives
 - **Connect** submitting PI to local HLT members
 - **Discuss** TIN goals, workflow, and timeline as well as role of local HLT
 - **Review** submitting PI’s brief, working description of multi-center trial or study
 - **Identify** opportunities to leverage local hub resources (to complement potential support from TIN)
- Studio may not be necessary in all instances

Process Map: Project Development & Connecting with Local CTSA Hub PI and HLT



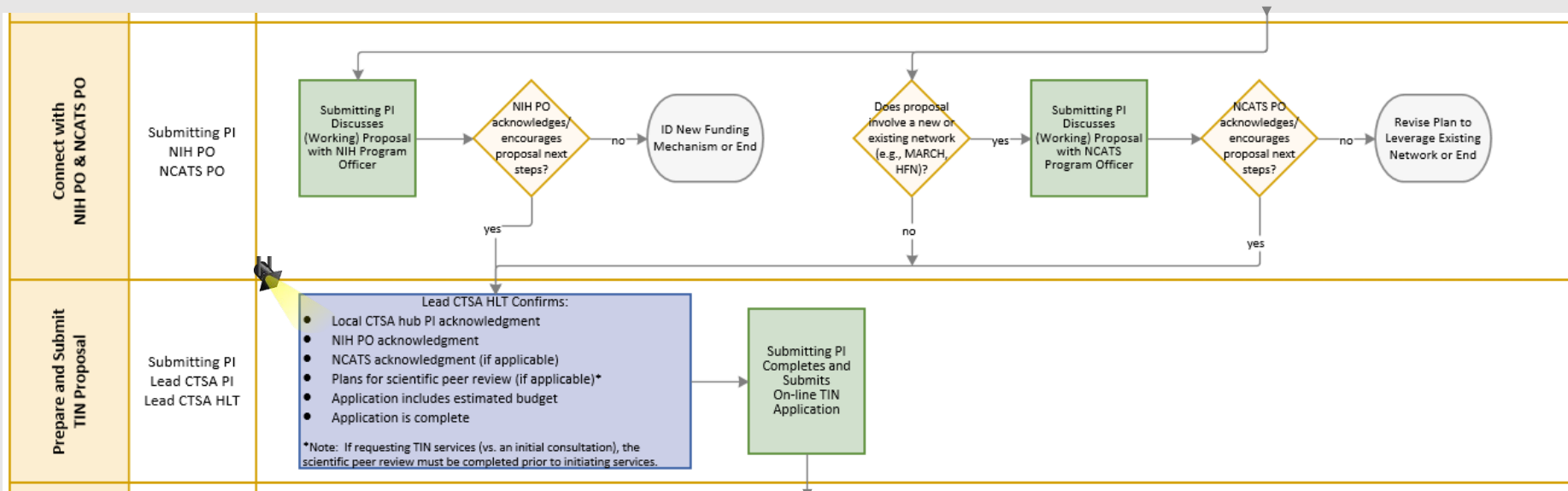
Next step: Connect with Program Officer

Color indicates primary actor:

Green: Submitting PI

Blue: Local Hub Liaison Team

Process Map: Connecting with Program Officer through TIN Proposal Submission



Next step: TIN Proposal Review

Color indicates primary actor:

Green: Submitting PI

Blue: Local Hub Liaison Team



Finalizing the TIN Proposal

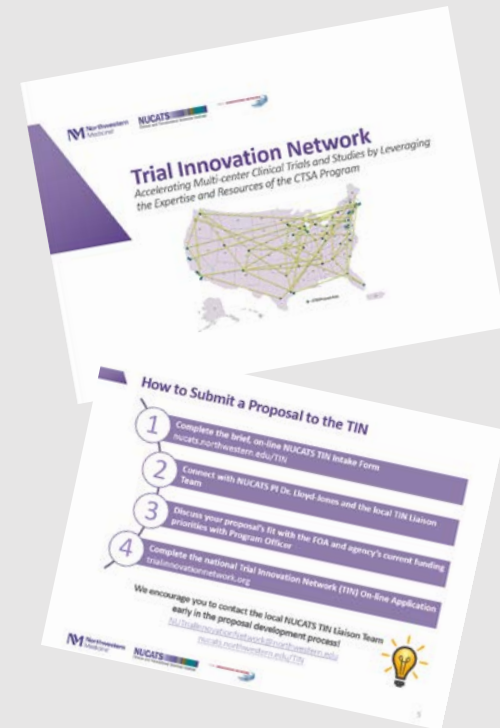
- HLT Navigator works closely with submitting PI and/or study team member to confirm:
 - ☑ Application is complete – and includes:
 - ☑ Local CTSA hub PI acknowledgment
 - ☑ NIH Program Officer acknowledgment
 - ☑ NCATS acknowledgment (if applicable)
 - ☑ Plans for scientific peer review (if applicable)*
 - ☑ Estimated budget (if applicable)
- Track proposal activity in local REDCap database



*Note: If requesting TIN services (vs. an initial consultation), the scientific peer review must be completed prior to initiating services.

Investigator Outreach & Identifying Local Investigator Contacts

- Raise awareness about the TIN to the Northwestern research community
 - Email newsletter
 - “Minute”
 - NUCATS Web site
 - Departmental presentations
- Identify department & division HLT champions to assist with identifying local collaborators for studies based elsewhere
 - Build upon existing networks
 - Direct outreach to departmental leadership
 - HLT Roadshow presentations



Thank you!

NUCATS TIN Liaison Team
NUTrialInnovationNetwork@northwestern.edu



Trial Innovation Network Discussion

Hub Liaison Teams

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Hub Liaison Team Discussion

- Proposal Process at Hubs
- How Can We Stimulate More Proposals?

Trial Innovation Network Website Resources

Michelle Jones

Paul Harris

Project Lead, VU

PI, VU RIC

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Trial Innovation Network Resources

The screenshot shows the Trial Innovation Network website. At the top, there is a dark red header with the logo on the left and 'CTSA Clinical & Translational Science Awards' on the right. The main content area has a white background. On the left is an image of a lightbulb with gears inside. In the center, the text reads 'TRIAL INNOVATION NETWORK Operational innovation, excellence, and collaboration.' Below this is a paragraph: 'The Trial Innovation Network has received more than 40 proposal submissions! We continue to accept new proposals. Click the submit button to get started.' To the right is a circular button that says 'INVESTIGATORS! SUBMIT A NETWORK PROPOSAL' with a 'Submit' button below it. A green arrow points to this button. Below the main content is a blue section titled 'WELCOME!' with a paragraph: 'The Trial Innovation Network is a collaborative national network that focuses on operational innovation, excellence and collaboration and will leverage the expertise and resources of the CTSA Program.' At the bottom is a grid of six red boxes, each with an icon and a title. A red arrow points to the 'Trial Innovation Network Proposal Process' box.

TRIAL INNOVATION NETWORK

CTSA Clinical & Translational Science Awards

TRIAL INNOVATION NETWORK
Operational innovation, excellence, and collaboration.

The Trial Innovation Network has received more than 40 proposal submissions! We continue to accept new proposals. Click the submit button to get started.

INVESTIGATORS!
SUBMIT A NETWORK PROPOSAL

Submit

WELCOME!

The Trial Innovation Network is a collaborative national network that focuses on operational **innovation, excellence and collaboration** and will leverage the expertise and resources of the CTSA Program.

Who We Are

Resources For CTSA Hub Liaison Teams

Trial Innovation Network Proposal Process


Central IRB System

Engagement, Recruitment, & Retention

FDP-CTSA Standard Agreement

Trial Innovation Network

Submitting a Proposal

TRIAL INNOVATION NETWORK 

LOGIN [CREATE A PROFILE](#)

First Name

Last Name


Phone

Institution

Email

Password

[Go](#)

TRIAL INNOVATION NETWORK 

LOGIN [CREATE A PROFILE](#)

Email

Password

TRIAL INNOVATION NETWORK  [Sign Out](#) [Create New Proposal](#)

Proposals in Process

Proposal ID	Proposal Title	PI Name	PI Institution	Date Submitted	Status	Proposal Documents	Actions
151	Test	John Jones	Vanderbilt University Medical Center		Pending Submission	Current Proposal	Edit Application Withdraw Application


Approved Proposals

Proposal ID	Proposal Title	PI Name	PI Institution	Date Submitted	Status	Proposal Documents	Actions

Archived Proposals

Proposal ID	Proposal Title	PI Name	PI Institution	Date Submitted	Status	Proposal Documents	Actions

Trial Innovation Network Proposal Intake System

TRIAL INNOVATION NETWORK 

TRIAL INNOVATION NETWORK Proposal Intake Form


We will take you through a few quick questions to set up your submission. You can save your submission and return at any time to complete it. Click [HERE](#) to download instructions on how to complete the form. For any questions, please contact us at PAT@trialinnovationnetwork.org. Thank you!

PROPOSAL TITLE

What is the title of the Trial Innovation Network Project Proposal?
* must provide value

What is the short title for the Trial Innovation Network Project Proposal?
* must provide value

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TRIAL INNOVATION NETWORK Proposal Intake Form

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OVERSIGHT/REVIEW OF THE PROPOSAL

PROTOCOL SYNOPSIS
Please enter additional study details below.

What is the phase of this study?
* must provide value

STUDY DESCRIPTION
Provide a short description of the protocol, including a brief statement of the study objectives in a few sentences in length.
* must provide value

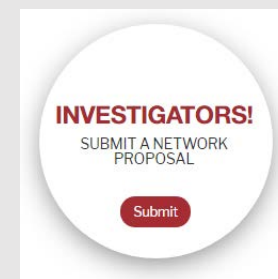
Please limit to 100 words


PROTOCOL DESIGN
Provide a brief description of the manner in which the trial will be conducted.

For interventional trials: the primary purpose of the intervention is to evaluate the effect of the intervention on participants (cross-over, single group, etc.), the trial design, randomization, blinding, and masking.

For observational studies: the primary strategy for participant selection, observation period to time of participant enrollment (prospective), description and retention, target follow-up duration, and number of participants.

* must provide value



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TRIAL INNOVATION NETWORK Proposal Intake Form

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CONSULTATIONS AND SERVICES

Based on the information you provided regarding your funding status, the Trial Innovation Network could provide the following:

Consultations or Services
* must provide value

Initial Consultation
 Services (see list of services below)

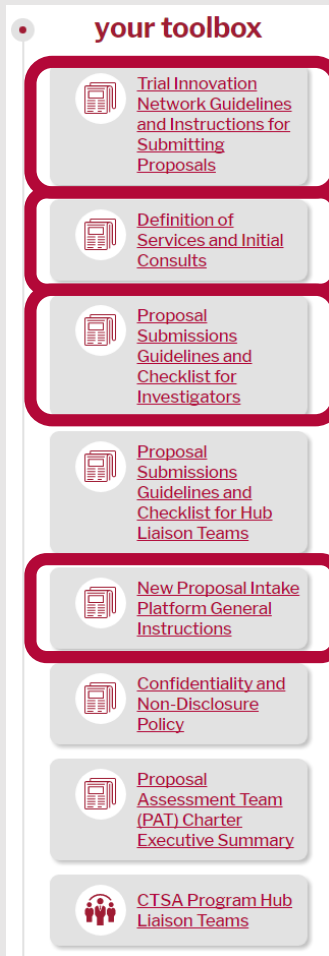
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Trial Innovation Network Resources

Trial Innovation Network

Resources - Submitting Study PI











Resources for Submitting Study PIs:

- Define services and consultations
- Provide guidelines and a checklist for study PIs
- List instructions on how to fill out the proposal intake form

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Resources - CTSA Hub Liaison Teams

your toolbox

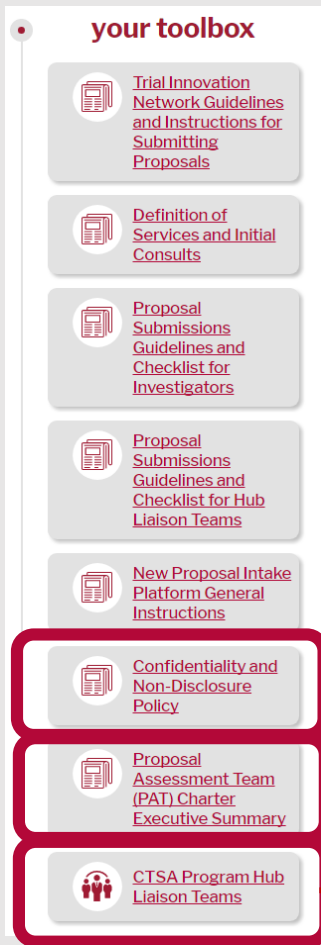
-  [Trial Innovation Network Guidelines and Instructions for Submitting Proposals](#)
-  [Definition of Services and Initial Consults](#)
-  [Proposal Submissions Guidelines and Checklist for Investigators](#)
-  [Proposal Submissions Guidelines and Checklist for Hub Liaison Teams](#)
-  [New Proposal Intake Platform General Instructions](#)
-  [Confidentiality and Non-Disclosure Policy](#)
-  [Proposal Assessment Team \(PAT\) Charter Executive Summary](#)
-  [CTSA Program Hub Liaison Teams](#)

Resources for Hub Liaison Teams:

- Define services and consultations
- Provide guidelines and a checklist for Hub Liaison Teams

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Resources – Proposal Submission Process



Resources for All:

- Identify Partners
- Increase transparency
- Break down the submission process

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What's Next...

- Person Management Database
 - Authentication
 - Hub Liaison Team
- Network
- Input from Hub Liaison Team Working Group



Upcoming Webinars

Trials Today Kickoff Meeting

June 7th (Vanderbilt)

Moving Beyond Return of Results To Return of Value

June 29th (Vanderbilt)

Novel approaches to clinical trials recruitment: Lessons learned from the 2017 Buffalo Creative Scientist Workshop

August 30th (University at Buffalo)

Special Populations: Measurement and engagement approaches for including LGBT Populations in clinical research trials

October 24th (University of Illinois at Chicago)

[Learn More](#) | [Register](#)

SMART IRB EXCHANGE

Demonstrations:

- June 7th
- June 8th
- June 14th
- June 15th

[Learn More](#) | [Register](#)



Clinical Trials Toolkits

Recruitment & Retention Toolkit
[Accepting Resource Submissions](#)

Trial Innovation Network

***Next Meeting: August 1, 2017, 3-4:30PM ET
(No meeting on July 4th)***