

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

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**CTSA** Clinical & Translational<sup>®</sup>  
Science Awards

TRIAL INNOVATION NETWORK



# 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

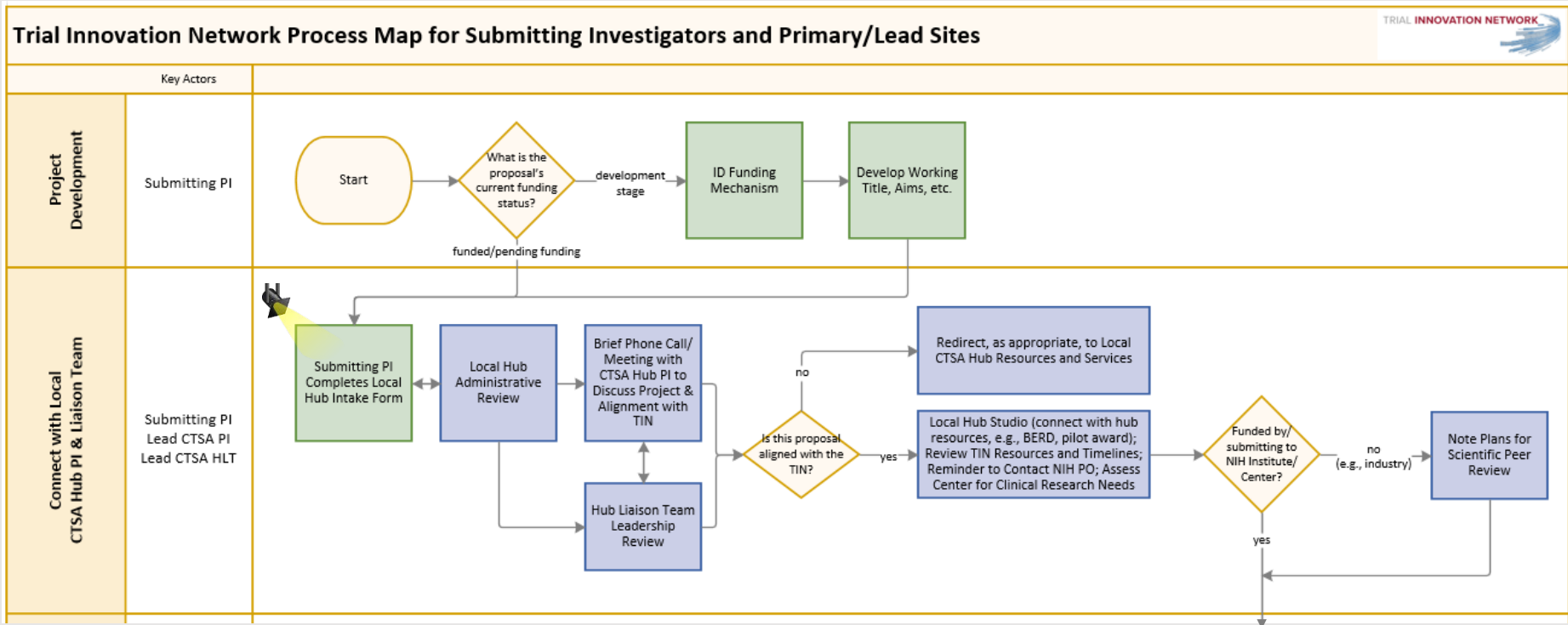


**Lynda Wolter**  
Domain expertise: Standard Agreements  
Northwestern University Office for Sponsored Research

# 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

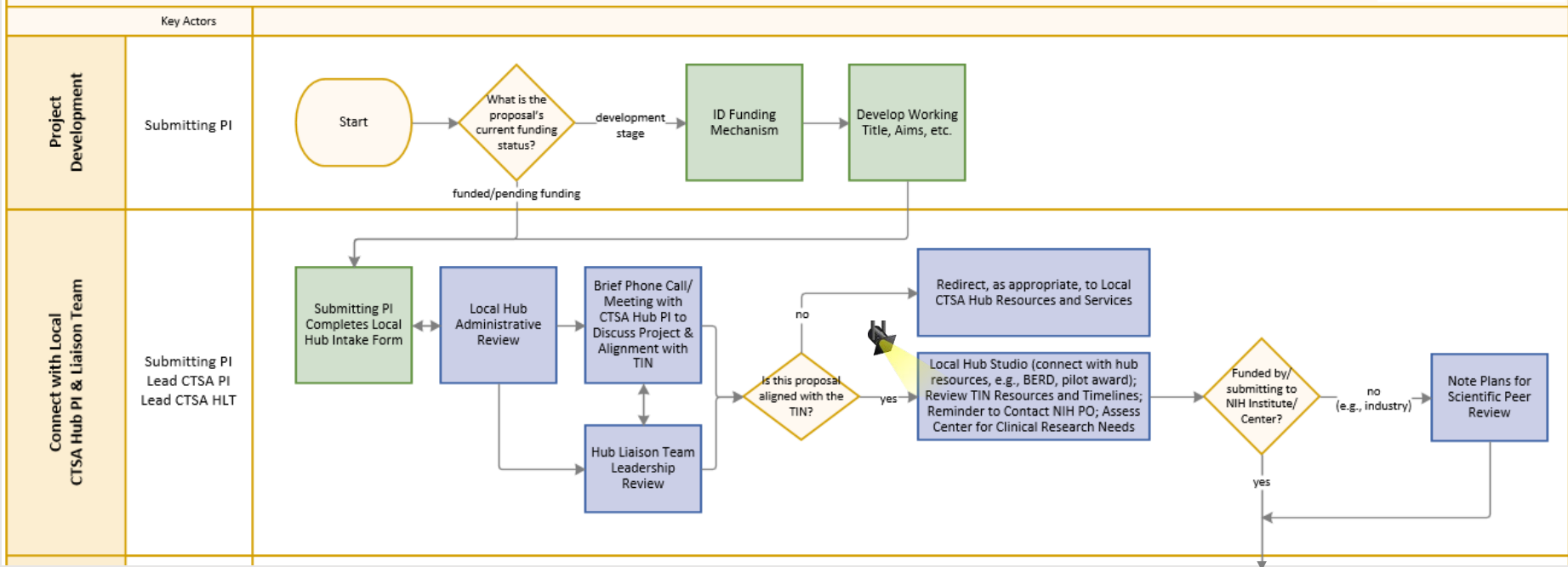
If your proposal is selected to receive support from the Trial Innovation Network (TIN), please indicate which services you may be interested in utilizing for this study \*  
 Initial Consultation through to Study Implementation (Developmental stage only)  
 Community Engagement Studio  
 Operationalize 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](mailto:NUCATS@northwestern.edu)

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

Trial Innovation Network Process Map for Submitting Investigators and Primary/Lead Sites



Next step: Connect with Program Officer

Color indicates primary actor:

Green: Submitting PI

Blue: Local Hub Liaison Team

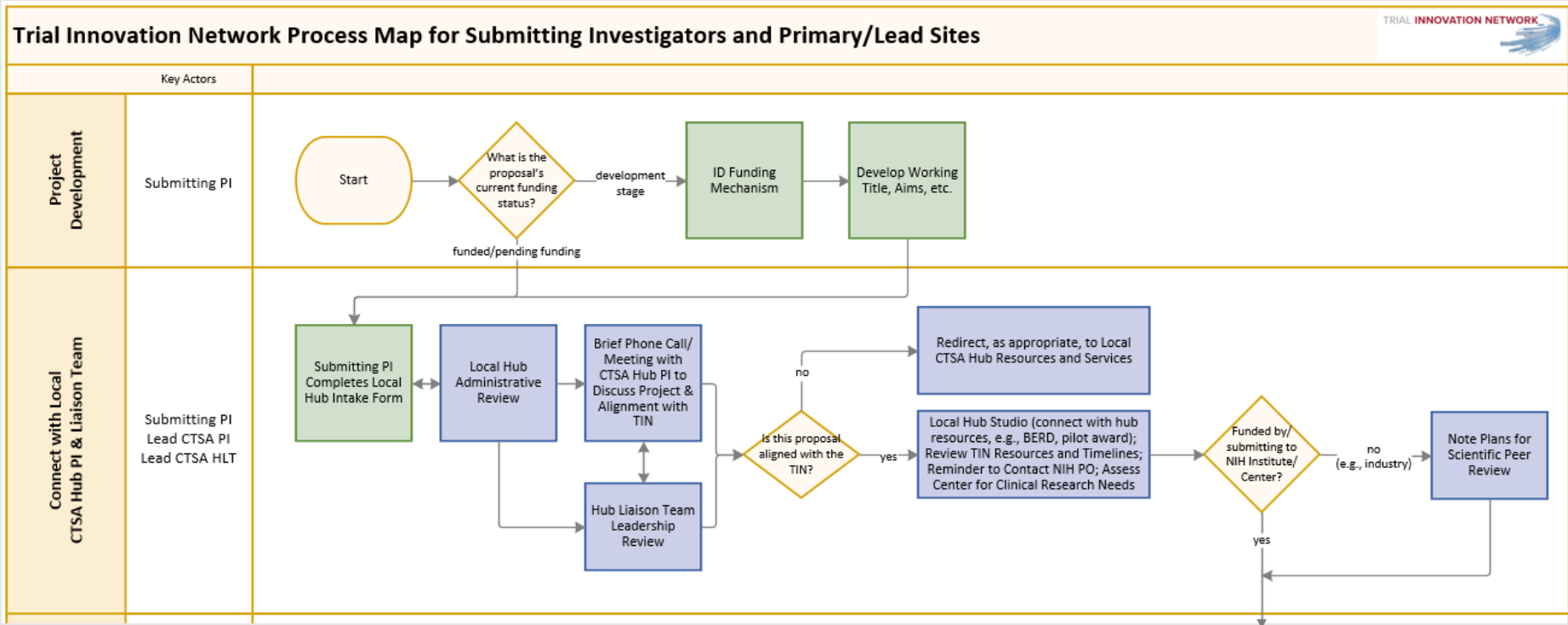




# Local HLT “Studio”

- 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



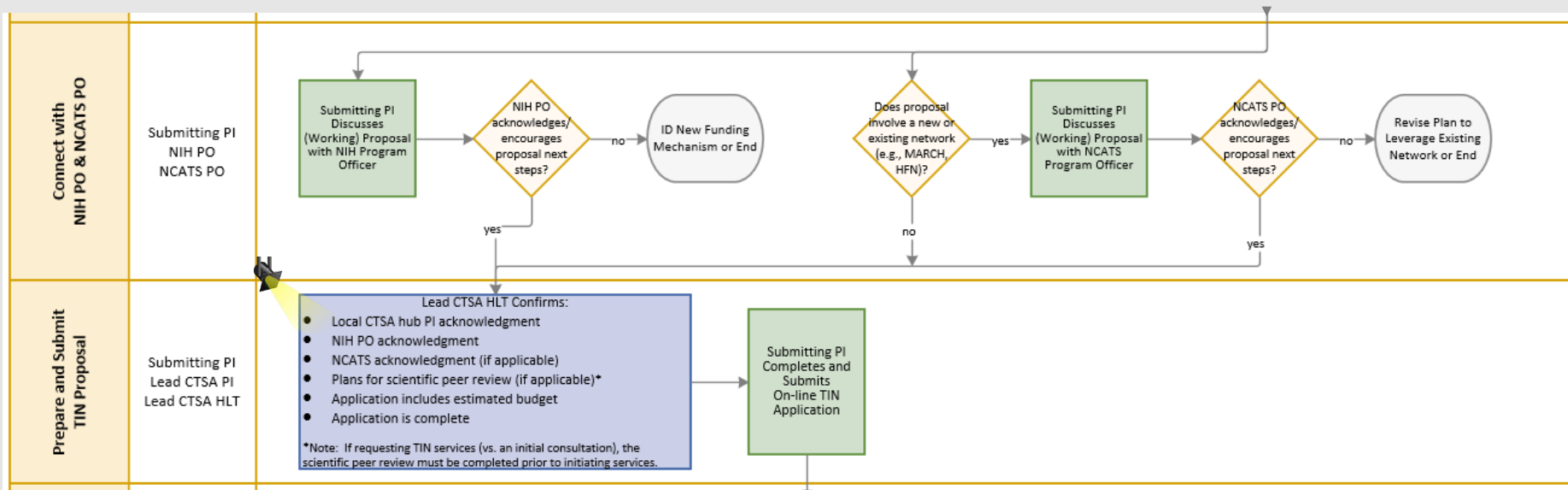
Next step: Connect with Program Officer

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

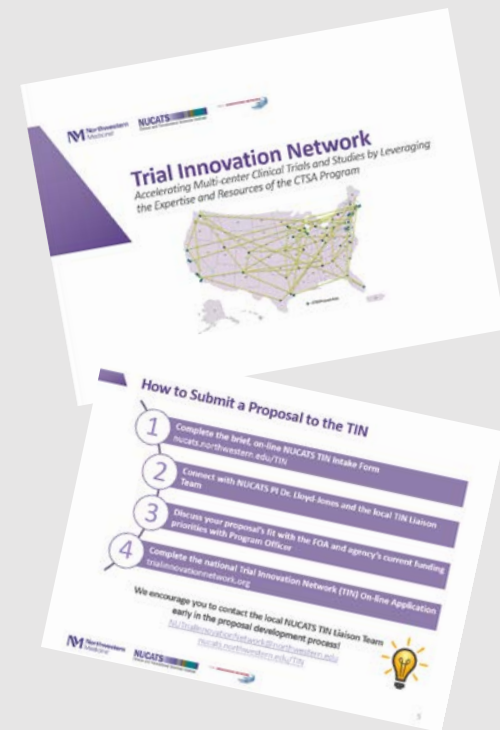
- HLT Navigator works closely with submitting PI and/or study team member to confirm:
  - ☑ Application is complete – and includes:
    - ☑ Local CTSA hub PI acknowledgment
    - ☑ NIH Program Officer acknowledgment
    - ☑ NCATS acknowledgment (if applicable)
    - ☑ Plans for scientific peer review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