NUCATS TIN Hub Liaison Team: Intake Form & Process Map

Keith Herzog Northwestern University Clinical and Translational Sciences (NUCATS) Institute









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



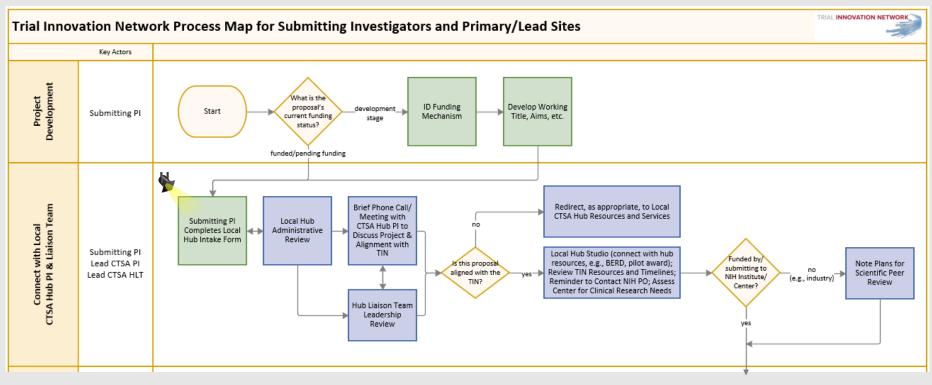
Process Map

- 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: <u>Green</u>: Submitting PI Blue: Local Hub Liaison Team



Local HLT Intake Form

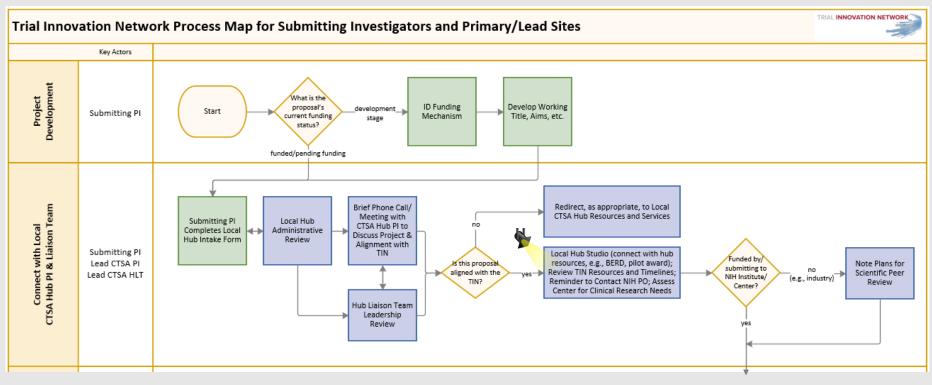
- Goals for local intake form
 - Confirm eligibility for TIN support (e.g., multicenter trial/study, not requesting support for P01 administrative core)
 - Collect basic proposal details in advance of call with local CTSA hub PI (e.g., current funding status, proposal aims, TIN services of interest)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

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



Next step: Connect with Program Officer

Color indicates primary actor: <u>Green</u>: Submitting PI Blue: Local Hub Liaison Team



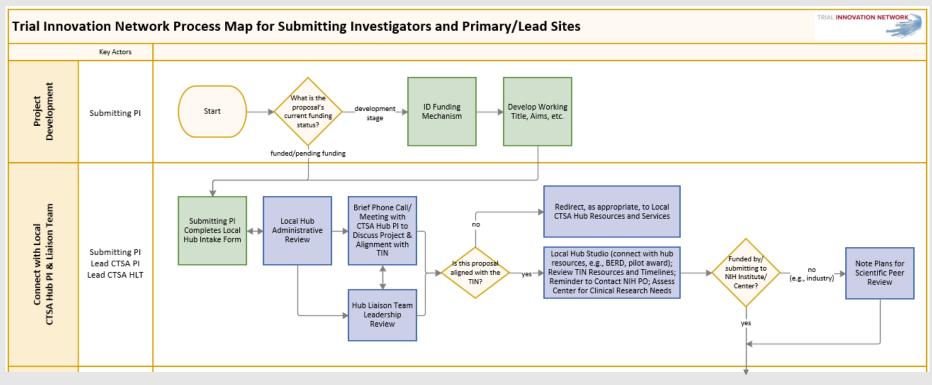


- Based on successful NUCATS hub and Center for Clinical Research studio models
- TIN "Studio" objectives
 - **Connect** submitting PI to local HLT members
 - Discuss TIN goals, workflow, and timeline as well as role of local HLT
 - **Review** submitting PI's brief, working description of multi-center 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

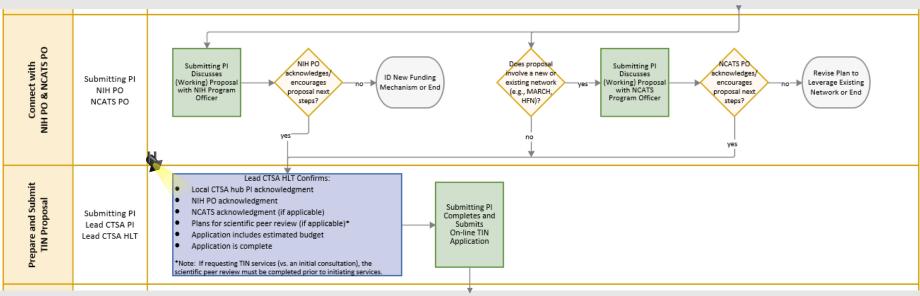


Next step: Connect with Program Officer

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Process Map: Connecting with Program Officer through TIN Proposal Submission



Next step: TIN Proposal Review

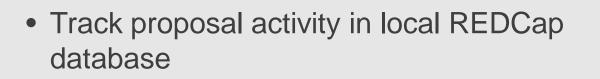
Color indicates primary actor: <u>Green</u>: Submitting PI Blue: Local Hub Liaison Team





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)



Clinical & Translational [®] Science Awards

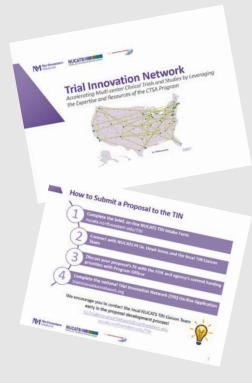
*Note: If requesting TIN services (vs. an initial consultation), the scientific peer review must be completed prior to initiating services.





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









NUCATS TIN Liaison Team NUTrialInnovationNetwork@northwestern.edu







