

### Organization of the Trial Innovation Network

- **Trial Innovation Network**
  - Key organizational components include the TICs, RIC, and CTSA Program Hubs
  - All are key partners of the Trial Innovation Network and make unique and essential contributions
  - Other important partners include NIH Institutes, other federal and non-federal stakeholders, researchers, patients, providers, and the public
- **Trial Innovation Centers (TICs)**
  - Innovation Centers focused on operational excellence, operational innovation, and quality by design
  - The TICs are charged with coordinating and providing innovative, high quality operational support for clinical trials.
  - TICs – Duke University/Vanderbilt University; University of Utah; Johns Hopkins University/Tufts University
- **Recruitment Innovation Center (RIC)**
  - Innovation Center focused on innovative and evidence-based approaches to participant recruitment, retention, and engagement
  - The RIC will provide tools and services to enhance participant recruitment and retention
  - RIC – Vanderbilt University with partners at Columbia University, the Ohio State University, Rockefeller University, and the University of Utah
- **Trial Innovation Network Hub Liaison Teams**
  - Frontline of the Trial Innovation Network. The Trial Innovation Network Hub Liaison Teams (formerly referred to as TIC Liaisons and RIC Liaisons) will lead the Network at the local level and will connect the Hubs to the TICs and RIC.
  - Trial Innovation Network Hub Liaison Teams will use their experience and knowledge of the local environment to coordinate Trial Innovation activities at their Institutions, tailoring general Network plans into more specific action plans that are best suited for their Hubs.
  - The Trial Innovation Network Hub Liaison Teams will work with the TICs and RIC to operationalize Level 1 and Level 2 Network Projects.
  - Potential initial members of a Trial Innovation Network Hub Liaison Team might include a Medical Director (an experienced clinical investigator knowledgeable about clinical trials and the local environment) who would lead the team, and experienced clinical research staff with expertise in IRBs, contracts, and informatics.
- **Network Executive Committee (NEC)**
  - Includes PI representatives from the TICs and RIC and NCATS. The NEC also includes 3 individuals who act as TIC PIs and CTSA Program Hub PIs. The NEC is accountable for collective executive decisions for the Trial Innovation Network and provides regular updates to the CTSA Program. The NEC is advisory to NCATS.

# TRIAL INNOVATION NETWORK

## *Key Terminology and Definitions*

- The NEC is responsible for collaborative strategic planning and day to day management of the Trial Innovation Network. The NEC responsibilities include developing and implementing the vision, goals, and strategic plan (including the operational scientific strategic priorities) of the Trial Innovation Network, collaboratively engaging stakeholders, and ensuring excellence and harmonization across the Trial Innovation Network
- The NEC has committed to fostering an environment of teamwork, collaboration, and productivity by proactively communicating across the Trial Innovation Network and CTSA Program, working together on the common goals and shared vision of the Trial Innovation Network, and focusing on results, operational excellence, and operational innovation.

### **Trial Innovation Network Projects**

- **Level 1 Network Projects (Limited Consultation or Service)**
  - Trial Innovation Network provides specific in-kind consultations or services (up to a pre-specified threshold) but the Trial Innovation Network is not responsible for recruiting patients or managing study data.
- **Level 2 Network Projects (Comprehensive Consultation)**
  - The Trial Innovation Network provides comprehensive in-kind consultations (up to a pre-specified threshold) to develop a proposal into a protocol. A Comprehensive Consultation could include an array of enhanced consultations such as in-depth protocol development, statistics, recruitment feasibility, recruitment plans, study budgets, and other key elements. During the Comprehensive Consultation, input from the CTSA Program Hubs on the protocol and proposed study budgets would be sought.
  - After a Level 2 Network Project Comprehensive Consultation, the Principal Investigator has the option to independently develop an application for a clinical trial using the TICs/RIC as the Coordinating Centers and the Hubs as the recruitment sites.
- **Trial Innovation Network Project Proposal Intake Process**
  - Network Project Proposal intake process currently being developed for investigators to submit proposals and access the resources of the Trial Innovation Network. The Trial Innovation Network Project Proposal Intake Process is in a pilot phase.

### **Trial Innovation Network – Working Groups (WG)**

#### **Trial Innovation Network Central IRB System WG**

##### **WG Charge**

- Develop harmonized processes, models and workflows for the three Central IRBs of the Trial Innovation Network

# TRIAL INNOVATION NETWORK

## *Key Terminology and Definitions*

### Key Early Deliverables

- Develop early models and workflows for how the TICs will work with the Trial Innovation Network Hub Liaison Teams to operationalize Central IRBs for Trial Innovation Network Projects

### Key Definitions

#### **Central IRB (CIRB)**

- An Institutional Review Board (IRB) that has been designated as the “IRB of record” for a study or group or network of studies. The TICs will serve as the designated CIRBs for Network Projects and Trial Innovation Network trials.

#### **TIC IRB Point of Contact (POC)**

- A Project Manager or other representative from a TIC who serves as the point of contact from the TIC Central IRB to the Trial Innovation Network Hub Liaison Team.

#### **Trial Innovation Network Hub Liaison Team IRB Point of Contact (POC)**

- A member of the Trial Innovation Network Hub Liaison Team who serves as the Point of Contact from the Trial Innovation Network Hub Liaison Team to the TIC IRB Point of Contact. The Trial Innovation Network Hub Liaison Team POC should have knowledge and experience in IRB and human research protection program (HRPP) issues to be able to operationalize the TIC Central IRB.
- Each Trial Innovation Network Hub Liaison Team will have flexibility in determining specific responsibilities of the Network Hub Liaison Team IRB POC, but key tasks may include
  - Working with the Institution’s IRB to determine whether or not to cede review to the TIC CIRB for a specific study
  - Working with a local investigator to submit materials to the local IRB for initial sign-off on reliance, as well as final submission to the TIC CIRB
  - Serving as a liaison between the TIC CIRB and the local study team, as needed
  - Ensuring the local study team understands and complies with any remaining local IRB policies and procedures.

#### **SMART IRB Authorization Agreement**

- The master IRB reliance agreement that will be used to support single IRB review of all Trial Innovation Network studies.

#### **SMART IRB Exchange**

- The IT platform that will be used to support the Trial Innovation Network CIRB workflow, including the decision to cede review for a study, the initial and ongoing review and approval of studies, and ongoing communication around reliance.

### **Trial Innovation Network Master Agreements and Budgeting WG**

#### **WG Charge**

- Sign on all CTSA Program Hubs and potential sites to the FDP-CTSA Master Agreement Template
- Work through critical issues with the CTSA Program Hubs for sign on to the FDP-CTSA Master Agreement Template

# TRIAL INNOVATION NETWORK

## *Key Terminology and Definitions*

### Key Early Deliverables

- Develop standardized processes and workflows for sign on to the FDP-CTSA Master Agreement Template and management of future amendments

### Key Definitions

#### **Master Subaward Agreement Template**

- A subaward template that participating institutions and organizations have mutually agreed upon.

#### **MA & B**

- Abbreviation for the Trial Innovation Network Master Agreements & Streamlined Budgeting Working Group, which is responsible for disseminating the Master Agreements and developing key performance metrics for the Master Agreement process

#### **Federal Sub Award**

- Issued under Grants and Cooperative Agreements and are most typically issued for the support of collaborative research activities in an academic setting.

#### **Federal Sub Contract**

- Issued under contracts and are typically for the procurement of a good or service.

#### **FDP-CTSA - FDP Fixed Price Clinical Trials Subaward Agreement**

- A subaward template for federally funded clinical trials that most domestic institutions could accept and that may eliminate the need for more extensive negotiations.

#### **TIC Master Agreements Point of Contact (POC)**

- A Project Manager or other representative from a TIC who serves as the point of contact from the TIC to the Trial Innovation Network Hub Liaison Team.
- Serves as the facilitator between the Trial Innovation Network and the CTSA Program Hub regarding all template and master agreement issues. This individual is responsible for sending the FDP-CTSA Master Agreement or Work Order to the Trial Innovation Network Hub Liaison Team Master Agreement POC and returning the signed agreement to the TIC Contract Office.

#### **Trial Innovation Network Hub Liaison Team Master Agreement Point of Contact (POC)**

- A representative from the Trial Innovation Network Hub Liaison Team who serves as the point of contact from the Trial Innovation Network Hub Liaison Team to the TIC for issues related to Master Agreements.
- Would be responsible for collecting all required documentation (i.e. budget, scope of work, etc.) and sending the documents, along with the FDP-CTSA Master Agreement to the Hub's Contract Office for signature. This individual is also responsible for sending the signed FDP-CTSA Master Agreement or Work Order back to the TIC Master Agreements Project Leader.

### **Trial Innovation Network Workflows and Network Projects WG**

#### **WG Charge**

- Work in partnership with other Trial Innovation Network WG to develop a library of critical workflows and processes that will be a roadmap for the Trial Innovation Network
- Develop the assessment criteria, organization, and governance of the Proposal Assessment Team

# TRIAL INNOVATION NETWORK

## *Key Terminology and Definitions*

### **Key Early Deliverables**

- Develop draft Network Project Proposal Intake Workflow
- In collaboration with Central IRB WG, develop draft Trial Innovation Network Central IRB Workflow
- In collaboration with Master Agreements WG, develop draft Trial Innovation Network Master Agreement Workflow

### **Key Definitions**

#### **Network Project Proposal Intake Workflow**

- Network Project Proposal intake process currently being developed for investigators to submit proposals and access the resources of the Trial Innovation Network. The Trial Innovation Network Project Proposal Intake Process is in a pilot phase and will evolve as the Network evolves.

#### **Proposal Assessment Team**

- Team charged with assessing proposals submitted to the Trial Innovation Network. Team is developing charter for organization and administration of assessment process. Currently in pilot phase.

### **Trial Innovation Network Engagement – CTSA Program Hubs**

#### **WG Charge**

- Develop approaches to engage CTSA Program Hubs as key partners in the Trial Innovation Network
- Develop frameworks to help the CTSA Program Hubs organize the Trial Innovation Network Hub Liaison Teams

### **Key Deliverables**

- Preliminary list of key roles and responsibilities for Trial Innovation Network Hub Liaison Teams to assist CTSA Program Hub PIs in conceptualizing how to organize their Hubs

### **Key Definitions**

- Trial Innovation Network Hub Liaison Team
  - A multidisciplinary team at each of the 64 CTSA Program Hubs responsible for leading the Trial Innovation Network at the Hub level.
  - The Trial Innovation Network Hub Liaison Teams will work with the Trial Innovation Network Coordinating Centers (TICs and RIC) to operationalize Level 1 and Level 2 Network Projects

### **Trial Innovation Network Engagement – Patients, Providers, and Public**

#### **WG Charge**

- Develop strategies to meaningfully engage key stakeholders including patients, providers, and the public, leveraging strengths among the Collaboration/Engagement and Informatics Domain Task Force and other expertise across the CTSA Program Hubs.

### **Key Early Deliverables**

- First draft/outline of Engagement Plan
- Draft of initial messaging to stakeholders

# TRIAL INNOVATION NETWORK

## *Key Terminology and Definitions*

### **Key Definitions**

#### **Patients**

- Individuals with current or past experience of illness or injury; includes their family members, caregivers (unpaid), patient surrogates, and patient advocates

#### **Providers (Clinicians)**

- Health care professionals who provide health care services in a clinical setting

#### **Public**

- The broader lay community including consumers of health care

#### **Community**

- A group of individuals affiliated by geographic proximity, specific medical conditions, or similar situations with purpose of addressing issues affecting the health and well-being of themselves or others

#### **Engagement**

- A bidirectional relationship or interaction between stakeholder and researcher that results in informed decision-making about the selection, conduct, and use of research

#### **Community-Engaged Research**

- A framework or approach to research that describes a continuum of research conducted with community members or stakeholders actively involved

### **Trial Innovation Network Website**

#### **WG Charge**

- Develop a website that
  - Highlights key themes of the Trial Innovation Network – operational excellence, operational innovation, and collaboration
  - Facilitates communication about the Trial Innovation Network to various stakeholders – CTSA Hubs, NIH Institutes, federal and non-federal partners, the research community, patients, providers, and the public
  - Functions as a portal of information to the CTSA Program about the Trial Innovation Network
  - Functions as a platform for collaboration and crowdsourcing of ideas from many stakeholders

#### **Key Early Deliverables**

- Website pages to provide an introduction, overview, and information about the Trial Innovation Network
- Website pages to encourage and guide investigators on how to submit a Trial Innovation Network Project proposal for review
- Website pages to showcase engagement and collaboration opportunities for the investigator community through open innovation feedback submission, webinars, and vetted tools and resources

### **Key Definitions**

#### **trialinnovationnetwork.org**

- Official domain of the Trial Innovation Network website