Trial Innovation Network
Guidelines and Instructions for Submitting Proposals

Objective: This document describes the Trial Innovation Network proposal assessment process and standards for confidentiality. It also provides guidelines and instructions to facilitate submission of proposals.

Proposal Review

The Trial Innovation Network proposal assessment process consists of the steps below.

1. **Administrative Review**
   a. The purpose of the Administrative Review is to ensure the proposal form is complete and that the CTSA Hub PI has approved the proposal.
2. **NCATS Review**
   a. The purpose of the NCATS Review is to ensure that the proposal is aligned with the mission of NIH, NCATS, and the Trial Innovation Network. In addition, the NCATS review will assess if there is NIH scientific or budgetary overlap, and if there has been appropriate communications with the NIH Institute Program Officer where funding has been awarded or will be sought.
3. **Trial Innovation Network Proposal Assessment Team (PAT) Service or Initial Consult Review**
   a. The initial PAT Review will address the following key criteria: 1) Funding/Budget Feasibility; 2) Study Feasibility; 3) Opportunity for Operational Innovation; 4) Impact (scientific, public health, social); and, 4) Program Balance.

Confidentiality

The Trial Innovation Network seeks to engage researchers in conducting innovative research projects consistent with the mission and goals of this network. As such, it is imperative that researchers who submit proposals to this network can be confident that their proposals and project ideas will be kept confidential and only disclosed to the extent necessary to provide consultation or services to the investigator.

It is understood that investigators may submit confidential information to the Trial Innovation Network including but not limited to proposals and application materials, regardless of whether such information is designated as confidential information at the time of its disclosure.

All proposals and application materials submitted to the Trial Innovation Network will be kept confidential and not disclosed to anyone except as required by law, or to the extent necessary to evaluate the proposal or provide the requested consultation or services associated with the proposal. Each Trial innovation Network team member shall acknowledge that they will maintain the confidentiality of the proposal information and associated materials consistent with the policy set forth herein prior to reviewing any proposals or associated information.

Guidelines for Submitting Proposals

- The Trial Innovation Network will prioritize proposals for multi-center clinical trials and studies with patient-oriented endpoints with the potential for impact on clinical practice and operational innovation
- Proposals that foster collaborations with other NIH ICs will be prioritized.
- Investigators are requested to first leverage local CTSA Program resources, particularly for protocol design and statistical plans, before submitting a proposal to the Trial Innovation Network.
- Early stage investigators with limited experience in clinical trials and clinical research should first seek support from their CTSA Hub resources, including the training program and the pilot program, their BERD (Biostatics Epidemiology Research Design program), and other NIH training resources before submitting a proposal to the Trial Innovation Network.
- Proposals with funding and funding plans will be prioritized.
- Pilot studies funded through the CTSA Hub award will not be eligible for additional CTSA award support through the Trial Innovation Network.
- Proposals in response to a Program Project grant (P01) funding mechanism will not be eligible to submit to the Trial Innovation Network.
- Existing networks (or investigators preparing applications for new networks) seeking to leverage the Trial Innovation Network should first contact NCATS to discuss the proposal.

Instructions for Submitting Proposals

BEFORE submitting a Trial Innovation Network Project Proposal, please review the instructions below to ensure there are no delays in review.

1. **Communicate with your CTSA Hub PI and the CTSA Hub Liaison Team**: The Principal Investigator of a proposal should communicate with his/her CTSA Hub PI and Trial Innovation Network Liaison Team. A list of CTSA Program Hub PIs may be found at https://ncats.nih.gov/ctsa/about/hubs. Prior to submitting a proposal, the PI should contact his CTSA Hub PI to discuss the proposal, and request the CTSA Hub PI to send an e-mail confirming approval. The PI should attach the letter of approval when submitting his/her proposal.

2. **Communicate with the NIH Program Officer at the NIH Institute where funding has been awarded or will be sought**: The Principal Investigator for the proposal should communicate with the NIH Program Officer where funding has been awarded or will be sought and should include the name of the Program Officer in the proposal submission form. The PI should receive feedback that the proposal is appropriate for submission to the Trial Innovation Network.

3. **Peer Review Status**: The PI should indicate the peer review status of a proposal. Proposals requesting a Service will be required to have undergone scientific peer review before that Service is executed by the Trial Innovation Network. If peer review is either planned or has already been provided by a group other than NIH, then please include details of the reviewing organization and

the review process. Include a timeline for reviews that are planned but not completed. Please note that IRB review does not constitute peer review.

4. **Project Funding Status**: Include amount of awarded funding or describe plans for funding in order for the Proposal Assessment Team to adequately assess budget feasibility. If funding has not been awarded please include an estimated budget and, if appropriate, the mechanism of the NIH grant that you will be applying for.

5. **Proposal Completeness**: Confirm the proposal is complete (all fields have information), verify that requested information has been provided, and include any additional information you consider necessary as attachments to the proposal (protocol, budget information, peer review documents, etc.). Please note that missing information will delay the review of your proposal.

If you have questions about these instructions or the proposal submission process, please contact the PAT Development Team at info@trialinnovationnetwork.org.