

Trial Innovation Network

Proposal Submissions

Guidelines and Checklist for Investigators

Objective: The purpose of this document is to provide guidelines and a checklist to study investigators interested in submitting a proposal to the Trial Innovation Network.

Guidelines

The Trial Innovation Network is a collaborative research network funded by the [National Center for Advancing Translational Sciences](#). The Trial Innovation Network will provide study investigators with a broad range of services and consultations to optimize clinical trials and studies. These services and consultations are designed to help investigators develop proposals into protocols, optimize study operations, and enhance recruitment and enrollment.

Prior to submitting a Trial Innovation Network Project Proposal, investigators must discuss the proposal with his/her CTSA Program Hub Principal Investigator and the Trial Innovation Network Hub Liaison Team.

Trial Innovation Network Project Proposals may be submitted online through the [Trial Innovation Network Website submission portal](#). Chrome is the recommended browser to submit a proposal.

Please note that this is Version 2.0 of these guidelines and checklist and that it will undergo further refinements and revisions as we learn and develop the proposal assessment process. Please check the Trial Innovation Network website frequently in order to ensure that you are using the most recent version of these documents when guiding investigators.

The Trial Innovation Network recognizes that maintain confidentiality is an integral part of the proposal assessment process. As such, 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.

Checklist of Actions for a Proposal Requesting a Service or Consultation

Please ensure the following have been completed before submitting an proposal

Eligibility

- A. Confirm understanding that the Trial Innovation Network will prioritize proposals for multi-center clinical trials and studies with patient-oriented endpoints with potential for impact on clinical practice and operational innovation.
- B. Confirm understanding that the Trial Innovation Network will prioritize proposals that foster collaborations with other NIH ICs over proposals seeking funding from NCATS.
- C. Confirm that the proposal is not a multi-center study funded through the CTSA Program award.

- D. Confirm that the proposal is not for a P01 (Program Project Grant) funding opportunity announcement

Preparatory Work

- E. Ensure that local CTSA Program resources for protocol design and statistics have been leveraged before submitting a proposal to the Trial Innovation Network.
- F. Early stage investigators should seek support from CTSA Hub resources, including the training program and the pilot program, and other NIH training resources, before submitting a proposal to the Trial Innovation Network.

Approvals

- G. Confirm that the Trial Innovation Network Hub Liaison Teams have been consulted for guidance on how to submit a proposal.
- H. Confirm approval of the proposal from the CTSA PI (may include a review by the CTSA Hub Liaison Medical Director) and that the CTSA PI has sent an e-mail to the investigator documenting approval
- I. Confirm approval to submit a proposal from an NIH Program Officer (PO) at the Institution where funding has been received or will be sought.
- J. Confirmation of approval from NCATS if developing a proposal that will include collaboration with an existing network. In addition, you should also receive prior approval from NCATS if preparing an application for a new network wishing to leverage the Trial Innovation Network.
- K. Confirm that Scientific Peer Review has been obtained or indicate the date at which peer review is scheduled. Please note IRB review does not constitute peer review.

Other

- L. Confirm the proposal includes the potential source of funding, the estimated budget, and, if appropriate, the mechanism of the NIH grant they will be applying for.
- M. Ensure the entire application is complete.

Documents

- N. Confirmation of approval by the CTSA PI (and CTSA Hub Liaison Medical Director as appropriate) to be attached to proposal submission.
- O. Confirmation of scientific peer review. Attach to application, documentation and details related to the peer review that has been conducted or is planned. Please note IRB approval does not constitute scientific peer review.
- P. Confirmation of budget plans. For funded studies, include grant number, or funding source and budget. If study is not funded, provide an estimated budget and describe funding plans, including which grant mechanisms the investigator will be applying for.
- Q. For a consultation, notes or summary of consultation from local CTSA program resources