

Trial Innovation Network Proposal Submissions Guidelines and Checklist for Hub Liaison Teams

Objective: The purpose of this document is to provide guidelines and a checklist to assist Hub Liaison Teams in providing information to potential investigators about the proposal submission process.

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. The Hub Liaison Teams are a critical part of the Trial Innovation Network proposal process and this document is designed to provide guidelines and a checklist to assist you in carrying out your responsibilities as the Hub Liaison Team.

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. As the Network Hub Liaison Team, you should be able to answer questions about the Trial Innovation Network and be able to provide information prior to submission.

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 by the investigator before submitting an proposal

Eligibility

- A. Confirm that the investigator understands 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 that the investigator understands 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 investigator's proposal is not a multi-center study funded through the CTSA Program

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award.

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

Preparatory Work

- E. Ensure that the investigator has first leveraged local CTSA Program resources for protocol design and statistics before submitting a proposal to the Trial Innovation Network.
- F. Ensure early stage investigators have sought 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 investigator has consulted with the Trial Innovation Network Hub Liaison Teams for guidance on how to submit a proposal.
- H. Confirm that the investigator has received 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 documenting approval to the investigator.
- I. Confirm the investigator has received approval to submit a proposal from an NIH Program Officer (PO) at the Institution where funding has been received or will be sought.
- J. Confirm that the investigator has received approval from NCATS if they are developing a proposal that will include collaboration with an existing network. In addition, investigators preparing applications for new networks who wish to leverage the Trial Innovation Network should also first receive approval from NCATS.
- K. Confirm that the investigator has obtained Scientific Peer Review or the date at which peer review is scheduled. Please note IRB review does not constitute peer review.

Other

- L. Confirm that the investigator's 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 investigator has completed the entire application.