
Trial Innovation Network

Proposal Assessment Team (PAT) Charter

Executive Summary

Objective: Summarize the Trial Innovation Network Proposal Assessment Team processes, working practices, and guidelines for managing the review and assessment of proposals submitted to the Trial Innovation Network requesting a specific service(s) or consultations.

Scope: This document applies to practices and processes associated with the review and assessment of proposals submitted to the Trial Innovation Network.

Review and Revision: The PAT Charter Executive Summary will be reviewed, refined and updated periodically as we continue to develop the proposal assessment processes.

I. PAT Membership

The Proposal Assessment Team (PAT) is comprised of voting members and non-voting members. Voting members are investigators and project leaders from each Trial Innovation Center (TIC) and Recruitment Innovation Center (RIC), and two members from NCATS. Non-voting members are the PAT Chair and an administrative project leader.

II. PAT Roles and Responsibilities

Voting Members are responsible for consistently reviewing and assessing the proposals submitted to the Trial Innovation Network according to the criteria established by this team, voting to approve or not approve each proposal, and documenting their review and vote in a timely manner within the IT platform.

The Chair is a non-voting Network Principal Investigator responsible for providing overall leadership to the PAT for the assigned period of time. The Chair will lead the PAT meetings, facilitate the discussion of each proposal, summarize the reviewer comments, open the floor for discussion, moderate and close the discussion and take the formal vote from each PAT member to approve or not approve each proposal.

The Primary Reviewer is the voting member responsible for presenting assigned proposals to the rest of the PAT using a standard format to initiate the discussion on the respective proposal.

III. Managing Conflicts of Interest

The Trial Innovation Network will engage in practices that preserve the public trust and assure research will be conducted without bias and with the highest scientific and ethical standards. In keeping with this commitment, the PAT members have an obligation to recognize potential conflicts of interest and to abstain from voting on a proposal when a conflict has been identified.

For the purposes of the PAT, all voting members may vote on a proposal unless the voting member has provided direct assistance in completing the proposal, has had direct discussions with a particular Institute or Center regarding the proposal, or otherwise provided anything more than a “curbside” consultation (defined as a 30 minute to 1 hour phone call or discussion about the proposal) with the submitting investigator/investigator’s team. In addition, it is the responsibility of each TIC/RIC PI to disclose any conflicts or other affiliations that he/she may have with any networks, consortia, or other organized research program associated with the submitted proposal or the submitting PI/team or the recommendations being made to the investigator.

Notwithstanding the foregoing, each PAT member may abstain from voting (or facilitating if the PAT Chair) on any proposal in which the PAT member perceives he or she may have a conflict of interest even when it does not rise to the level defined herein or any then current Trial Innovation Network policies, practices, or guidelines.

Whenever a voting PAT member abstains from voting on a specific proposal due to a conflict of interest, this will be documented in the IT platform as well as the PAT meeting minutes.

IV. Confidentiality

The Trial Innovation Network seeks to engage researchers in conducting innovative research projects consistent with the mission and goals of this network. As part of the proposal submission process, the Trial Innovation Network recognizes that confidential information may be disclosed and has developed a Confidentiality Policy that allows researchers to be confident that their proposals and project ideas will be kept confidential by the Trial Innovation Network team members and only disclosed to the extent necessary to provide consultation or services to the investigator and study team.

Each Trial innovation Network team member, including all members of the PAT, is required to review and acknowledge this confidentiality policy prior to reviewing proposals and associated information submitted to the Trial Innovation Network. These acknowledgment records and signatures of the Trial Innovation Network Team Members are electronically recorded and maintained by the administrative project staff for the Trial Innovation Network.

V. PAT Review Process

Initial PAT Review:

After an investigator has submitted a proposal to request initial consultation or a specific service, the proposal will go through the following steps:

- **Administrative Review** is the first step of the proposal intake process and is designed to ensure that the investigator has completed the proposal application and that there is no missing information in the proposal application.
- **NCATS Preliminary Review** is the second step in the proposal intake process and is designed to ensure that key internal NIH criteria have been assessed and important communication with other NIH Institutes have occurred prior to a proposal being reviewed by the PAT.
- **PAT Review** the third step in the proposal intake process and is designed to 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.

After the initial PAT review, if the study is approved, the investigator will be informed of the approval and assigned a specific TIC and/or RIC to work with to provide the initial consultation or requested service.

Subsequent PAT Review:

If the investigator was approved at the initial PAT review for services, no further review by the PAT is required.

If the investigator was approved for an initial consultation by the Trial Innovation Network, the proposal will be reviewed again at the PAT after the completion of the initial consultation.

At the conclusion of the initial consultation, the assigned TIC/RIC presents the initial consultation information to the PAT along with a recommendation. The recommendation may be any of the following:

- Proceed with a comprehensive consultation for the proposal and potential implementation of the trial;
- Offer discrete services for the proposal if subsequently funded; or
- Initial Consultation completed and no further follow-up needed.

After reviewing the recommendations of the TIC/RIC, the PAT will vote to approve or not approve the proposal consistent with the recommendations made by the assigned TIC/RIC subject to the following:

- If the recommendation includes one or more discrete services, the PAT may approve consistent with the recommendations or approve the proposal for a fewer number of services consistent with the capacity of the Network at the time;
- If the recommendation includes comprehensive consultation, then a unanimous vote of the PAT is required as well as NCATS approval before the assigned TIC/RIC begins the consultation. In addition, the PAT has the discretion to not approve the proposal for comprehensive consultation and to offer discrete services for the proposal consistent with the capacity of the Network at the time.

If the proposal proceeds with a comprehensive consultation, the assigned TIC/RIC will keep the PAT informed of any issues that may require further discussions at the PAT as well as the status of funding and trial implementation.