Pre-Application Webinar for RFA-CA-24-035

NCI National Clinical Trials Network – Open Competition

Network Group Integrated Translational Science Centers (UG! Clinical Trial Not Allowed)

NIH NATIONAL CANCER INSTITUTE

November 12, 2024

Agenda

1. Overview of Application for RFA

2. Eligibility for Organizations & PDs/PIs

3. Main Research Objectives, Functional Components & Research Strategy

4. Application Sections & Special Issues

5. Review Criteria & Scoring

6. Budget Issues

7. Data Management & Sharing Plan

8. Terms of Award

Application Overview

- Application Due Date: Feb. 24, 2025 (earliest submission Jan. 24, 2025)

- **Open Competition (Clinical Trial Not Allowed**) as applications do not propose clinical trials - **Both New & Renewal Applications allowed**

- Letter of Intent is not required, is not binding, & does not enter into review; however, it does help NCI staff estimate potential workload & plan the review – Due Jan. 24, 2025

- Single Project UG1 Cooperative Agreement with 2 Function Components

  - **Instructions in the How to Apply - Application Guide**

- Project Period: **6 years** (Planned project period from 3-1-2026 to 2-29-2032)

- Just-in-Time information, if applicable, will be required (Updates to "Other Support" & Human Subjects Protection Training for Key Personnel)

Eligible Organizations

- Application organization eligibility is per the RFA

- Applicant organization may submit more than one application, provided that each application is scientifically distinct; the NIH will not accept duplicate or highly overlapping applications under review at the same time, per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application.

Also:

- Non-domestic (non-U.S.) Entities (Foreign Organizations) **are not** eligible to apply.

- Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply

- Foreign components, as defined in the *NIH Grants Policy Statement*, **are** allowed.

Eligible Program Directors (PD) / Principal Investigators (PIs)

- For institutions/organizations may propose multiple PDs/PIs, per the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the [How to Apply - Application Guide](#)

- The named PDs/PIs for applications for NCTN Network Translational Science Centers **cannot** be named as PDs/PIs on applications for the NCTN Network Group Operations Center (under RFA-CA-24-030)

- However, and individual who is designated as a PD/PI on the application for the NCTN Network Group Integrated Translational Science Center can, if appropriate, be listed as key personnel on applications for the NCTN Network Group Operations Centers

Main Research Objectives & Requirements

The Network Integrated Translational Science Center application must address 2 required functional components:

- **Integrated Translational Science Program** - This functional component provides support for well-defined approaches, policies, and procedures to help incorporate translational science into the late phase NCTN trials of new therapies and/or advanced imaging, especially with respect to specific disease areas and research focus. This component should also provide support for enhancing participation of translational science investigators in NCTN Network Group scientific activities and NCTN Program Initiatives

- **Pilot Studies and Collaborative Projects** - This component should support studies (as well as collaborations) with other NCTN Program components and/or NCI-sponsored programs to facilitate incorporation of translational science discoveries into late phase NCTN trials.

Research Strategy in PHS Research Plan & Attachments in Other Project Information for NCTN ITSCs RFA-CA-24-035

Research Strategy with 3 Sub-Sections	Research Strategy Page Limit	Other Attachments included under SF424(R&R) Other Project Information
Research Strategy Subsections: A: ITSC Overview B: Integrated Translational Science Program C: Pilot Studies and Collaborative Projects (Sub-sections B and C are the 2 functional components for application)	30 pages for entire Research Plan (divided up in any way)	Only 1 Attachment #1: Conflict of Interest Policy (use filename COIPolicy)

Overview of Application Sections

- SF424(R&R) Cover

- SF424(R&R) Project/Performance Site Locations

- SF424(R&R) Other Project Information

- SF424(R&R) Senior/Key Person Profile

- R&R Budget

- R&R Subaward Budget

- PHS 398 Cover Page Supplement

- PHS 398 Research Plan

  - Specific Aims / Research Strategy with 3 Sub-sections / **Letters of Support / Resource Sharing Plan, IF applicable / Appendix material is limited as per the RFA / Other Plan(s) which includes the Data Management & Sharing Plan**

- PHS Human Subjects & Clinical Trials Information Form, PHS Assignment Request Form

Special Issues NCTN ITSC Application

- **Letters of Support (Special Instruction):** The application section on Letters of Support should include a Letter(s) of Support from the PD(s)/PI(s) of the Network Group Operations Center(s) that are supporting the application

- **Appendix Materials:** Only limited Appendix materials are allowed per the instructions for the Appendix as described in the How to Apply - Application Guide

  - No publications or other material, with the exception of blank questionnaires or blank surveys, may be in the Appendix (but only if applicable; these would not be expected to apply to the content of the ITSC application)

- **Other Plan(s):** Data Management & Sharing Plan should be provided under the "Other Plan(s)" section. Consistent with the 2023 NIH Policy for Data Management and Sharing, when applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirement as outlined in the NIH Grants Policy Statement

Special Issues With PHS Human Subject and Clinical Trials Information Form

- For any answer of "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, applicant must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study record**

  - The delayed onset form includes a question **"Anticipated Clinical Trial?"** and this question for the ITSC application should be answered with **"No".**

- All the NCTN RFAs involving Human Subjects involve Delayed Onset Study/Studies as research trials are anticipated within period of award, but definite plans are not yet known & cannot be described in applications

- Since multiple delayed onset trials are anticipated, they can be included together in a single delayed onset study entry with **"Multiple Delayed Onset Studies"** as the title of record

Review Criteria & Scoring for RFA-CA-24-035

- Reviewers access the application against the Review Criteria in the RFA

- Reviewers will provide an overall impact score to reflect their assessment of likelihood for project to exert a sustained, powerful influence on the research involved, in consideration of the main review criteria

- Reviewers will consider each of the review criteria (Significance, Investigator(s), Innovation, Approach, & Environment) in determination of scientific merit and give a separate score for each

- Reviewers will evaluate the "additional items" for review specific to the NOFO/RFA while providing an overall impact score but will not give separate scores for these items

Budget Issues for NCTN ITSC Application

- Requested budget must not exceed $850,000 in Direct Costs per year

- Actual funding will depend on funds available at the time of award

- The application consists of a single budget for a 6-year budget period

Data Management & Sharing Plan

- Data Management & Sharing Plan to be provided with application submitted in response to this NOFO/RFA should adhere to the Data Management and Sharing requirements as outlined in the [NIH Grants Policy Statement](#)

- An optional format page for preparing this required plan in applications subject to the Data Management and Sharing (DMS) and/or Genomic Data Sharing (GDS) policies can be accessed at: [Data Management and Sharing Plan Format Page](#)

- Upon approval of a Data Management and Sharing Plan by the NCI staff overseeing the NCTN Program, it is required that the recipients implement the plan as described

Terms of Award

- In addition to standard terms of award under NIH Grant Policy, the RFA sets out other Terms of Award

- These terms are set out explicitly in the Cooperative Agreement Terms and Conditions of Award in the NOFO/RFA

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