Pre-Application Webinar for RFA-CA-24-031

Limited Competition: NCI National Clinical Trials Network – Network Group Statistics & Data Management Centers (U10 Clinical Trial Required)

NIH NATIONAL CANCER INSTITUTE

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Agenda

1. *Overview of Application for RFA*
2. *Eligibility for Organizations & PDs/PIs*
3. *Multi-Component Application (Components/Cores)*
4. *Review Criteria & Scoring*
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6. *Data Management & Sharing Plan*
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Application Overview

- Application Due Date: Feb. 24, 2025 (earliest submission Jan. 24, 2025)
- Limited Competition (Clinical Trial Required) – Renewals only
- Modular Format for U10 Cooperative Agreement with 3 Cores
  - **Multi-Project (M) Instructions in the How to Apply - Application Guide**
  - **Human Subjects & Clinical Trials form: Delayed Onset Study/Studies** as research anticipated within period of award, but definite plans not yet known & cannot be described in application
    - Since multiple delayed onset studies anticipated, include together in a **single delayed onset study entry with "Multiple Delayed Onset Studies" as the title of record** (Studies Plan, Justification & Dissemination Plan)
- 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

- **Only** the current award recipients under RFA-CA-17-057 are eligible to submit applications in response to this NOFO/RFA.

- In the NCTN Group Ops Ctr NOFO/RFA, there is restriction stating that an organization applying for an NCTN Group Operations Center award **cannot** apply for a NCTN Statistics & Data Management Center (SDMC) for the same project period

- Foreign components, as defined in NIH Grants Policy Statement, allowed

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

- Individual designated as a PD/PI for an NCTN Group Statistics and Data Management Center (SDMC) **must not** be designated as a PD/PI for any NCTN key component listed below:
  - NCTN Group Operations Center
  - Canadian Collaborating Clinical Trials Network
  - NCTN Lead Academic Participating Sites
  - NCTN Radiotherapy and Imaging Core Services Center (IROC)

- PD/PI for an NCTN Group SDMC **can**, if appropriate, be Key Personnel for associated NCTN Group Operations Center and/or NCTN IROC but **not** on applications for other RFAs listed above or on applications for **another** NCTN Group Operations Centers.

Multi-Component Application for NCTN SDMC RFA

- Application is designed around 4 Main Components
  - Overall
  - Administrative Core
  - Statistics Core
  - Data Management Core
- Each component has a specific page limit and may or may not have required Attachments
- No Appendix Material should be provided in any component

Overall Component

- SF424 (R&R) Cover
- PHS 398 Cover Page Supplement
- Research & Related Other Project Information **(include Project Narrative in this component)**
- Project/Performance Site Locations
- Research & Related Senior/Key Person Profile
- Budget **(only budget this component is estimated Project Funding section of SF424 (R&R) Cover)**
- PHS 398 Research Plan
  - Specific Aims / Research Strategy / **Letters of Support** / **Resource Sharing Plan in this component, IF applicable** / **Other Plan(s) which includes the Data Management & Sharing Plan for the entire application** /**Appendix (No appendix material is allowed given delayed onset for trials)**
- PHS Human Subjects & Clinical Trials Information **w/ PHS Assignment Request Form**

All Other Components

- SF424 (R&R) Cover
- PHS 398 Cover Page Supplement
- Research & Related Other Project Information
  - Human Subjects / Vertebrate Animals / **Project Narrative (Do NOT Complete as this is included only in the "Overall" component** / Other Attachments
- Project/Performance Site Locations
- Research & Related Senior/Key Person Profile
- Budget
- PHS 398 Research Plan:
  - Specific Aims / Research Strategy / **Data Safety Monitoring in Admin Core only / For Resource Sharing Plan, IF applicable, only provide information in the OVERALL Core only / Appendix (No appendix material is allowed given delayed onset for trials)**
- PHS Human Subjects and Clinical Trials Information (Admin Core only, if possible)
  - **We believe the PHS Inclusion Enrollment Report will not be required** as part of the application since the human subjects study will be entered as a "Delayed Onset" study

Summary of Main Components – RFA-CA-24-031

U10 Main Component	Page Limit	Sub-sections for Research Strategy	Attachments (or Plans) for Component
Overall	30	A: Significance B: Innovation C: Approach D: Progress Report	No Attachments Other Plan(s): Data Management & Sharing Plan
Administrative Core	12	A: Leadership & Structure B: Collective Management C: Collaborative Research	#1: Auditing Policy #2: COI Policy (+DSMB policy if no other area / attach in Admin Core)
Statistics Core	12	A: Structure B: Approach	#1: Key Standard Operating Procedures (SOPs) #2: Model Statistical Analysis Template #3: Current NCTN Trials Supported
Data Management Core	12	A: Structure B: Approach C: Training	#1: Key Data Mgt & Monitoring Policies & Procedures for Trials #2: Key Procedures to Ensure Security & Confidentiality of Pt Data #3: General Data Quality & Timeliness for NCTN Trials #4: Data Quality & Data Timelines for AEs/SAEs on NCTN Trials Led by the associated NCTN Group Operations Center

Summary Special Issues on Components

- Data Management & Sharing Plan should be provided **only** in "Overall" component
- Data Safety Monitoring Plans/DSMB Policy should be provided **only** in the "Administrative Core" component; if there is no other place to put the DSMB Policy, it should be included following the COI Policy in Attachment #2
- Human Subjects and Clinical Trials Information form with a single "Delayed Onset Study" record should be provided **only** in the "Administrative Core" component if possible; we believe the PHS Inclusion Enrollment Report will not be required as part of the application since the study will be entered as a "Delayed Onset" study
- Resource Sharing Plan(s), if applicable, should be provided **only** in the "Overall" Component
- **No** Appendix Materials allowable under the research plans of any component, including the "Overall" component
- Letters of Support in Admin Core from Applicant's Institution & PDs/PIs associated NCTN Group Operations Center
- Although the Data Management & Sharing Plan and Data Safety Monitoring Plans/Policy must be provided in the application, prior to funding of an award, these plans (and any updates to the plans) must be reviewed & approved by NCI DCTD/CTEP program staff prior to funding an award

Summary Special Issues on Components (continued)

- The Project Narrative is required **only** for the “Overall” component (as per the RFA, it should not be included in any other components)
- PHS Human Subjects and Clinical Trials Information form with a single “Multiple Delayed Onset Studies” study record should be in Administration Core only, if possible
- Key Personnel and Performance Sites for each component should follow the instructions in the RFA/User Guide for NIH Grant applications

Special Note on Inclusion of Children: RFA-CA-24-031

- Any NCTN Group can lead a network-wide AYA trial (i.e., NCTN AYA trial) and all Groups must offer participation to their sites. In addition, if an Adult Group leads an NCTN AYA trial, the Group must ensure appropriate monitoring for the patient population and must ensure that membership on their DSMB can provide appropriate oversight for such a trial
- NIH policy requires children are included in all human subjects research conducted or supported by the NIH, unless there are clear and compelling reasons not to include them as described at: http://grants.nih.gov/grants/funding/children/children.htm
  - *For cancer clinical research, Network Groups conducting research in adult cancers can provide a rationale for not including children because the majority of children with cancer in the US are already accessed by a Network Group devoted to pediatric cancer research, so that requiring inclusion of children in the proposed adult trials would be both difficult and unnecessary (since the research question is already being addressed in children by the pediatric network) as well as potentially counterproductive since fewer children would be available for the pediatric Network study if other studies were required to recruit and include children.*

General Comment on Review Criteria

- This review criteria for this NOFO/RFA are related to the “research strategy” the NCTN Group plans to employ for each of the 4 components for multiple delayed onset studies.

- Some of the standard NIH review criteria, however, for RFAs with a “Clinical Trial Required” designation remain and may be interpretated as applying to 1 specific trial being proposed. However, additional review criteria language was included in the NOFO/RFA to stress the intent of this RFA (research strategy for development & conduct for multiple delayed onset trials over the course of the project period).

- Although applicants may reference the types of trials that the Group may pursue or have pursued and how those decisions are made in its research strategy, applicants should **not** propose new/specific trials for review in the application as intent of the RFA is to evaluate the research strategy for delayed onset studies.

Review Criteria & Scoring

- Reviewers will review the entire application (all components & sections)
- Reviewers assess the application against the Review Criteria in the RFA
- Reviewers will provide an overall impact score for the entire application. In addition, reviewers will also provide individual "criterion scores" for the Overall application but not for the other components
- All other components of the Network (i.e., Administrative Core, Statistics Core, and Data Management Core) will be evaluated but each will receive only an overall “adjectival” rating

Budget Issues

"Overall" Component:

- The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover
    - *A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.*

Other Components:

- Budgets are required for each of the other Components of the Application (i.e., Administrative Core, Statistics Core, & Data Management Core). Budget for each Core should be as representative as possible with cross-cutting budget items across cores included in the Administrative Core budget.
- In the Administrative Core, applicant can explain how level of support required varies depending on the complexity of the trials and number of patients enrolled.

Budget Issues – Administrative Core

- **PD/PI Effort Commitment:** Minimal effort commitment for the Contact PI/PD must be 1.8 person-months per year. Effort commitment for other PDs/PIs (if multiple PIs) must be a minimum of 1.8 person-months per year. These effort commitments cannot be reduced in later years of the award.

- **Travel Expenses:** Applicants must budget travel funds as per the RFA for NCTN-related meetings.

- **Other Expenses:** Applicants must include in the budget appropriate expenses to cover support for the Data Safety Monitoring Board activities, auditing activities, preparation of data sets for applicable trials for the NCTN/NCORP Data Archive, and coordination activities with the associated NCTN Group Operations Center and tumor bank(s) to support linking of biospecimens and clinical data for the NCTN Navigator project and NCI/Cancer Therapy Evaluation Program (CTEP) approved integral and integrated correlative studies for ongoing trials as well as NCI/CTEP approved correlative studies using banked specimens.

Data Management & Sharing Plan

- The Data Management & Sharing Plan to be provided with the 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

- NCI DCTD/CTEP will be providing a prototype of an acceptable Data Management & Sharing Plan to those organizations under this Limited Competition RFA in conjunction when the transcript of the Pre-Application Webinar is posted on CTEP's website (targeted for within 2 weeks after the webinar)

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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