Pre-Application Webinar for RFA-CA-24-033

NCI National Clinical Trials Network – Open Competition

Network Lead Academic Participating Sites (UG1 Clinical Trial Not Allowed)

NIH NATIONAL CANCER INSTITUTE

October 28, 2024

Agenda

1. *Overview of Application for RFA*
2. *Eligibility for Organizations & PDs/PIs*
3. *Application / Functional Components*
4. *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**
- Letters of Intent are not required, is not binding, & does not enter into review, it does help NCI staff estimate potential workload and 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 (Slide 1 of 3)

- Eligible institution/organization is defined as an academic hospital and/or academic clinic program providing direct medical care to patients that is considered **one integral organizational entity under a single financial management system and governance structure**.

- **Academic centers for this application are distinguished from large medical centers whose primary mission is patient care**. In addition to patient care, academic centers have comprehensive medical training programs and have preclinical laboratories that perform basic research.

Eligible Organizations (Slide 2 of 3)

- Hospitals, clinics, military or VA hospitals or treatment facilities, & health care organizations that may provide services in collaboration with the applicant institution in a network, **but which are not an integral component of the academic organization** under a single financial management system and governance structure that comprises the applicant institution (i.e., Network Lead Academic Participating Site consisting of an academic center and its essential components) **may not be considered part of the academic institution.**

- **These other organizations may be considered "affiliates" of the Network Lead Academic Participating Site** & be included in the application under the "affiliate" designation only if the Network Lead Academic Participating Site will provide complete management services for the affiliate site related to enrollment of patients on NCTN trials.
    - Affiliates can be included in the application for administrative convenience of the Lead Academic Center; **however, the affiliates' accrual & other activities are NOT part of the review criteria and should not be included in any attachment on accrual, etc**. They are only included in the application for the funding convenience of the Lead Academic Center since the Center provides complete management services for the affiliate – and **thus are referenced only in the Budget & Roster sections of the application.**

Eligible Organizations (Slide 3 of 3)

- An academic institution/organization for the **purposes of this award cannot** be an NCI Community Oncology Research Program (NCORP) Community Site funded by the NCI Division of Cancer Prevention (DCP).
  - However, an existing NCORP site may apply for a LAPS grant, but the site can only receive an award for as a LAPS site or an NCORP site since the NCORPs participate in NCTN studies through an integrated site roster.

- Only 1 application per institution (normally identified by having a unique UEI or NIH IPF number) is allowed.

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 not** allowed.

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

- The named PDs/PIs for applications for NCTN Network Lead Academic Participating Sites **cannot** be named as PDs/PIs on applications for:
  - NCTN - Network Group Operations Centers (RFA-CA-24-030)
  - NCTN - Network Group Statistical and Data Management Centers (RFA-CA-24-031)
  - NCTN - Canadian Collaborating Clinical Trials Network (RFA-CA-24-032)
  - NCTN - Network Radiotherapy and Imaging Core Services Center (RFA-CA-24-034)

- However, an individual who is designated as a PD/PI on the application for the NCTN Network Lead Academic Participating Site can, if appropriate, be listed as key personnel on applications for any of the RFAs listed above.

Main Objectives & Requirements

Network Lead Academic Participating Site (LAPS) application must address 2 required functional components related to clinical treatment trials & advanced imaging trials **for adult cancer patients only**:

- **Clinical Trial Program** - This functional component encompasses the LAPS scientific leadership in helping to develop and conduct clinical trials in association with one or more Network Groups, including the LAPS support of NCTN initiatives and mentorship of junior investigators.

- **Site Accrual Program** This functional component provides robust accrual to NCTN trials across the Network, including accrual to rare cancers and accrual from special populations (e.g., minority and underserved communities, adolescents and young adults), as well as timely activation of trials and good clinical trial stewardship.

Research Strategy in PHS Research Plan & Attachments in Other Project Information for NCTN LAPs RFA-CA-24-033

Research Strategy with 3 Sub-Sections	Research Strategy Page Limit	Other Attachments included under SF424(R&R) Other Project Information
Research Strategy Subsections: A: LAPS Overview B: LAPS Clinical Trial Program C: LAPS Accrual (Sub-sections B and C are the 2 functional components for application)	30 pages for entire Research Strategy (divided up in any way)	#1: Lead Academic Participating Site Roster #2: Key Leadership Staffing for NCTN Groups #3: Important Trial Primary Scientific Achievements (NCTN Trials) #4: Other Important Trial Achievements on NCTN Trials #5: Leadership on NCTN Trials by Major Cancer Category #6: Summary of Accrual on All NCTN Clinical Trials #7: Summary of Accrual by Trial Disease & Trial Phase #8: Summary of Timelines for Local Activation of NCTN Trials

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, only IF applicable /**Other Plan(s) which includes the Data Management & Sharing Plan / Appendix (No appendix material is allowed given delayed onset for NCTN trials under these RFAs)**
- PHS Human Subjects & Clinical Trials Information Form, PHS Assignment Request Form

Special Issues NCTN LAPS Application

- **Letters of Support (Special Instruction)**: If the application includes affiliates for which the lead academic center provides complete management services, the application should include Letters of Support from the affiliate organizations acknowledging that the affiliate site supports its inclusion in the application & agrees to receive NCI funding for patient data management on **ALL** NCTN trials they participate in via the LAPS grant should it be funded
  - An affiliate cannot be an affiliate of another institution for purposes of its NCTN Program participation; it would only participate & receive funding for patient data management in NCTN trials through the applicant's LAPS grant

- Data Management & Sharing Plan should be provided under the "Other Plan(s)" section (and will explain why data sharing not possible under this grant as will be done by the NCTN Group Operations Centers grant that conducts the NCTN multi-site clinical trial)

- **No** Appendix Materials allowable under the research plan

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 a LAPS 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

Special Issues for Attachments on Accrual

- Accrual should be reported as the **unique number of patients enrolled on a trial over the reporting period** regardless of whether the patient underwent screening on study only or screening and intervention (as reflected in CTSU screening and/or intervention accrual records)
- Only **Adult trial accrual** (or **NCTN AYA trial cancer patient accrual credited to an Adult NCTN Group** of which it is a member) is included in a LAPS application
- Reports on accrual should come only from NCTN trials open between 3-1-2019 & 8-31-2024; a list of these NCTN trials will be provided on CTEP website with Pre-application Webinar slides
- Biospecimen collection is **NOT** considered "accrual" for demonstrating a record to accrual in support of this application; however, it will be part of the "per-case" budget for the next project period

Review Criteria & Scoring for RFA-CA-24-033

- 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 & additional review criteria

- Reviewers will consider each of the review criteria in determination of scientific merit & give a separate score for each.

Budget Issues for NCTN LAPS Application

- Requested budget must not exceed $1,700,000 in Direct Costs per year
- Actual funding will depend on funds available at the time of award (supplements may be awarded to compensate for increased accrual based on funds availability in any grant year during the project period)
- The application consists of a single budget for a 6-year budget period

Determination of Level of Overall Funding (Slide 1 of 3)

The NCTN provides general total cost support for different types of accrual for LAPS depending on accrual type category & site category (main site and integral components versus affiliates)

For intervention accrual at the Main Academic Site & all Integral Component Sites

- Total cost funding for "per case management" for treatment intervention trials is expected to be provided in following **estimated** amounts by accrual category per enrolled patient as below:
  - IND-Exempt Intervention Treatment Trial: $5,300
  - Non-CTEP IND Intervention Treatment Trial: $5,800
  - CTEP IND Intervention Treatment Trial: $6,500
  - Primary Imaging Base Intervention Trial: $1,350
  - Screening Only on Treatment/Primary Imaging Trials: $700 (pt does not go onto intervention of trial)
  - One Biospecimen Collection “Package” per Patient: $600 (for Intervention Treatment/Primary Imaging Trial enrollments only)

Usually not all patients submits all components of a collection, so usually one estimates a certain % of patients enrolled on treatment or imaging interventions will receive the full amount

Determination of Level of Overall Funding (Slide 2 of 3)

For affiliate sites of the Main Academic Site (non-integral component sites)

- Total cost funding for "per case management" for treatment intervention trials is expected to be provided in following **estimated** amounts by accrual category per enrolled patient as below:
  - IND-Exempt Intervention Treatment Trial: $3,700
  - Non-CTEP IND Intervention Treatment Trial: $4,200
  - CTEP IND Intervention Treatment Trial: $5,000
  - Primary Imaging Base Intervention Trial: $1,350
  - Screening Only on Treatment/Primary Imaging Trials: $700 (pt does not go onto intervention of trial)
  - One Biospecimen Collection “Package” per Patient: $600 (for Intervention Treatment/Primary Imaging Trial enrollments only)

    Usually not all patients submits all components of a collection, so usually one estimates a certain % of patients enrolled on treatment or imaging interventions will receive the full amount

Determination of Level of Overall Funding (Slide 3 of 3)

- From estimated "ballpark" total cost level of funding for all **anticipated accrual (see next slides),** the applicant should create a standard grant "level-of-effort" budget using the cost categories for the standard R&R budget application
  - Applicant can allocate the total cost amount across all allowable cost categories in any amount or distribution pattern the applicant believes is appropriate
  - Applicant can request more (or less) than estimated amounts with appropriate justification; however, budgets are based on estimated costs associated with “type” of per-case accrual

- To justify the budget, the applicant needs to describe, using an "Accrual Input Table or Narrative" in the budget narrative, the number of patients by site category (main academic site & integral components versus affiliates) expected to be accrued in the various accrual types listed on the previous two slides

Example of Table(s) to Develop Overall Funding
Slide 1 of 4: Main Academic Site

Institution Name:
University of XXX

Institution Type:
Lead/Main Academic Site

Type of "Per-Case" Mgt Funding	Total Cost "Per-Case"	Number Patients	Total Cost (All Patients)
Screen Only - Tx or Primary Imaging Trial	$700	50	$35,000
Intervention - Tx (IND-Exempt)	$5,300	15	$79,500
Intervention - Tx (Non-CTEP IND)	$5,800	15	$87,000
Intervention - Tx (CTEP IND)	$6,500	50	$325,000
Intervention Primary Imaging Trial	$1,350	5	$6,750
Biospecimen Collection Package	$600	40	$24,000
Total Cost			$557,250

Example of Table(s) to Develop Overall Funding
Slide 2 of 4: Integral Component Site

Institution Name:
University of XXX
at Crystal Lake

Institution Type:
Integral
Component

Type of "Per-Case" Mgt Funding	Total Cost "Per-Case"	Number Patients	Total Cost (All Patients)
Screen Only - Tx or Primary Imaging Trial	$700	25	$17,500
Intervention - Tx (IND-Exempt)	$5,300	10	$53,000
Intervention - Tx (Non-CTEP IND)	$5,800	10	$58,000
Intervention - Tx (CTEP IND)	$6,500	25	$162,500
Intervention Primary Imaging Trial	$1,350	2	$2,700
Biospecimen Collection Package	$600	20	$12,000
Total Cost			$305,700

Example of Table(s) to Develop Overall Funding
Slide 3 of 4: Affiliate Site

Institution Name:
Timber Lakes Hospital

Institution Type:
Affiliate

Type of "Per-Case" Mgt Funding	Total Cost "Per-Case"	Number Patients	Total Cost (All Patients)
Screen Only - Tx or Primary Imaging Trial	$700	15	$10,500
Intervention - Tx (IND-Exempt)	$3,700	5	$18,500
Intervention - Tx (Non-CTEP IND)	$4,200	5	$21,000
Intervention - Tx (CTEP IND)	$5,000	15	$75,000
Intervention Primary Imaging Trial	$1,350	2	$2,700
Biospecimen Collection Package	$600	15	$9,000
Total Cost			$136,700

Example of Table to Justify Overall Funding - RFA-CA-24-033

Slide 4 of 4: Sum of Total Costs and Coordination (Ballpark Total Cost)

LAP Institution Type (Name)	Total Cost from Previous Tables
Lead/Main Academic Site (University of XXX)	$557,250
Integrated Component (University of XXX at Crystal Lake)	$305,700
Affiliate (Timber Lakes Hospital)	$136,700
Sum of Total Costs Across Sites	**$999,650**
Additional 20% for Coordination (Total Cost)	**$199,930**
GRAND TOTAL COST FUNDING LEVEL	**$1,199,580**

- Sum **"Total Cost"** from each LAPS site and **add a 20% "Coordination" cost** to calculate "ballpark" total cost level of funding for all anticipated accrual
- Applicant should then **create standard grant "level-of-effort" budget** using the cost categories for the standard R&R budget application
- Applicant can allocate this total estimated funding amount across all allowable cost categories in any amount or distribution pattern the applicant believes is appropriate

Additional Budget Issues

- Scientific leadership positions in NCTN Groups will be funded by NCTN Groups Operations Centers or Statistical & Data Management Centers (e.g., support for activities of academic center investigators on Group oversight committees such as Data Safety Monitoring Committees or Executive Committee & support for Study Chairs, etc.)
    - *Applicants can include these scientific leadership positions as accomplishments for the review to demonstrate how the LAPS application has the potential to provide leadership for the NCTN Program, but budget support, if provided for these positions,* ***is included in the NCTN Group Operations Centers and SDMCs application budget, not in the LAPS application budget.***
- Travel Expenses: Applicants must budget travel funds as per the RFA for NCTN-related meetings.
- NCI does not support costs associated with routine patient care as a budget expense under this NOFO/RFA

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; however, the plan should explain why data sharing is not possible under this grant, as data sharing will be done by the NCTN Group Ops Centers grant that conducts the NCTN multi-site clinical trial

- 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; however, NCI DCTD/CTEP will be providing a prototype of an acceptable Data Management & Sharing Plan for potential LAPS applicants given this unique situation 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

www.cancer.gov

www.cancer.gov/espanol