Pre-Application Webinar for NCTN Lead Academic Participating Sites (LAPS) 2017 FOA

RFA-CA-17-059

NIH NATIONAL CANCER INSTITUTE

November 7, 2017

Pre-Application Webinar Topics – RFA-CA-17-059

1. Overview of Application for RFA
2. Special Eligibility Criteria (Institutions, PIs/PDs)
3. Research Plan: Research Strategy Sub-sections
4. Letters of Support & Resource Sharing Plans and Attachments on Accrual
5. Budget Issues
6. Review Criteria
7. Terms of Award

Overview of Application for RFA-CA-17-059 (UG1)

1. Reissue with “New” Applications Only
   (not a renewal – prior “pink sheets” not given to reviewers and awardees prior targets not applicable for this new application; this is a complete re-start)

2. Application is electronic

3. Letter of Intent is due December 19, 2017

4. Just-in-Time information (not a part of the application) will be required, if applicable, for updates to “Other Support” for key personnel and Human Subjects Protection Training for key personnel

Special Eligibility for RFA-CA-17-059

Select Information on Eligibility for Institutions Submitting Applications (See FOAs for Other Eligibility Criteria)	Select Information on Eligibility of PDs/PIs on Applications (See FOAs for Other Eligibility Criteria)
OPEN Competition **An academic institution/organization for the purposes of this award cannot be a NCI Community Oncology Research Program (NCORP) Community Site funded by the NCI Division of Cancer Prevention (DCP)**	**PDs/PIs for this application cannot overlap with PDs/PIs on applications for:** **Group Operations Centers** **Group Statistics & Data Management Centers** **Canadian Collaborating Clinical Trials Network** **RT and Imaging Core Services Center** 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.

Additional Special Eligibility - Applicant Institution/Organization RFA-CA-17-059

- Eligible institution/organization for the purposes of this application 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.

Additional Special Eligibility - Applicant Institution/Organization RFA-CA-17-059

- Hospitals, clinics, military or Veterans Administration (VA) hospitals or treatment facilities, and 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., 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 Lead Academic Participating Site will provide complete management services for the affiliate site related to enrollment of patients on NCTN trials.

Additional Special Eligibility - Applicant Institution/Organization RFA-CA-17-059

- 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.

Research Plan: Research Strategy Sections – RFA-CA-17-059

UG1 Research Plan for LAPS (Research Strategy Sub-sections)	Page Limits	# of Attachments for Components (Brief Titles of Attachments)
A. Lead Academic Participating Site Overview	30 pages for entire Research Strategy & Sub-Sections (divided up in any way)	**8 Attachments** 1-Lead Academic Participating Site Roster 2-Key Leadership Staffing for NCTN Groups 3-Important Trial Primary Scientific Achievements on 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 Major Disease Category and Trial Phase by Group Members 8-Summary of Timelines for Local Activation of NCTN Clinical Trials
B. Lead Academic Participating Site Clinical Trial Program		
C. Lead Academic Participating Site Accrual Program		

Letters of Support & Resource Sharing Plans: RFA-CA-17-059

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

- **Resource Sharing Plan**: All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan. Since it is expected that the applicants will follow the Resource Sharing Plans of the associated Network Group(s)' Operations Center(s) leading trials on which it participates, the applicant should indicate in its application that it is bound by these plans (i.e., the resource sharing plans that may have been submitted by the associated Network Group(s) including but not limited to general NIH/NCI data sharing as well NIH/NCI genomic data sharing).

- The Data Sharing Plan and other resource plans (or rationale for not providing sharing certain resources) should be provided in the research application; however, prior to funding of an award, all resource sharing plans will also need to be reviewed and approved by NCI/DCTD program staff prior to any award in order to ensure that the plans are in compliance with the NIH/NCI regulations and Terms of Award for this key component of the NCTN Program. *This will be done on the Network Group grants.*

Attachments for Reporting Accrual: RFA-CA-17-059

Attachments Related to Accrual:

- ❑ Unique # patients enrolled on a trial over the reporting period regardless of whether the patient underwent screening on study only or screening and intervention
- ❑ Only adult cancer patient accrual to NCTN trials is included in the LAPS application
- ❑ Biospecimen collection is NOT considered accrual for this application
- ❑ No attachments report on biospecimen collection as that is reviewed under the Tumor Banking Grant (an average estimate for “per-case management funding” is only provided in the application budget)
- ❑ Accrual is reported in 2 tables (one for the large screening trials of S1400 (Lung-MAP), A151216 (ALCHEMIST-Screen), and EAY-131) and the other for all other trials. This directive is not applicable to pediatric application.

Budget Issues for LAPS - General: RFA-CA-17-059

- *Requested Budget.* The requested budget must not exceed $1,500,000 in direct costs per year. Actual funding will depend on funds available at the time of award. Supplements may be award to compensate for increased accrual based on funds availability.

- *Budget Period.* The application consists of a single budget for a 6-year budget period. A special Notice for this RFA in the NIH Guide listed below explains how to access the correct forms to provide a 6-year budget under this RFA.

NOT-CA-18-017:
Notice of Change to Application Package for RFA-CA-17-059 and RFA-CA-17-061
available at https://grants.nih.gov/grants/guide/notice-files/NOT-CA-18-017.html

New application packages with the Competition ID of "FORMS-D-REVISED" were posted on October 27, 2017 and must be used to successfully submit to the January 19, 2018 due date. If you initiated an application using an application package with the Competition ID of "FORMS-D" you need to copy your application content to the revised form package.

Budget Issues for LAPS - General: RFA-CA-17-059

General determination of level of overall funding

The NCTN provides general total cost support for different types of accrual for LAPS depending on the accrual type category and site category where patient enrollment occurred.

For intervention accrual at the main academic site and all integral component sites, **total cost** funding for "per case management" is expected to be provided in the range of $4,800 to $6,000 for each patient enrolled on treatment trials (screening on study plus intervention).

There may be occasional treatment trials that have only total cost “per case level” similar to what is given to affiliate sites because the trial has more limited data management and the funding for those trials is at the basic rate used for affiliates in the range of $2700 to $3900 for each patient enrolled on treatment trials.

For affiliate sites, this **total cost** funding for "per case management" range is expected to be $2700 to $3900 for each patient enrolled on treatment trials.

Budget Issues for LAPS - General: RFA-CA-17-059

General determination of level of overall funding

For all sites (regardless of category type), this **total cost** funding range is expected to be:

$600 for "screening only" accrual on treatment or primary imaging trials
(i.e., patient does not go onto the intervention phase of the trial),

$1,500 for base interventional accrual on primary imaging studies, and

$600 for patient biospecimen collection per enrollment on a treatment or primary imaging trial.

Usually not all patients submit all components of a collection so usually one targets a certain % of patients enrolled on tx or imaging interventions will receive this full amount.

Budget Issues for LAPS - General: RFA-CA-17-059

General determination of level of overall funding

From the estimated "ballpark" total cost level funding for all anticipated accrual, the applicant should then create a standard grant "level-of-effort" budget using the cost categories for the standard R&R budget application. The applicant can allocate the total cost amount across all allowable cost categories in any amount or distribution pattern that the applicant believes is appropriate.

The applicant can request more (or less) than the estimated amounts with appropriate budget justification; however, budgets are based on estimated ranges for the infrastructure costs associated with per case management.

To justify the budget, the applicant needs to describe, using an "Accrual Input # Table or Narrative" in the budget narrative, the # of patients, by category site type (main academic site and integral components versus affiliates) expected to be accrued in the following categories

"screen only" category for treatment and/or imaging trials
intervention category for treatment trials (screen plus intervention)
intervention category for primary imaging trials
1 patient biospecimen collection for each enrollment on a treatment or primary imaging trial (% rate)

Budget Issues for LAPS - General: RFA-CA-17-059

Example of creating estimated "ballpark" total cost level funding for all anticipated accrual

Institution Name	Institution Type	Type of Per Case Management Funding	Amount of Total Cost Funding Per Patient	Year 1	
				# Pts	Amt
University of XXX	Lead/Main Academic Site	"Screen Only" for Tx and Primary Imaging Trials	$600	60	$36,000
		High Intervention for Tx Trials (Screen + Intervention)	$6,000	60	$360,000
		Basic Intervention for Tx Trials (Screen + Intervention)	$3,900	10	$39,000
		Intervention for Primary Imaging (Screen + Intervention)	$1,500	10	$15,000
		Biospecimen Collection (Est. 50% "intervention" pts w/ $600 collection)	$600	40	$24,000
University of XXX at Crystal Lake	Integrated Component	"Screen Only" for Tx and Primary Imaging Trials	$600	30	$18,000
		High Intervention for Tx Trials (Screen + Intervention)	$6,000	30	$180,000
		Basic Intervention for Tx Trials (Screen + Intervention)	$3,900	5	$19,500
		Intervention for Primary Imaging (Screen + Intervention)	$1,500	5	$7,500
		Biospecimen Collection (Est. 50% "intervention" pts w/ $600 collection)	$600	20	$12,000

Total Cost Funding for Year 1 for Lead/Main Site + Integrated Component: $711,000

Budget Issues for LAPS - General: RFA-CA-17-059

Example of creating estimated "ballpark" total cost level funding for all anticipated accrual with 1 affiliate site added

Institution Name	Institution Type	Type of Per Case Management Funding	Amount of Total Cost Funding Per Patient	Year 1	
				# Pts	Amt
Timber Lanes Hospital	Affiliate	"Screen Only" for Tx and Primary Imaging Trials	$600	15	$9,000
		High Intervention for Tx Trials (Screen + Intervention)	N/A	N/A	N/A
		Basic Intervention for Tx Trials (Screen + Intervention)	$3,900	16	$62,400
		Intervention for Primary Imaging (Screen + Intervention)	$1,500	8	$12,000
		Biospecimen Collection (Est. 50% "intervention" pts w/ $600 collection)	$600	12	$7,200

Total Cost Funding for Year 1 Affiliate Site: $ 90,600

Plus Total Cost Funding for Year 1 for Lead/Main Site + Integrated Component: $711,000

"Ballpark" Grant Total Cost Funding for Year 1 for all Sites Listed: $801,600

Budget Issues for LAPS - General: RFA-CA-17-059

- Scientific leadership positions in the Network Groups will be funded by the Network Groups Operations Centers or associated Statistical & Data Management Centers (i.e., support for the activities of academic center investigators on Group oversight committees such as the Data Safety Monitoring Committees or Executive Committee and support for study chairs as well as Chair and Vice or Co-Chairs of scientific committees and administrative committees).

  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 Network Group Operations Centers and SDMCs application budget, not in the LAPS application budget.

- *Travel Expenses.* Applicants must budget travel funds for 2 persons (2 PDs/PIs or PD/PI and an additional senior investigator) to attend up to 4 NCTN Network Lead Academic Participating Site in-person meetings over the grant's entire project period in addition to other travel expenses.

- NCI does not support costs associated with routine patient care as a budget expense under this FOA.

Review Criteria for LAPS – RFA-CA-17-059

- **Overall:** Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

- **Scored Review Criteria:** Reviewers will consider each of the review criteria (i.e., Significance, Investigators, Innovation, Approach, & Environment) in the determination of scientific merit, and give a separate score for each. *An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.*

- **Additional Review:** As applicable for the project proposed, reviewers will evaluate the additional items listed in the RFA while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Terms of Award for LAPS – RFA-CA-17-059

- LAPS (as well as all Group sites) must be members of NCI CIRB & must use it to enroll patients on NCTN trials

- In addition to standard terms of award under NIH Grant Policy, the RFA sets out other Terms of Award, including compliance with the following for PDs/PIs of the LAPS Awards:

  - Part 1 of the NCI National Clinical Trials Network (NCTN) Program Guidelines/Handbook dated December 15, 2012 (https://ctep.cancer.gov/initiativesPrograms/docs/NCTN_Program_Guidelines.pdf) and any subsequent updated versions of the Guidelines/Handbook

  - Handbook for Clinical Investigators Conducting Therapeutic Clinical Trials Supported by the Cancer Therapy Evaluation Program (CTEP), DCTD, NCI at (https://ctep.cancer.gov/investigatorResources/investigators_handbook.htm)

  - NCI Guidelines for Auditing Clinical Trials for NCTN Program, CCOP/NCORP Program and Research Bases at (https://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring_coop_ccop_ctsu.htm),

  - NCI/DCTD CRADA agreements & Intellectual Property Option to Collaborators at (https://ctep.cancer.gov/branches/rab/intellectual_property_option_to_collaborators.htm) for NCTN trials