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

Summary Transcript (*) from October 28, 2024, Lead Participating Sites Pre-Application Webinar and Q&A from November 12, 2024, Webinar

(*) condensed version of full transcript highlighting the most important information & key points with any Clarifications /Corrections as a companion to the updated Webinar Slides)

Slide 1 - Intro

This is the Pre-Application Webinar for RFA-CA-24-033: Open Competition for the NCTN Network Lead Academic Participating Sites (UG1 Clinical Trial Not Allowed). The call is being recorded solely for creating a Summary Transcript for the webinar; however, the Webinar slides will be posted on CTEP website at **https://ctep.cancer.gov/initiativesPrograms/nctn.htm** 2 days after the Webinar.

Slide 2 - Agenda

First, we will provide an overview for this particular RFA application, the eligibility for organizations and PD(s)/PI(s), the application's functional components, some special issues, review criteria, budget issues, the data management and sharing plan,(which you'll have to fill out, but we'll explain how you fill it out), and a reference to the Terms of Award.

Slide 3 – Due Date and Application Overview

For this application, everything is **due by February 24, 2025**. However, if you would like to submit your application early, the earliest it can be submitted is January 24, 2025.

It is an open competition. It is listed as a UG1, which is a single project because what you are doing is enrolling to NCTN program clinical trials, so that is considered a single project. It is listed as clinical trial not allowed, which means your application does not propose those clinical trials.

This RFA accept "new" applications from eligible institutions that are not currently in the LAPS program as well as "renewal" application from those currently in the program. One of the advantages of that for "renewals" is that you can more easily refer back to what you have done to date within the current project period as a LAPS.

Letters of Intent are not required; they are optional, not binding, and does not enter into the review process. For the LAPS program, it is very helpful to have this for NCI staff in the Division of Extramural Activities and their planning for the Special Emphasis Panel for the review of these applications. Planning for this review is very challenging, as you might imagine, because DEA needs to ensure there are sufficient reviewers with no conflicts. So, if you do intend to apply, it would be greatly appreciated if you could send in a Letter of Intent by the due date of January 24, 2025, a month before the application due date. However, you can send it in pretty much any time now.

This UG1 cooperative agreement with two functional components is a single project. We have included the URL link for "How to Apply" from the NIH guide in the Webinar slides.

The LAPS application is for **a 6-year project period, from March 1, 2026 to February 29, 2032**, which is a leap year so we get one extra day.

There will be some "Just-in-Time" information, mainly updates to "Other Support" and "Human Subjects Protection Training" for key personnel.

Slide 4 – Eligible Organizations

The LAPS application has stricter eligibility criteria for the eligibility for the organizations because it is aimed to sites that offer a combination of patient care and academic research.

The main institution or organization is one integral organization under a single financial management system and governance structure. The LAPS are distinguished from a large medical center that is just providing patient care because the academic organization has to have some kind of comprehensive medical training program and laboratories that perform basic research in addition to providing patient care. The review criteria for an LAPS applicant also focuses on the people at the organization, the PIs, investigators, and clinical staff who contribute to the scientific direction of the NCTN Groups in the Network, as well as how well the organization does at enrolling patients on NCTN trials.

Slide 5 – Eligible Organizations Continued

Questions have come up in the past as to whether a military or VA hospital that is connected with an academic organization could be part of their LAPS grant. We cannot consider those sites as integral components of the academic institution because they are not under the financial management and governance of the Lead LAPS institution. The VA does not belong to the academic institution; it is part of the federal government.

However, these types of sites may be considered an "affiliate" under the LAPS award if they fulfill the definition of an affiliate – i.e., affiliate designation means the academic center, for the purposes of doing the clinical trials, is really providing complete management services for the affiliate site for their NCTN enrollments. Sometimes that happens if you have a small VA in conjunction with a very large academic institution, or in some other situations.

Although we do allow affiliates in a LAPS application, it is something we allow only for the convenience of the Lead Academic Center. What we found early on in the formation of the NCTN ins 2014 is that academic centers would communicated that they sometimes provide all the services for NCTN trials for sites that were not part of the their center and that it was very difficult if they were getting money one way for the main LAPS academic site and its integrated sites, but the "affiliates" they managed were receiving funding for their enrollments in another way when the main LAPS academic site was providing full management services for the "affiliate" with their staff involved in providing the clinical trials support at the "affiliate". So, we created this "affiliate" category so these types of sites can be included in this application for the administrative convenience of the main LAPS academic site.

It is important to note that the affiliate site accrual and the affiliate's other activities are **not** part of the review criteria for the application. Accrual and other activities from affiliate sites should **not** be included in any of the attachments or descriptions of accrual. Affiliates are only included to

manage this special situation when the main Academic site is really providing all management services for enrolling patients on trials at the affiliate site and the affiliate site is **not** an integrated part of the main Academic site's organization. The only reference to affiliate sites should be in the budget and the roster sections of the application.

Slide 6 – Eligible Organizations Continued

In addition, there is an integrated roster between the NCTN and the NCORP, with the Division of Cancer Prevention, DCP, to allow NCORPs to participate in NCTN cancer treatment and primary advanced imaging studies. There are some academic centers that are minority or underserved NCORPs. But because the roster is integrated, those NCORP sites participate in NCTN trials as NCORP sites. We cannot have one site have 2 different designations, as an NCORP site and a LAPS site. A site has to either be an NCORP site, or a LAPS site, or what we call a Rostered site (which means it is not a LAPS and it is not an NCORP). A site can only have 1 designation of those 3 designations.

Due to the integrated roster, a LAPS award cannot be made to a site that is also an NCORP site. However, NCORP sites **can** apply for the LAPS grant, because they potentially might want to change categories. But before an award can be made, the site would have to make the determine if they really want to change categories.

There can be only 1 application per institution for US academic centers that are participating as part of the adult NCTN groups on adult and AYA trials in the NCTN. The NCTN pediatric group (Children's Oncology Group) has its own program for high performing sites within its grant that predated the NCTN, so that was kept intact and the LAPS grant is just for sites that participate and are members of at least 1 NCTN Adult Group adult (although they will be able to put AYA patients on NCTN AYA trials even if COG leads the NCTN AYA trial, but they will just need to credit one of the NCTN Adult Groups that they are members of if they wish to receive funding/credit for that enrollment under the LAPS grant.

As previously state, LAPS application must come from US academic centers subject to all the eligibility criteria provided in RFA-CA-24-033. Foreign organizations and foreign components of a US organization are **not** eligible to appl, and LAPS applications are **not** allowed to have foreign components.

Slide 7 – Program Directors – PD(s) or Principal Investigators – PI(s)

There are some restrictions for the program directors/principal investigators for a LAPS grant, in that they cannot be a PD/PI for an NCTN Group Operation Center, NCTN Statistical and Data Mgt Center, NCTN Canadian Collaborating Clinical Trials Network, NCTN Radiotherapy and Imaging Core Services Center (IROC). That means an individual cannot be a PD/PI on both types of applications/grants, to prevent certain types of conflicts. However, an individual who is a PD/PI on a LAPS grant can, if appropriate, be key personnel on any of those RFAs and awards. In fact, that often happens because part of the review criteria for the LAPS involve what the LAPS does for scientific leadership for the adult NCTN groups.

Slide 8 – Application Objectives and Functional Components

As an UG1, the LAPS is a single project grant (it does not have different cores within the grant application). Instead, it has 2 major objectives which the application addresses in 2 required functional components (i.e., the "Clinical Trial Program" and the "Site Accrual Program") related to adult and AYA NCTN cancer treatment trials and NCTN primary advanced imaging trials.

The LAPS "Clinical Trial Program" focuses on what the LAPS staff and investigators do in terms of leadership in helping to develop and conduct clinical trials in association with one or more NCTN groups and how the LAPS institution supports general NCTN initiatives, mentorship of junior investigators related to NCTN trials, and NCTN collaborations.

The LAPS "Site Accrual Program" focuses on accrual from the main academic center and any integrated component sites and does **not** include accrual from any affiliate sites. This component includes how the main academic site and its integrated components provide robust accrual to NCTN trials from any NCTN group or combination of groups, including accrual to rare cancers and from special populations, & how sites activate trials in a timely manner with good clinical trial stewardship.

Slide 9 – Research Strategy

As a single project grant, there is just 1 research plan with a research strategy, but the research strategy does have 3 sub-sections (i.e., the LAPS "Overview", the LAPS "Clinical Trial Program", and the LAPS "Site Accrual Program"). The sub-sections B and C of the research strategy listed in the table on the Webinar slide represent the 2 functional components. **The entire research strategy here has a page limit of 30 pages, but it can be divided up in any way.** That is similar to what was required in the previous RFA.

There are other attachments that are required (8 of them), and you see them listed in the Webinar slides on Slide #9, and they are explained in more detail in the RFA-CA-24-033.

Slide 10 – Application Sections

We wanted to point a few key things about the Research Plan.

Under the PHS 398 Research Plan, you have a specific aims section, and then you have the research strategy which will have those 3 sub-sections we just talked about (the overall component and the 2 functional component sub-sections).

There are Letters of Support that are required as specified in the RFA-CA-24-033.

There is something called a resource sharing plan section. We do not know if that's going to be at all applicable to your LAPS. You can read about the section and see what it says goes in it. In the past, the Data Management and Sharing Plan used to go in the resource sharing plan section, even though for the LAPS that plan is mainly just to say that the LAPS follows the NCTN Groups' Data Management and Sharing plans for the trials the LAPS participates in. NCTN trials are all multi-site trials being run by a central Lead NCTN Group, and a LAPS cannot share just its data on patients it enrolls when the data are part of an integrated whole for a multi-site trial.

The "Other Plans" section is where you will put the Data Management and Sharing (DMS) Plan" now. We have a template for you to use for that plan that provides the justification for why the LAPS site cannot share the scientific/clinical data it generates under the LAPS grant, and then you can provide that document in the other plans section. The template DMS plan will be uploaded with slides & transcript on CTEP website at **https://ctep.cancer.gov/initiativesPrograms/nctn.htm .**

The RFA also refers to appendix material. You can read what is included there, but it doesn't make sense for any of the RFAs under the NCTN program because it's really about blank forms or CRFs and is more for a single trial that's being performed under a single grant. The only other appendix material allowed has to be specifically written into the RFA by program and we did not do that for any of the NCTN RFAs because sufficient information is provided in all of the other attachments and research plan text to address the review criteria for reviewer assessment.

In addition, since you are not proposing a specific trial, we have specific instructions for filling out the Human Subjects and Clinical Trials Information form, which we'll explain in the next slide.

Slide 11 – Special Issues in the Application

In terms of the Letters of Support, you can include Letters of Support from your applicant organization, and sometimes from you're the NCTN Groups you participate in.

But, **if you want to include an affiliate site in your application, a Letter of Support from the affiliate site is required that states they agree that you will be providing complete management services for what they do for NCTN trials, and acknowledging that if your application is funded, then funding for their participation will go through the LAPS grant**, however, the LAPS decides how to allocate that funding or split it with the affiliate.

And, as previously mentioned, the Data Management and Sharing Plan should be provided under the "Other Plans" section, and we will post a template for that on the website where the slides are posted. Also, no appendix materials should be submitted.

Slide 12 – Special Issues with the PHS Human Subjects and Clinical Trials Information Form

There is this section in the application called the "PHS Human Subjects and Clinical Trials Information" form, and that was not in the LAPS RFAs for previous competitions – this is a new form.

And as part of that form, **there will be a question "Are Human Subjects Involved?" The answer to that is obviously "Yes" for your application.** However, you are not actually proposing a trial in the application. But because you answered "Yes" to the human subjects question, you have to have at least 1 human subjects study. Because you do not know what studies will be done, **you should complete the "Delayed Onset Study Record" and within that, there will be a question that says "Anticipated Clinical Trial?" and for the LAPS grants, the answer would be "No".** These answers will help the reviewers understand that you are not going to propose trials yourself within this application, but you will be participating in these trials and contributing to the trials through the various NCTN Group Operations Centers and their associated Statistical & Data Mgt Centers.

Since your LAPS will hopefully participate in many NCTN trials, it is still considered just 1 Delayed Onset Study Record, but you use the title **"Multiple Delayed Onset Studies"** and the record should simply state in 1 sentence that your LAPS anticipates participating in multiple delayed onset studies led by the NCTN Groups. This section/form should be simple for you to fill out, but it is new in this application.

Slide 13 – Special Issues for Accrual Attachments

For accrual, even if your institution has never participated as a LAPS in any of the previous NCTN program project period, if your institution has been participating as a rostered site or maybe an NCORP site, you will need to show your accrual to NCTN trials as part of the LAPS "Site Accrual" functional component. You should use the unique number of patients enrolled on a trial over the reporting period, which is March 1st, 2019 through the end of August, August 31st, 2024. The unique number of patients means that regardless of whether that patient was just enrolled via OPEN on the screening step to a study, or was enrolled to the screening step and then went on to the intervention step, or was enrolled to a study with just an intervention step, each of those patients counts as 1 patient accrual to the specific NCTN trial.

Only accruals to adult or AYA NCTN trials that were credited to the adult NCTN groups should be included in the LAPS application. If you participated in an NCTN AYA trial led by the pediatric group, COG, and put on someone who was credited to COG (because your site happens to a full member of COG), you should NOT include that accrual as a "LAPS" accrual since you credited the accrual to COG not an adult NCTN Group.

The accruals should only be for patients enrolled between March 1, 2019, and August 31, 2024. A list of the applicable NCTN trials during that period will be posted on the website where we post the slides (*and will be updated to include a column showing whether the trial is conducted as an "IND-Exempt" trial, a "CTEP IND" trial, or a "Non-CTEP IND" trial*). We do find there can be some confusion about trial because of the way we function with the NCORP sites, but this application is just about the NCTN trials. We know the NCORP is very important and that hopefully your academic center participates in NCORP studies, but because this application pertains only to accrual to NCTN trials, only accrual to NCTN trials should be included in an LAPS application. Please Note: the List of NCTN trials does include the NCI COVID Natural History study (the NCCAPS study) and the Alliance Immune-Related Adverse Events study, because those NCTN studies involve clinical data collection so patients enrolled to those studies credited to one of the NCTN adult groups count for inclusion in your accrual tables in in the application.

Biospecimen collections alone are **not** considered accrual. However, funding is provided to help support collection of biospecimens in the budget since the NCTN program does provide funding support for specimen collection on NCTN trials.

Slide 14 – Review Criteria

The review criteria are exactly the same as in the previous RFA. Applicants receive an overall impact score to reflect the reviewers' assessment of whether they think what your LAPS is doing has a sustained and powerful influence on the research involved, according to the main review criteria

and the additional review criteria in RFA-CA-24-033. The reviewers will also consider each of the review criteria and give a separate score for each.

Slide 15 – Budget Issues

When we presented the NCTN program to the NCI Board of Scientific Advisors (BSA), we presented a request for a budget increase that was quite substantial, and the NC BSA did recommend that budget increase at that time for RFAs. But we want to emphasize that we do not know what the budget situation will be like in FY2026, when the new project period is scheduled for funding and whether we will get that additional funding or not. So, although the requested budget must not exceed $1.7 million in direct costs, that is probably the ceiling of what NCI might possibly be able to fund but we will not know the exact funding levels for these awards until the time award.

Some institutions have very large budget requests because their main site is large or has a lot of integrated components, and some institutions have a much smaller site program. Both small and large sites are very important and can apply, but the amount limit specified in the RFA is the ceiling and the actual funding for any award will depend on the funds available at the time of award.

Those of you who have been participating in the LAPS grants know that the program tries to provide supplements if, for any reason, the LAPS goes over its accrual targets and requested budget. For the most part we have been very successful in being able to provide additional funding if a LAPS exceeds its budget target for all its accrual; however, whether the program can do that always depends on funding availability during the particular time period in which a LAPS exceeded its budgeted target.

Lastly, in terms of the application, there's just a single budget for the six-year project period.

Slide 16 – Determining Overall Funding – LAPS Main Site and Integral Component Total Cost Per Case Management Amounts

The way we determine the amount of **Total Cost Funding** that would be provided for a LAPS is guided by how funding is determined for all sites participating in NCTN trials, including NCORPS and Rostered sites.

Lead Academic Participating Sites are competitively reviewed and selected because on how your institution/components are driving NCTN scientific/clinical research and providing robust accrual to NCTN trials, so your per-case management funding for accrual is set at a higher level as opposed to what is set for Rostered sites. NCORPs have high performance and regular sites, so we try to make funding equivalent between the high performing NCORP sites and the LAPS main sites and integral component sites.

Because the NCTN Program RFAs were recommended for higher funding, we have upped the per-case management amounts shown in the RFA for the LAPS. We are using these higher amounts as estimates for the application budget process, but actual amounts may change depending on funding availability at the time of award.

You can see the amounts listed in the Webinar slides by the different categories for the LAPS main academic site and its integral component sites. We provide more funding for IND trials because

they are more complex than an IND exempt trial and requiring a higher level of data collection for regulatory compliance. There is somewhat more funding for CTEP IND trials because CTEP does receive some funding from its CRADA company collaborator to help support the contract-supported centralized infrastructure for CTEP clinical trials networks.

We also have funding for the base intervention in a primary imaging study, which is just for the enrollment and basic study data collection and conduct of the study. If there is a non-standard experimental scan in the study, the extra funding for that scan or experimental imaging would be provided directly by the NCTN Group that conducts the imaging studies, so those funds are not in the LAPS grant but are provided to the LAPS (including to its integrated and affiliates) from the Group the NCTN Group that the LAPS sites credited with their accrual.

The same thing happens with industry funding, if an industry collaborator on any of NCTN study provides additional funding outside of the grant to the NCTN Group running the study, for participating sites, the NCTN Group is required under their Terms of Award to pass the funding on to all sites participating in the trial, and so the LAPS sites would receive that funding from the NCTN Group that it credited with the accrual and not through the LAPS grant.

Screening only funding is for patients only enrolled to the screening step of a treatment or imaging study, which means the patient is enrolled and was screened but the patient did not go onto the intervention step of the trial. We want to make sure there is some funding for the portion of the study that the patients were on, so we have specified a particular payment for patient on trial on that step only who never went onto the intervention step. For biospecimen collections for patients on study, for ease of calculating the budget, we have what we call a biospecimen collection package of $600 per patient. Some trials have no biospecimens, and not all patients enrolled will provide all the biospecimen collections requested, so we ask you to target a reasonable percentage of all patients who go on to the treatment and/or imaging studies for this payment category (based on your best estimate using your historical records of biospecimen collections from you site).

Slide 17 – Determining Overall Funding – LAPS Affiliate Site Total Cost Per Case Management Amounts

The previous slide include the per-case management funding for the Lead Academic Main site and its integrated for all accrual types. This slide shows the amounts for the “affiliate” sites that are not part of your academic organization but that are included in the budget for ease of administration if you are providing complete management services for their NCTN enrollments.

The affiliate sites get different amounts for the per-case management funding, and this will mirror what the Rostered sites would get. But if they are part of your LAPS, the money comes through your grant so that you can provide the services with some money going to them, or you have staff that you pay for in full to provide all the services to them, according to however you do it or whatever mix you want. So that's why these particular per case amounts are different, except for the screening only and the biospecimen package, which we set up with the same funding level for all sites.

Slide 18 – Determining Overall Funding – Total Cost Estimate as Basis for Standard Level of Effort Budget and Justification

The LAPS budget is based on the accrual your LAPS proposes for NCTN studies. If a staff member at your LAPS operates as a chair of a committee for an NCTN group, or as a member of an NCTN Group's Data Safety and Monitoring Board, or any similar activity directly for an NCTN Group, the funding for that role's activity comes from NCI to the NCTN Groups' grants, and then the NCTN Group would pass that funding on to you for your staff member's activity. None of that is funded through your LAPS grant. That is why those costs are not in the LAPS budget.

So, to create the Total Cost Budget estimate for your LAPS application, you take all the accrual at the different levels of per-case management, and then **create an estimated Total Cost Budget "ballpark" estimate. It is important that you understand that means Total Costs, not direct costs**. Then from that amount, you create a standard level-of-effort budget using all the regular cost categories for the standard allowable costs. You can allocate that funding however you think best for what you need to do at your LAPS to conduct NCTN clinical trials at your site for patients, including your lead academic site, any integrated components, and any affiliate sites.

You can always ask for more or less money. You can ask for more money, with appropriate justification, but unless there was something extraordinary, it is not likely to be funded. And, even though we are using the per-case amounts as shown in the slides for the application, we do not know what budget we will be given at the time of award in in FY2026.

In order to justify your budget request, you will need to include tables showing the amount of accrual that you think you occur at your main academic site, integrated component sites, and any affiliate sites. The next 4 slides give examples of those tables and how you come up with **the Total Cost "ballpark" estimate.**

Slide 19 – Example Table for Budget Justification – Main Academic Site

This slide is for the main academic site, which we called the University of XXX. We put all the categories of accrual in the table: screening only, different intervention amounts by IND type, primary imaging trials, and the biospecimen collection per-patient package.

And then you estimate the number of patients that you think your main site will enroll for each category, and you multiply the # of patients by the Total Cost Per Patient for each type of accrual to calculate the Total Cost estimate for that accrual category at you main academic site. In this example you can see 50 patients are entered for screening only, 15 patients on IND exempt trials, 15 patients on non-CTEP IND trials, and 50 patients on CTEP IND trials. A smaller number of patients on primary imaging trials, and then a percentage of the patients getting the full biospecimen collection per-patient package amount.

This is just an example, and we know your tables will not be exact, but based on your accrual history, you should be able construct a "ballpark estimate" based on what you think your LAPS main academic site will be able to do in the new project period.

You then you add all Total Costs for each type of accrual to get a Total Cost estimate for your main academic site, in this case, the estimated Total Cost for the main site is a little over $550,000.

Slide 20 – Example Table for Budget Justification – Integral Component Site

You then do the same thing for each integral component site that you have. Here it is the University of XXX at Crystal Lake. And the total cost per-case amount is the same as for the main site, but typically an integral component site has lower accrual numbers, with lower numbers of patients in each category.

Then you calculate the Total for each row and add it up for all rows to get the Total Cost estimate which in this example is a little over $300,000.

Slide 21 – Example Table for Budget Justification – Affiliate Site

If you do include one or more affiliate sites (and you do not have to have affiliates), then you would fill out a table with the lower total cost per-case amounts for the affiliate site. This affiliate for the University of XXX is called Timber Lakes Hospital, and the total cost per-case is lower because it is equivalent to the amount for a regular NCTN Rostered site, but it is coming through your grant, and usually the number of patients is a lower as well. Then you do the total costs for each accrual category and add them up - this comes to a little over $130,000 in this example.

Slide 22 – Example Table for Budget Justification – Sum of Total Costs and Coordinate for Ballpark Total Cost

You will need a separate table for each site on your proposed LAPS roster, and you will take the total costs from each of those tables and add them up. In this case, we had one site in each category, so we add those up to get the sum of all estimated Total Costs across all sites in the application, that is just under a million dollars.

The program does add in an additional 20% "coordination cost" for the work done by the LAPS to coordinate all work performed within the grant to coordinate enrollments and conduct NCTN trials. This is **not** an indirect cost rate, so please do not get confused. It is just additional funding at a level we could provide for the competitively selected LAPS for the work being done on the NCTN trials.

Then when you add the sum of total costs and the 20% coordination total cost, you get just about $1.2 million as an **estimated Grand Total Cost Funding level for the application**. This is the total cost amount from which you develop your regular "Level of Effort" budget to cover you sites' Direct and Indirect costs for this work. Your "Level of Effort Budget" can be distributed across any allowable cost categories appropriate for the work related to what your sites and sites' staff needs to enroll patients to NCTN trials and conduct the trials at your LAPS sites.

Slide 23 – Additional Budget Issues

We will just add a couple other things. As mentioned before, if your LAPS staff members have scientific leadership positions in the NCTN Groups, any support for those activities should come down through the NCTN Group's grant. Those roles could be overseeing a committee, being a member of the Data Safety and Monitoring Board committee, being a member of the Group's executive committee, etc. The NCTN Group might provide your investigators/staff with an

honorarium or subaward through the NCTN Group grant; these activities are not funded under the LAPS grant.

One budget requirement in the RFA pertains to reserving some funding in the grant application for travel funds for what we call NCTN-related meetings. So that funding can be used for an NCI DCTD/CTEP in-person meeting for the LAPS grantees during the project period or these travel funds could also be used for a steering committee meeting at ASCO, or CRA travel for training, or for investigators and research staff to attend an NCTN Initiative meeting held by NCI or anything that has some connection to the NCTN. We want you to have the capability to use those funds if we do not end up having an in-person grantee meetings.

Lastly, we do not support costs associated with routine patient care as a budget expense under this NOFO/RFA, or under any of the NCTN RFAs.

Slide 24 – Data Management and Sharing Plan

Regarding the required "Data Management and Sharing Plan", you can read about the requirements for such a plan from the NIH grants policy statement. However, for LAPS application, the plan must simply explain why data sharing is **not** possible under the LAPS grant. Any of the scientific or clinical data generated under a LAPS grant related to enrollment of patient at LAPS sites to multi-site NCTN trials is going to be done under the NCTN Group Operations Center grant and that of its associated Statistics and Data Management Center grant for the NCTN Group leading the particular multi-site trial. The clinical and scientific evidence the LAPS is generating under this award is **not** something you can publish or share on your own.

We are going to provide a template of an acceptable "Data Management and Sharing Plan" for LAPS applicants given this unique situation, and we will provide that on the website with the Webinar slides and this Summary Transcript. You can change that if you believe it is necessary, but that template should be a sufficient basis for explaining why you cannot share data under a LAPS award. Unfortunately, we could not provide this level of detail in the LAPS RFA so that you would not have to provide a "Data Management and Sharing Plan" because it is a required module in the application. So, you have to submit something and this template plan will provide the justification that you need to explain in the application why a LAPS cannot share the scientific and clinical data generated by enrolled patients at LAPS sites.

Slide 25 – Terms of Award

Terms and Conditions of award are listed in the RFA, and include the standard NIH grant policy, statement as well as specific Terms of Award for the LAPS awards. So, we'll stop here and open it up if there are any questions.

Questions and Answers - Note: Questions unrelated to the RFA were not included.

Q: Is there a minimum effort expected for a sole PI or for multi-PIs?

A: There is not a minimum in the RFA. For other NCTN grants, a PI is expected to provide 1.8 months per year, and that is probably a good target for at least the LAPS contact PI, but generally it just has to be something reasonable given the number of PIs on the LAPS included for the application.

Q: Do we really have to end our accrual and study activation reports on August 31, 2024?

A: Yes, to have the timeframe be consistent across all applicants.

Q: Is there an amount that should be budgeted for travel?

A: There is not a specific amount, because it might vary based on where your LAPS sites are located are in the country, but we are asking you to budget enough for 2 people to attend up to 3 in-person NCTN-related meetings over the course of the 6-year project period.

Q: How much do the accrual numbers used to calculate ballpark costs need to mirror our actual average accrual?

A: It does not need to exactly mirror your average accrual between 2019 and 2024, because you might be trending up and then you could justify something toward the higher end, or you might be trending down a bit given funding levels and support at your sites. What we really want you to do is use numbers you think are realistic (i.e., what you realistically think your sites will be able to do).

Q: Is there a minimum level of accrual expected?

A: Under the review criteria, you'll see the additional review criterion specific to this NOFO, and a question to the reviewers asks, "Does the LAPS applicant demonstrate the potential for robust accrual (e.g., 55 to 70 patients per year or more) to multi-institutional NCTN trials?" So, that provides an estimate of the range.

Q: If we have affiliate sites, could we ask for more than $1.7 million?

A: No. The $1.7 million ceiling for direct cost in any 1 LAPS application includes any site included in the application (main academic site, integrated components, and affiliates).

Q: For the accrual reports, do you want us to separate the screening and intervention accruals?

A: No, we are just asking for the total unique number of patients, not separated by screening and intervention. For the purposes of your budgets, it matters whether a patient is just on the screening step or goes on the intervention step, but for the purposes of demonstrating robust accrual, we want to show the reviewers the total number of patients enrolled. Especially in an era of precision medicine, you do not know how many patients will go on from a trial-specific screening step to the intervention step, as that is outside of your control since the patient was enrolled based on the eligibility criteria for the trial, but whether a patient goes onto the intervention step usually relates to the biology of the patient's cancer.

Now, we do have separate tables in attachments 6 and 7 for the older precision medicine studies, for Lung-MAP, and adult MATCH, and ALCHEMIST, so there is a screening table for those but only for those 3 trials because they had really big screening components. They have been winding down, but we left this in for those 3 trials. We did not do it for the new precision medicine trials, like ComboMATCH and MyeloMATCH because they are all in a modular format and there has not been much accrual through August 31, 2024, as they were activated recently.

Q: What is the start date of the competitive renewal? Is it December 2025 or March 1, 2026?

A: The December date is listed because NIH has standard language in all RFAs that includes an estimated start date that might be early, but that will **not** applicable for these grants. The start date will be March 1, 2026.

Q: Can you clarify what you mean by a patient who is just a screening accrual? Does this mean we can count screen failures?

A: If a patient is enrolled to the screening step in OPEN via the NCI Cancer Trials Support Unit (CTSU), they count as an accrual. Screen failures before the patient consents and is enrolled in OPEN would **not** count. Your accrual numbers should generally match the numbers in the CTSU system.

Q: Can you clarify what Letters of Support are required?

A: **What we really need are the letters of support from your affiliate sites if you are including affiliates in your application**. You can have other letters of support as well, and that is up to you. You do not have to have letters of support from the integral component sites because those sites are truly part of your institution, and so we assume an additional letter of support is not required because that site is already under the financial and governance structure of your institution.

Q: What is the expectation of institutional support, and should that be captured in a letter of support?

A: We would encourage people to provide letters of support that they think are important to show your institution is supportive of your participation in the NCTN and supports it because we know that this cooperative agreement funding does not cover the full cost of everything you need to do to support this work, and so if your institution wants to provide a letter of support, that is fine.

Q: What should we use as Day 1 for the timelines for local activation?

A: One starting point is when the trial opens or activates on the CTSU, and then there are differences in how people define the start of their site's review process. We would say it would be the start of the formal review at your site, when it is submitted for evaluation at your institution through a formal, required review process. And then we want to know what the timeline is until the date you could actually have put a patient on that NCTN trial (although the actual date of the 1st patient accrued may be later than the date the trial was open to accrual at your site).

Q: How are NCORP accruals paid for if you are a LAPS site?

A: Funding for participation in NCORP trials is provided by DCP per DCP's policies and is completely separate from the LAPS grant.

Q: Is the LAPS intended to affiliate with one NCTN group or is more than one permitted?

A: Participation in multiple Groups is permitted, and is typical, but is not required.

Q: If a LAPS affiliate is a member of an NCTN group, can they credit their accruals to that group but receive their payment through the LAPS, which is not a member of that group?

A: Since the LAPS is applying complete management for the affiliate site, the Group membership of the affiliate must be with a Group that the LAPS is also affiliated with. Affiliate sites can only participate in the NCTN program through their role as a LAPS affiliate. The LAPS may have Group memberships that the affiliate does not, but the affiliate can only credit NCTN Groups that the LAPS is also has membership in.

Q: How can we determine if a trial is IND exempt, CTEP IND, or non-CTEP IND?

A: We will be updating the Excel File List of NCTN trials to include a column for each trial indicating whether it is a CTEP IND, non-CTEP IND, or IND exempt trial. It is also noted on each NCTN trial funding sheet, just below the title (and it can also usually be found on the protocol title pages).

Q: To confirm, our institutional indirects are part of the total cost calculation? So, in the first example, $557,250 would be expected to include institutional indirects?

A: Yes, that is correct.

Q: If an affiliate site normally gets paid per event by us, if we add them as a LAPS affiliate, would they get a lump sum regardless of their total activity?

A: No, you would be able to distribute the per-case amount as you see fit. Some amount could be allocated to the affiliate site per event (per-patient) or there may be minimal funding provided to the affiliate site per event (per-patient) and the rest goes to the LAPS main site if the LAPS is providing services directly to that affiliate. This is something the LAPS and its affiliate have to work out between themselves and agree to together.

Q: Can you clarify what the 20% coordination line is intended to cover? Does this differ from the level-of-effort budget component?

A: The 20% coordination is part of the Total Cost that you can use in your “Level of Effort” budget in any way that you believe is needed to accomplish the aims of the LAPS as long as it covers an allowable cost.

Q: Is submitting an Letter or Intent (LOI) recommended in the case of a renewal?

A: Yes, we recommend everyone who expects to submit an LAPS application, new or renewal, submit an LOI to help in planning for the review panel.

Q: Is a progress report including publications required for a renewal application?

A: Yes, a publications list will need to be submitted for a renewal application.

Q: For renewals, there is an attachment requirement for progress report publications specifically, and we're wondering what do you want us to attach in the renewal application for pubs?

A: As best we can ascertain, when applying for an NIH renewal, you must include a Progress Report Publication List that lists all publications, manuscripts, patents, and other printed materials that resulted from the project since the last competitive review as listed below.

- What to include: List the titles and complete references for all relevant items.
- How to cite: Cite articles that fall under the public access policy. Include the NIH Manuscript Submission reference number or the PubMed Central (PMC) reference number for each article.
- Where to include: Attach the list to the application, but it does not count toward the Research Strategy page limit.

Q: What is meant by providing complete management services at the VA?

A: This is meant to cover the case in which your academic staff provides support for the clinical trial aspects for enrollment of patients and conduct of the NCTN clinical trial outside of the normal standard of care aspects for patient care, standard medical record reporting, general training including clinical trial training if it is not specific to the NCTN. Something that the affiliate site would do as basic support for the patient is not part of this, is more the clinical trial aspects only.

Q: Is a renewal application reviewed differently than a new application?

A: No, but if you are a current LAPS, submitting a renewal application allows you to refer to your work from the current project period more easily. The reviewers, however, assess the application against the review criteria; they do not compare applications.