Frequently Asked Questions (FAQs) for the Funding Opportunity Announcements (FOAs) and the Guidelines Document for the new NCI National Clinical Trials Network (NCTN) Program

December 15, 2012

This FAQ document has 4 sections:

- **FAQs for ALL Funding Opportunity Announcements (FOAs) under the new NCTN Program**
- **FAQs for Network Group Operations Centers, Network Group Statistics and Data Management Centers (SDMCs) & Canadian Collaborating Clinical Trials Networks**
- **FAQs for the Lead Academic Participating Sites**
- **FAQs for the RT and Imaging Cores Services Centers**

There are no special general FAQs for the Integrated Translational Science Request for Application (RFA)/FOA; however, the general FAQs in Section 1 apply to this RFA/FOA as they do to all RFAs/FOAs under the new NCTN Program. Applicants for the Integrated Translational Science RFAs/FOAs are encouraged to request a pre-application consultation call if they have any questions about the application.

Section 1: FAQs for ALL Funding Opportunity Announcements (FOAs) under the NCTN Program

Has the Guidelines document been updated for the NCTN Program?

Yes. A revised version of the Guidelines document for the NCTN Program dated December 15, 2012 is posted to the NCI/CTEP website. This revision is an update to the initial version of the Guidelines posted on July 20, 2012. All updates/modifications to the Guidelines are highlighted in **RED text** in the posted revision. A list of all changes made (by page number with a brief description) is provided on pages 239 – 241 of the revision. In particular, extensive clarifications are made in the Tables and Budget areas in the Appendices – Part II, Part IV, Part VI, Part X, and Part XI. Changes have been made to the text so as to keep the original page numbers from the initial Guidelines document intact. **Applicants are encouraged to read carefully through all these clarifications in the tables, application requirements, and budget examples as they were made in response to numerous, common questions about the tables and budgets across various RFAs/FOAs. These clarifications are <u>not</u> all duplicated in these FAQs; instead all clarifications are provided in the revised Guidelines.** Minor math errors in the budget algorithm examples have also been corrected.

Are there any new tables in the revised Guidelines document?

No, however, there are substantial changes in 2 tables for applicants for the Network Group Operations Center application and 1 table for the Network Group Statistics and Data Management Center (SDMC) application and numerous clarifications have been made in all tables for all applicable applications. Table 11 (Audit Table) for the Operations Center application on page 201 has been modified to provide summary information on all Group member institutions/sites by membership category only (and NOT a listing of audit results for individual member institutions). Also, Network Group Operations Center applicants should NOT submit the accrual input table on page 236 for all member institutions/sites with their applications – that table will be requested as "Just-in-Time" information. Instead applicants must submit just a listing of their member institutions/sites with the applications per the suggested table format on page 238. For the SDMC application, Table 3 on data quality and timeliness is now limited to summary information only for all member institutions combined (listings for individual institutions should NOT be submitted and the previous reference to individual institution listings has been removed).

Is there a standard reporting period for all the information provided in the application and any associated tables?

Information from the past 5 to 6 years may be included in the application to demonstrate the applicant's potential to fulfill the review criteria. No specific reporting period is required within that general time frame. A suggested reporting period for all the tables is provided (i.e., January 1, 2007 through June 30, 2012; however, an applicant may have a different period within the past 5 to 6 years. Applicants can also submit post submission materials. Applicants are required to follow the instructions for post submission materials, as described in NOT-OD-10-115.
Note: Because applications submitted in response to the RFAs/FOAs for all the key components of the NCTN Program have only one due date, applicants may submit materials per the exceptions list in NOT-OD-10-115 using the specified page limits (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-115.html).

Will page limitations for various sections of the application be strictly enforced?

Yes, all page limitations will be strictly enforced. Applications that do not abide by the page limitations will not be reviewed. Specific page limitations are provided for the Research Plans under each of the 6 different RFAs/FOAs under the NCTN Program and in the Guidelines document. All other page limitations are described in the instruction for the PHS398 application (see http://grants.nih.gov/grants/funding/phs398/phs398.html).

Does the Resources section of the PHS398 which will contain the required tables for an application have a page limitation?

No, the Resources section of the PHS398 does not have a page limit; **however,** all applicants for any of the RFAs/FOAs are strongly encouraged to make the tables required under the RFAs/FOAs brief and concise and, in particular, tables on achievements should highlight the most important major accomplishments – this will help reviewers assess the application. For some RFAs/FOAs, key standard operating procedures (SOPs) may be required to be submitted in the Resources section of the PHS398. Applicants should ensure that only the key SOPs requested are submitted.

What materials can be submitted in the Appendix for an application?

There are strict guidelines for what can be summated as Appendix Material for these applications. Applicants should refer to the RFA/FOA that there are applying under as well as the corresponding sections in the Guidelines document to determine what can be submitted as Appendix Material.

Is there any accommodation for applicants at institutions affected by Hurricane Sandy with respect to application deadlines?

Yes, NCI will honor NIH policy regarding delays in submission of applicants due to Hurricane Sandy. NIH has published a notice in the NIH Guide regarding delays in submission of applications due to complications caused by Hurricane Sandy available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-006.html.
NCI will honor these guidelines for submission of an application in response to any of the RFAs/FOAs under the NCTN Program per the regulations in the NIH Guide. Applicants are encouraged to let the NCI know if they will be submitting an application under the conditions of the NIH Guide notice by emailing that information to the NCTN Program mailbox at ncictepanalyst@mail.nih.gov.

Is the option for Multiple PD(s)/PI(s) available of all the RFAs/FOAs under the new NCTN Program?

Yes, the Multiple PD(s)/PI(s) option is available for all the RFAs/FOAs. NCI encourages applicants to consider this option as it was designed to reward team science; however, it is an option and is not required. Applicants should decide whether they think the option is appropriate and beneficial for their particular application and circumstances. Information on the option, including the responsibilities of PDs/PIs under the option, is available in the PHS398 application instructions and at http://grants.nih.gov/grants/multi_pi/index.htm. If this option is selected, the PHS398 application has a special section on the Multiple Program Director/Principal Investigator (PD(S)/PI(S)) Leadership Plan that must be included in the application. There is not a limit on the number of PDs/PIs for an application as it depends on the particular RFA/FOA.

Is there a minimum level of effort required to qualify as PD/PI? What are the current salary limitations?

Each PD/PI must have measurable effort (greater than zero), and the level of effort must be adequate to achieve the propose goals. None of the RFAs/FOAs under the NCTN Program include a specific minimal level of effort for PDs/PIs. Effective with grant awards with an initial Issue Date on/after December 23, 2011, the salary limitation is limited to Executive Level II of the Federal Pay Scale, $179,700. NIH competing grant awards with categorical budgets reflecting salary levels at or above the new limit that have an initial Issue Date on/after December 23, 2011, will reflect adjustments to the current and all future years so that no funds are awarded or committed for salaries over the limitation. Please see **NIH NOT-OD-12-035** (***Notice of Salary Limitation on Grants, Cooperative Agreements, and Contracts***) at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-035.html for additional information. Questions related to grant policy on salaries and other issues can be directed to the Office of Grants Administration at NCI.

Why are there specific eligibility requirements on organizations and individuals for the different RFAs/FOAs under the NCTN Program that restrict certain organizations and/or individuals from being the applicant organization or PI/PD or key personnel on different grants?

Information on the eligibility requirements for applications (i.e., eligible organizations and eligible individuals) is provided in the Request for Applications (RFAs)/Funding Opportunity Announcements (FOAs) for all the key components of the NCTN Program. Applicants must meet these eligibility requirements in order for an award to be funded under the NCTN Program.

In addition, there are eligibility requirements for organizations and individuals based on relationships across the six RFAs/FOAs of the Program. In particular, there cannot be overlap between the applicant Multiple PD(s)/PI(s) teams for awards under certain RFAs/FOAs and there cannot be overlap between applicant organizations for awards under certain RFAs/FOAs. This information is given in detail in the specific RFAs/FOAs. The reason for these restrictions is to ensure/promote a level of independence between different components of the NCTN Program. Examples are provided on page 99 of the revised Guidelines, but applicants should review the eligibility requirements that are described in detail for the RFA/FOA that they intend to apply under to ensure that they meet the eligibility requirements.

Applicants are encouraged to discuss any questions regarding fulfilling these or other eligibility requirements under the RFA/FOAs with the NCTN Program staff in a pre-application consultation call if they have questions on these requirements.

Based on the plan for all grants under the new NCTN Program to start on March 1, 2014, should the proposed budgets be based on that start date?

Yes.

The Guidelines refer to a Common Budget Outline in Part IV – Appendix IX on pages 233-235. Do all applications need to submit a Common Budget Outline?

No, the Common Budget Outline (CBO) should be submitted only by Network Group Operations Center applicants under RFA-CA-12-010. It does not apply to any other RFA/FOA under the NCTN Program. The Network Group Operations Center applicants will need to work with their associated Statistics and Data Management Centers to develop the Common Budget Outline, but the CBO should be submitted only by the Network Group Operations Center applicant with its application (it should not be submitted ahead of the application).

Will the review process for applications under the NCTN Program include a site visit or "Q&A" session with key leader of the applications?

No, the review process for all applications submitted under any of the RFAs/FOAs under the NCTN Program will be based strictly on the written application.

Where do I go if I still have questions about the RFAs/FOAs after reading the revised Guidelines document and FAQs?

We hope that the initial "Q&A" sessions, revised guidelines document, FAQs, and pre-application consultation calls we have had with many parties interested in submitting an application will answer most questions; however, applicants may still submit questions to the NCTN Program mailbox at ncictepanalyst@mail.nih.gov and/or request a pre-application consultation call up until the due date for the applications. After that date, the applications are considered "under review" and questions on the applications will be referred to the NCI Division of Extramural Activities (DEA) which oversees the review process.

Section 2: FAQs for Network Group Operations Centers, Network Group Statistics and Data Management (SDMC) & Canadian Collaborating Clinical Trials Networks

What is expected for the Director of Operations position for the Operations Center and SDMC grants?

The description/requirements of this position are addressed in the Guidelines document under the Research Plan and Review criteria for these 3 RFAs/FOAs. The individual in this position is expected to have key responsibilities with respect to coordinating operational activities between the Network Group Operations Center and the associated Network Group Statistics & Data Management Center. However, the particular functions of the individual may be different depending on the Network Group. The Director of Operations does not need to be a faculty member; the individual should be an experienced administrator capable of handling these responsibilities. This individual should be listed as key personnel; however, all key personal designation decisions for the application are made by the PD(s)/PI(s), although the NCI may require that this individual be identified as key personnel in the Notice of Grant Award if the individual is not identified as key personnel in the application. This position could be filled by 2 individuals; however, the application should describe clearly how responsibilities will be divided.

There is a reference in the Guidelines/Application information that the Network Groups will provide data management, trial operations, and staff support for approved multi-center phase 2 and 3 trials originating from outside of the Network. What would an example of this be?

All large phase trials conducted by the Network will be prioritized by the disease specific steering committees or other NCI/DCTD review process for disease areas without a steering committee. There are some programs that allow non-Network Group investigators, such as SPORES or cancer centers, to bring forward a late phase clinical trial idea/concept. If the appropriate Steering Committee or review body approves the study, NCI/DCTD will discuss the concept with the Network Groups to determine if one of the Network groups could run the trial. NCI may be able to provide additional support for these types of trials depending on funds availability. In addition, Network Groups are encouraged through the review criteria and Terms of Award to develop study collaborations with other NCI-supported investigators and programs as well as other researchers and to incorporate collaborative study ideas into the NCTN Program.

Applicants may have had differing membership models for clinical trial conduct. What is the expectation for the membership roster of a Network Group under the NCTN Program?

A Network Group Operations Center will be responsible for having a comprehensive and consolidated membership roster of all its sites and associated investigators and research staff and for maintaining the roster for both auditing and financial management purposes with "real-time" status of all members within the Regulatory Support System (RSS) of the NCI Cancer Trials Support Unit (CTSU) under the Terms of Award for the NCTN Program. All member institutions/sites must have appropriate and accurate NCI institutional codes approved by NCI. Institutions/sites are assigned to one of the following mutually exclusive categories across the entire Network for the NCTN Program for purposes of NCI/DCTD funding and crediting of accrual: (1) Lead Academic Participating Sites; (2) Affiliates included in a Lead Academic Site award (because they are completely managed by the Lead Academic Participating Site); (3) CCOP; (4) MB-CCOP; (5) Pediatric site; and (6) other Network Group member institutions/sites. For example, a site that is a CCOP has that designation across the entire NCTN Program regardless of the number of Network Groups to which it belongs. A Network Group Operations Center applicant must submit a listing of its comprehensive roster of defined institution/site membership with its application per the table format on page 238 of the revised Guidelines. It is understood that an Operations Center applicant will not know if one of its institutional members will receive a Lead Academic Participating Site Award with or without affiliates, so the comprehensive roster submitted should reflect the current situation. **This comprehensive roster must be ordered by institution only. Rosters that split out membership based on any other type of categorization are not acceptable – i.e., rosters must be based on institutions/sites membership only (not individual investigators) and institutional membership must be integrated across all diseases or disciplines (an institution cannot have a designation for 1 particular disease or discipline and a second membership based on another disease area or discipline).**

How should information on activities that encompass staff at both the Operations Center and the associated SDMC be reported in the 2 applications (e.g., auditing activities)?

Each application should explain only what it does with respect to the particular activity and only costs it will incur for that activity should be included in its budget. The SDMC application, for example, does not have to explain what the Operations Center does with respect to auditing, only what it does; however, the SDMC application may refer to the fact that those other activities are performed by the Operations Center if that helps clarify the narrative in the application that describes what the SDMC does.

How do Network Group Operations Center and SDMC applicants include "legacy" studies and costs in its application and budgets?

A Network Group Operations Center applicant will be requested to supply a list of legacy trials that it wishes to transition to the new NCTN program as "Just-in-Time" information. Only studies previously supported under the NCI-sponsored Cooperative Group Clinical Trials Program funded by the Division of Cancer Treatment and Diagnosis (DCTD), including primary advanced imaging trials funded by the NCI Cancer Imaging Program, can be transitioned to the new NCTN program. The Network Group Operations Center should specify all legacy trials that do not have a status of "complete" in the NCI/DCTD enterprise system, both open and closed, this it wishes to transition to the new program. The Network Group Operations Center must specify which trials it anticipates will still be open to accrual at the time of transition to the new program. Please see page 113-114 of the revised Guidelines.

Regarding budget requests for legacy studies, Network Group Operations Center applicants and Canadian Collaborating Clinical Trials Network applicants can include expenses related to restricted capitation for follow-up on phase 3 legacy studies from the former NCI-sponsored Cooperative Group Clinical Trials Program; however, such requests must be accompanied by a detailed budget justification (not to exceed 1 page in the budget section) and apply only to legacy phase 3 studies for a maximum of 5-years at $50 per year per patient for accrual from sites that were NOT institutional U10 members or CCOPs/MB-CCOPs under the legacy program since institutional U10 members and CCOPs/MB-CCOPs did not receive follow-up payments under the legacy program. Applicants can also request funding for tumor banking activities that were previously covered in the Operations Center grants of applicants that participated in the former NCI-sponsored Cooperative Group Clinical Trials Program (and are not yet covered by their current Tumor Banking R24 grant); however a detailed budget justification must be provided with this request (up to a 1 page maximum in the budget section) and these costs CANNOT cover reference laboratory activities. Please see page 104 of the revised Guidelines.

Regarding budget requests for legacy studies, Network Group SDMCs (including the SDMC of Canadian Collaborating Clinical Trials Network applicants) Applicants can also include expenses related to data management for legacy studies from the former NCI-sponsored Cooperative Group Clinical trials Program; however, such requests must be accompanied by a detailed budget justification (not to exceed 1 page in the budget section) and would only be funded based on unusual circumstances (e.g., very large and complex study). Please see page 117 of the revised Guidelines.

How do the budgets of the Network Lead Academic Participating Sites connect to the budgets for the Network Group Operations Centers?

The NCTN Program is a brand new program. All applications submitted under the RFAs/FOAs for the NCTN Program are Type 1 application (new, competing applications). The Network Group Operations Center applicants will not know at the time they submit their applications which of their member institutions may eventually receive a Network Lead Academic Participating Site award. A Network Group Operations Center applicant should determine its budget based on its entire membership, including member academic centers that it knows will be submitting an application for a Lead Academic Participating Site award. After the Network Lead Academic Participating Sites have been chosen, the NCI will make appropriate adjustments in the funding plans for the Operation Centers based on the anticipated accrual that the Operations Centers thought they might fund in their applications. Because of this situation, Operations Center applicants only need to submit a list of their member institutions per the suggested

table format on page 238 of the revised Guidelines document (Version dated 12/15/2012) in the Resources section of the PHS398 application. The accrual input table that is given on page 236 of the Guidelines document showing anticipated annual accrual from each of the Network Group Operations Center's member institutions/sites over the 5-year budget period summarized by accrual category will be requested as "Just-in-Time" information; it should NOT be submitted with the application.

Likewise, travel to regular, semi-annual Network Group meetings for staff at Lead Academic Participating Sites is part of the Lead Academic Site budget. Network Group Operations Centers and/or associated Network Group Statistics and Data Management Centers should include travel for investigators, including statisticians, from the Lead Academic Sites for special committee meetings, oversight committee meetings, and trial planning meetings in their budgets, as appropriate. Information on travel budgets support for attendance at regular, semi-annual Network Group meetings should also be provided as "Just-in-Time" information to the NCI after the Lead Academic Sites are selected so that appropriate adjustments can be made in the funding plans for the Operations Center awards (or SDMC awards, if applicable). See information on all "Just-in-Time" information required for Operations Centers on pages 113-114 of the revised Guidelines document.

Please note that scientific leadership costs in the Operations Center budget should include funding for scientific research and administrative committee chairs and/or vice-chair or co-chair positions as well as study chairs, as applicable for the Group. These costs are NOT part of the Lead Academic Participating Site awards as these services are provided by investigators to specific Network Group Operation Centers and investigators provide these services at the discretion of the Network Group.

What type of information, especially accrual information, should be included in the Required Tables for the Network Group Operations Center Application?

Network Group Operations Center applicants should include key leadership, scientific achievements, accrual, and other information (e.g., operational efficiency timelines) from participation in the former/current NCI-sponsored Cooperative Group Clinical Trials Program. Only if the applicant did not participate in the former NCI-sponsored Cooperative Group Program should the applicant provide accrual and other information from cancer clinical treatment trials supported by an equivalent non-profit, late-phase (primarily phase 3) clinical trials network organization that conducts oncology treatment trials (not industry, investigator-initiated, or early phase trials).

Accrual tables are for cancer treatment trials only; if an applicant wishes to emphasize significant past accrual on primary advanced imaging studies under the NCI Cooperative Group Program funded by NCI Division of Cancer Treatment & Diagnosis (DCTD) or equivalent system for applicants who did not participate in the NCI Cooperative Group Program, that information can be presented in the text of Research Plan under "Member Site Accrual Program." Leadership, scientific achievement, and other information from DCTD-sponsored Cooperative Group primary advanced imaging studies can be included in the appropriate non-accrual tables with achievements from treatment trials.

Please see pages 195 to 201 and page 238 for clarifications on the tables required to be submitted with the Network Group Operations Center application.

Can the Canadian Collaborating Clinical Trials Network applicant submit an additional accrual table to those specified for the US Network Group Operations Center applicants related to its own Network's accrual?

Yes, Canadian Collaborating Clinical Trial Network applicants can also include 1 separate accrual table (modified Table 7) to show treatment trial accrual for trials they lead for their own organization to highlight their potential for accrual across a range of diseases; however, this table must be clearly labeled as accrual distinct from the accrual tables on their past participation in NCI-sponsored Cooperative Group Clinical Trials Program.

For the Data Timeliness and ADR/SAE reporting tables for the SDMC application (Tables 2 and 3 on pages 202-203 of the Guidelines), what is the rationale for the particular mix/matrix of reporting elements and can an applicant re-format these tables?

The tables are to describe and provide the reviewers with data on the accuracy and timeliness of data submission to clinical trials that the Network Group leads. The table formats are suggested formats only; the information can be re-formatted by the applicant to provide the information to the reviewers on this topic in a manner and content according to what the applicant thinks best addresses the review criteria; each applicant has the leeway to re-format the tables – no pre-approval is required by NCI.

Where does the SDMC provide information and the budget for Information Technology (IT)?

Budget items related to IT should be described in the data management section of the research plan. For budget items, the cost of the equipment should be justified under "supplies, equipment, and other costs" and other costs related to IT may be provided under this item and/or under the cost items for data management depending on what is being provided.

Also, it is anticipated that the current support for Medidata-Rave for the current NCI-Sponsored Clinical Trials Cooperative Group Program via central hosting will be provided in the new NCTN Program, so those costs are covered by the NCTN Program and should NOT be included in SDMC budget applications. If any arrangements change with respect to how Medidata-Rave services are provided in the future, appropriate accommodations would be made at that time.

Section 3: FAQs for the Lead Academic Participating Sites

What is meant by an essential or integral component of an Academic Center as opposed to an affiliate? Can an affiliate be included in the application?

An essential or integral component of an academic center is one that is under the single financial management system and governance structure of the academic center but may be at a different geographic location (e.g., a clinic center in the suburbs of a city distinct from a downtown location for the academic center). These integral components usually have a separate NCI institution code. Other organizations that are associated with an academic center (e.g., VA Hospitals), but that are not under the same financial management and governance structure, may be considered "affiliates" of the Lead Academic Participating Site and may be included in the application under that designation (i.e., "affiliate"), if the Lead Academic Participating Site will be providing complete management services for the affiliate site related to enrollment of patients on NCTN trials (although the complete management services do not have to include IRB services).

Affiliate(s) that meet this description are allowed to be included in the application of the academic center for ease of administration for the academic center (i.e., so that the NCI) for data management of NCTN enrollments at the affiliate(s) go to the academic center directly from the NCI, but these affiliate(s) do NOT have to be included in the application). The accrual and other activities of the affiliate(s) are NOT part of the review criteria for the academic center application – affiliate accrual is only included to justify the budget request of the academic center as the goal of the academic center award is to provide funding for academic centers that have the potential to provide significant scientific leadership and accrual to the NCTN (it is not a goal of the award to build affiliate or regional networks). Thus, an academic center can have all its affiliates or some of its affiliates funded outside of the application.

In the circumstance that an affiliate of an academic center with a Lead Academic Participating Site grant is not funded via the grant, the affiliate would receive its "per-case management" funding via the Network Group it credits with the accrual per the membership funding rules of that Network Group. If an affiliate is included in a Lead Academic Participating Site application, then that affiliate will receive ALL NCI funding for data management associated with patient enrollment to any NCTN trial via the grant and any budget request in the application related to the affiliate should follow the methodology for budget preparation in the Guidelines document (i.e., the affiliate cannot be an affiliate of another institution for purposes of its NCTN program participation in treatment and advanced imaging trials). Please see page 128 of the revised Guidelines for a re-cap of this information.

If the Lead Academic Site application includes affiliates, Letters of Support from the affiliates should be included in the application since the affiliates will need to acknowledge in the letters that they agree to receive NCI funding for data management on all NCTN trials they participate in via this grant (i.e., an affiliate cannot be an affiliate of another institution for purposes of its NCTN program participation) and thus support their inclusion in the application. Please see page 135 in the revised Guidelines concerning this requirement.

Should accrual and other activities at the academic center related to pediatric patients be included in the Lead Academic Participating Site application?

No. This application is explicitly centered on the potential for the academic center to provide significant scientific leadership on adult cancer treatment trials and accrual of adult cancer patients to NCTN treatment trials. Because the NCI will be funding only up to 1 pediatric Network Group under the NCTN Program, all activities and accrual for pediatric patients will be handled under that award.

Should information on past accrual and other activities included in the required tables for the Lead Academic Participating Site application be limited to accrual and activities on former/current NCI-sponsored Cooperative Group Clinical Trials Program only?

Yes, if the applicant participates or participated in the former/current NCI-sponsored Cooperative Group Clinical Trials Program. Lead Academic Participating Site applicants should include key leadership, scientific achievements, and accrual information from participation in the former/current NCI-sponsored Cooperative Group Clinical Trials Program. However, this is an open competition so **if the Academic Site applicant did not participate in the former NCI-sponsored Cooperative Group Clinical Trials Program, the applicant should provide** accrual and other information from cancer clinical treatment trials supported by an equivalent non-profit, late-phase (primarily phase 3) clinical trials network organization that conducts oncology treatment trials (not industry, investigator-initiated, or early phase trials). If accrual came from a collaboration between one of the former/current NCI Cooperative Groups and another organization that was recognized by NCI/DCTD under the NCI-sponsored Cooperative Group Clinical Trials Program (i.e., collaboration between the Cooperative Groups and the NHLBI-NCI funded BMT-CTN, those accruals could be included in the accrual tables if the accruals were credited by the academic center to the Cooperative Group. If the accruals were credited to the BMT-CTN they should not be included as they would have been funded under a different NIH program. The same would be true of accrual by the academic center of a young adult patient credited to an adult Cooperative Group for a trial that was a collaboration between the adult Cooperative Group and the Children's Oncology Group under the former/current NCI-sponsored Cooperative Group Clinical Trials Program.

Please note that the accrual tables are accrual of adult patients for cancer treatment trials only; if applicant wishes to emphasize significant past adult patient accrual on primary advanced imaging studies under the NCI Cooperative Group Program funded by NCI Division of Cancer Treatment & Diagnosis (DCTD) [or equivalent system for applicants who did not participate in the NCI Cooperative Group Program], that information can be presented in the text of Research Plan under "Site Accrual Program."

Leadership and scientific achievement from DCTD-sponsored Cooperative Group primary advanced imaging studies should be included in the appropriate tables with achievements from treatment trials. Accrual and other information related to cancer control/symptom management and prevention studies should **NOT** be included in this application as those studies are funded through a separate grant program by the NCI Division of Cancer Prevention (DCP).

Is additional information/clarification available on the required tables for the Lead Academic Participating Site application?

Yes. The revised Guidelines (dated December 15, 2012) now contain additional information and clarifications to help applicants complete the tables based on applicant questions and pre-application consultation calls that NCI has held. Please review this information carefully which is provided on pages 204 to 208 of the revised Guidelines. Also, the summary accrual input table presented on page 237 of the revised Guidelines document is also required to be submitted with the tables in the Resources section of the PHS398 application.

Is it required that a Network Lead Academic Participating Site become a part of the NCI Central Institutional Review Board (CIRB) prior to submitting the application?

Membership to the NCI CIRB is a Term of Award; it is not part of the application or review criteria, so applicants do not have to be members of the NCI CIRB at the time that they submit an application. However, all U.S. institutions/sites participating in NCTN trials as members of 1 or more Network Groups (including Network Lead Academic Participating Sites, CCOPs, and MB-CCOPs) will be required to use the pediatric and/or adult NCI Central Institutional Review Board for any NCTN trial under an NCI CIRB's purview. This requirement may be waived by the Lead NCTN Program Director through an exemption review process if the institution/site can adequately show that NCTN studies can be reviewed in a timely manner by its local IRB (or other Central IRB) that is equivalent to the review timelines for the NCI CIRB (i.e., about 35 to 48 days for initial review) or if the institution/site can

demonstrate other exceptional circumstances that preclude it from using the NCI CIRB. A process will be set up as part of the roll-out of the new awards for member institutions/sites to become members of the NCI CIRB. In addition, in December 2012, the Association of the Accreditation of Human Research Protection Programs (AAHRPP) awarded the NCI CIRB with its independent model Full Accreditation. Information on the announcement of accreditation is available at: http://www.cancer.gov/newscenter/newsfromnci/2012/CIRBaccreditation and http://www.aahrpp.org/connect/whats-new/what's-new/2012/12/11/news-release-latest-accreditations-include-first-nih-entity-and-the-first-organization-in-taiwan

Can a Lead Academic Participating Site belong to more than 1 Network Group?

Yes. An institution can belong to multiple Network Groups. The NCI encourages institutions to participate in trials across the Network led by the different Network Groups, i.e. up to 4 adult Network Groups. An applicant will have to belong to at least 1 Network Group, but can belong to as many Network Groups as is appropriate for the particular institution.

The Guidelines indicate that the budget for the Lead Academic Participating Site might be reduced after 3 years if the academic center was not maintaining its accrual threshold, but what will happen if enrollment increases?

The application should indicate a site's historical ability to accrue and also the institutions potential for accrual. NCI/DCTD will review accrual on an annual basis and administrative supplements may be provided for accrual that is in excess of the anticipated threshold accrual on which the academic center's grant was initially funded.

Should biostatistics support be incorporated into the Lead Academic Participating Site budget?

No, with the exception of travel to regular, semi-annual Network Group meetings, if applicable, for statistical staff. This grant is to provide support for the scientific leadership activities/contributions and accrual across the entire to the Network. Funding for statistical support for the NCTN Program trials and related activities will be provided to the Network Group Statistics and Data Management Centers. An applicant can indicate if key personnel provide important contributions to the statistical plans of trials in the Research Plan of its application (or in the achievements tables if those achievements resulted in authorship for the academic center investigator), but funding for statistical support for the NCTN Program trials is provided under the SDMC grants. Travel to regular, semi-annual Network Group meetings for staff at Lead Academic Participating Sites (including statistical staff) is part of the Lead Academic Site budget. Network Group Operations Centers should include travel for investigators (and/or the associated Network Group Statistics and Data Management Center should include travel for investigators including statisticians) from the Lead Academic Sites for special committee meetings, oversight committee meetings, and trial planning meetings in their budgets.

Please provide a brief explanation of the algorithm provided to estimate the "ballpark" total cost figure for the budget for the Lead Academic Participating Site applicant?

The algorithm is explained on pages 128-130 of the revised Guidelines (with an example provided on page 215). The algorithm estimates a "ballpark" total cost figure for the entire budget for the Lead Academic Participating Site application based on anticipated accrual intensity for various categories of accrual over the project period plus some additional support (in estimated % ranges based on dollar amounts for intervention and non-intervention accrual for scientific leadership and coordination "infrastructure costs" at the academic center). From the estimated "ballpark" total cost figure (with total cost being defined as the sum of all indirect and direct costs), the applicant should create a standard grant "level-of-effort" budget using the cost categories for the application listed on pages 130-132. 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 total cost amount with appropriate budget justification based on changes in the estimated

ranges for infrastructure costs; however, budgets that are based on estimated ranges for the infrastructure costs that are in significant excess of the estimate ranges recommended in the Guidelines are unlikely to be supported. The algorithm table that the applicant uses to generate the total cost budget figure (i.e., example on page 215 table) does NOT need to be submitted with the application. The applicant only needs to submit the Accrual Input Table (example on page 237) that was used to help generate the budget in the Resources section of the PHS398 application.

A reference is made in the "Cost Components" table for budget preparation on page 211 of the Guidelines to a "Total Cost for Financial Management %" for Lead Academic Participating Sites; however, that % cost component is not used in the algorithm example used to generate the total cost budget figure for the Lead Academic Participating Site application on page 215. Is this a mistake?

Yes. Reference to this cost component for the Lead Academic Participating Site budget has been eliminated from the table on page 211 in the revised Guidelines document dated December 15, 2012. There is no "financial management %" cost component for the Lead Academic Participating Site because NCI is providing funding directly to the academic center. This cost component is for the applications of Network Group Operations Centers (Adult and Pediatric) which have financial management costs related to providing funding to their member organizations.

For scientific leadership, what aspects are funded through the Network Lead Academic Participating Site grant and what aspects are funded through the Network Group Operations Centers grant?

The revised Guidelines document outlines the cost categories that can be included in the budget for Network Lead Academic Participating Site on pages 130 to 133. The funding for scientific leadership for the academic centers is provided to support leadership and coordination activities, including management of accrual, across various disciplines at the academic center (and affiliates if included in the application). Scientific leadership positions in the Network Groups would be funded by the Network Groups Operations Centers or SDMCs (i.e., support for the activities of academic center investigators on Network 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 to show the reviewers how the academic center has the potential to provide leadership in the new NCTN Program, but budget support for these positions should be in the Network Group Operations Centers and SDMCs grants.

Section 4: FAQs for the RT and Imaging Cores Services Centers

Is there a budget limitation for the Network Radiotherapy & Imaging Core Services Center budget?

No, however, NCI intends to commit an estimated $7.5 million for up to 1 award in FY2014 with future amounts depending on annual appropriations. Applicants can submit a budget that is lower or higher with appropriate budget justification; however, actual funding will depend on funds availability in FY2014 and subsequent years.

Should the Radiotherapy and Imaging Core Services budgets be completely separate or are there any common items such as the development of a system for storing images, data, etc., that can be budgeted together? Would other activities be separated into the Radiotherapy Core budget and Imaging Core budget?

Coordination activities and the administrative infrastructure would not need to be put into separate budgets for imaging or radiotherapy core services. Other components that are specific to one core or the other should be explicitly accounted for in a restricted budget for either the imaging or radiotherapy cores, so that each cores' services are funded appropriately.

Periodically the Network Groups may require that the Core Services Centers perform data analyses to enhance the quality of a clinical trial. For example, atlases have been developed for studies that consumed resources at both the current NCI-sponsored Cooperative Groups and at Imaging/RT core quality assurance (QA) centers. In the new NCTN Program, where will this type of activity take place and how will it be funded?

If this work is being done for an approved trial and it is an important component of the trial, the work could be done in the QA center under the Network Radiotherapy & Imaging Core Services Center grant. The Network Radiotherapy & Imaging Core Services Center should prioritize requests from each Network Group for funding of special activities that might benefit a series of trials. If there is something in a trial that is specialized, the Collective Management team for the NCTN Program might need to evaluate it and determine if it should be supported under the Network Radiotherapy & Imaging Core Services Center grant.

The Network Radiotherapy & Imaging Core Services FOA indicates that there is a restriction on individuals serving as a Program Director (PD)/Principal Investigator (PI) on this grant and as a PD/PI on a Network Lead Academic Participating Site grant? Is this an eligibility requirement?

Yes, each of the RFAs/FOAs has a section detailing the eligibility requirements for applicant organizations as well as individuals. Applicant should read all these eligibility requirements carefully in the RFA/FOA. For the Network Radiotherapy & Imaging Core Services FOA, if a person is listed as one of the multiple PDs/PIs on the application, that person cannot be listed as one of the multiple PDs/PIs for an application for a Network Group Operations Center, Network Group Statistics and Data Management Center, Network Lead Academic Participating Site, or Canadian Collaborating Clinical Trials Network under the NCTN Program. These eligibility requirements are in place to ensure a level of independence between different components of the NCTN Program. However, an individual designated as a PD/PI on the application for a Network Radiotherapy & Imaging Core Services Centers application can, if appropriate, be listed as key personnel on one of the applications for a Network Lead Academic Participating Site, but not on the other applications listed above.

The required tables for the Network Radiotherapy & Imaging Core Services Centers application are centered on particular trials; however, these Centers provide some services to multiple trials, so what is the intent of the tables?

The tables under the radiotherapy core center section of the application are to highlight specific, important, services provided for clinical trials. Applicants should use these tables to highlight these important services for key phase 2 and phase 3 trials. The main type of services that the applicants propose to provide on all trials should be described in the text of the appropriate section of the Research Plan.

The Guidelines indicate that the Network Radiotherapy & Imaging Core Services Centers applicant is expected to be involved in the protocol development and the scientific development of the NCTN Program trials. How should budgeting for some of these activities be split between this grant and the Network Group Operations Center grants?

Scientific committee support and protocol development support would be included in the Network Group Operations Centers application as the Operations Centers are responsible for developing the trials. Thus, travel for Network Group Committee chairs to attend Network Group meetings would also be included in the Network Group Operations Centers budget. Once a trial has been developed, support for quality assurance and other activities for particular trials will come from the Network Radiotherapy & Imaging Core Services Centers grant.

Demand for core RT/imaging services may go up as investigators become more interested in how RT and imaging can help answer important clinical research questions. How should core services be prioritized across the Network?

This is a key issue that applicants are requested to address in response to the review criteria for the RFA/FOA. The applicants are asked to describe a process for how they would prioritize trials for services and how they would include representation from across the entire Network. There will be also be a Collective Management team for the entire NCTN Program that will look at prioritization issues (operations, statistical, core service centers) that could provide additional guidance on certain issues, but the Network Radiotherapy & Imaging Core Services Centers applicant is expected to propose the a prioritization process as part of the application.

Does the applicant under the Network Radiotherapy & Imaging Core Services Centers RFA/FOA need to provide information on legacy studies?

As part of "Just-In-Time" information, the Network Radiotherapy and Imaging Core Services Center applicants will be requested to supply a list of legacy for which it provides Core Services that it wishes to transition to the new NCTN Program. Only studies previously supported under the NCI-sponsored Cooperative Group Clinical Trials Program funded by the Division of Cancer Treatment and Diagnosis (DCTD), including primary advanced imaging trials funded by the NCI Cancer Imaging Program, can be transitioned to the new NCTN Program. The Network Radiotherapy and Imaging Core Services Center applicants should specify all legacy trials that do not have a status of "complete" in the NCI/DCTD enterprise system, both open and closed, this it wishes to transition to the new program and specify which of these trials it anticipates will still be open to accrual at the time of transition to the new program. It is anticipated that the budget provided in their applications will also cover the services for these trials as well as new trials to be developed after the start of the new NCTN Program.