Pre-Application Webinar for NCTN Stats/Data Mgt Centers 2017 FOA

RFA-CA-17-057

NIH ❯ **NATIONAL CANCER INSTITUTE**

November 6, 2017

Pre-Application Webinar Topics – RFA-CA-17-057

1. Overview of Application for RFA

2. Special Eligibility Criteria (Institutions, PIs/PDs)

3. Application Components
   Core Sections
   Special Issues

4. Budget Issues

5. Review Criteria

6. Terms of Award

Overview of Application for RFA-CA-17-057 (U10)

1. Reissue with Renewal Applications Only

2. Application is electronic with Modular Format for U10 mechanism

3. Modular Format includes 4 Components with repeated set sections & separate budget for each Component

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

Special Eligibility for RFA-CA-17-057

Select Information on Eligibility for Institutions Submitting Applications (See FOAs for Other Eligibility Criteria)	Select Information on Eligibility of PDs/PIs on Applications (See FOAs for Other Eligibility Criteria)
Limited Competition RFA Only current NCTN Statistics & Data Management Center (SDMC) awardees supported under FOA RFA-CA-12-011 are eligible to apply; however, a NOTICE for this RFA will be released clarifying that the grant can come from any institution associated with a currently named PI on the existing SDMC grant as long as the institution does not overlap with the Operations Center application institution **Each organization can submit only 1 application under this FOA**	PDs/PIs for this application cannot overlap with PDs/PIs on applications for: Group Operations Centers Canadian Collaborating Clinical Trials Network Lead Academic Participating Sites RT/Image Core Services Center *However, an individual who is designated as a PD/PI on the application for a Network Group Statistics and Data Management Center can, if appropriate, be listed as key personnel in the application for its associated Network Group Operations Center and/or the application for the Network Radiotherapy and Imaging Core Services Centers (RFA-CA-17-060), but not on applications for the other RFAs listed above and not on applications for other Network Group Operations Centers.*

4

Application Components – RFA-CA-17-057

U10 Components (Research Strategy Sub-sections)	Page Limits	# of Attachments for Components (Brief Titles of Attachments)
Overall Component A. Significance B. Innovation C. Approach D. Progress Report (does not replace annual report)	**30 pages**	**N/A**
Administrative Core Component A. Organizational Leadership and Structure B. Collective Management C. Collaborative Research	**12 pages**	**2 Attachments** 1-Auditing Policy and 2-Conflict of Interest
Statistics Core A. Structure B. Approach	**12 pages**	**3 Attachments** 1-Key Standard Operating Procedures 2-Model Statistical Analysis Template 3-Current NCTN Trials Supported
Data Management Core A. Structure B. Approach C. Training	**12 pages**	**4 Attachments** 1-Key Data Mgt & Monitoring Policies and Procedures for Clinical Trials 2-Key Procedures to Ensure Security and Confidentiality of Patient Data 3-General Data Quality and Timeliness for NCTN Trials 4-Data Quality & Data Timeliness for Serious Adverse Events on All NCTN Trials Led by the Network Group

Core Sections (Not OVERALL Component) – RFA-CA-17-057

SF424 (R&R) Cover (XXX Core)

PHS 398 Cover Page Supplement (XXX Core)

Research & Related Other Project Information (XXX Core)
Human Subjects:
Vertebrate Animals:
Project Narrative: Do not complete (only in the Overall Component)
Other Attachments

Project /Performance Site Location(s) (XXX Core)

Research & Related Senior/Key Person Profile (XXX Core)

Budget (XXX Core Core)

PHS 398 Research Plan (XXX Core)

    Specific Aims:
    Research Strategy & Sub-sections:
    Letters of Support (Only for Overall Component):
Provide a general Institutional Letter of Support (i.e., Letter of Support from the primary applicant institution or organization supporting the SDMC application). Also, a Letter of Support from applicant PD(s)/PI(s) of the associated NCTN Network Group Operations Center supporting the SDMC application
    Data Safety Monitoring Plans: Provide Only in the Administrative Core
    Resource Sharing Plan: Provide Only in the Overall Component
    Appendix: No Appendix materials are allowable under research plans of any Component

PHS Inclusion Enrollment Report: Provide Only in the Administrative Core

Note: Other sections such as Multiple PD/PI Leadership Plan, Letters of Support, etc. are in standard sections of the electronic application and are dependent on what is allowed or required in the RFA and what the application proposes.

Special Note on Inclusion of Children: RFA-CA-17-057

The NCTN Program as a Network Program supports up to 4 US Adult Clinical Trials Groups and up to 1 Pediatric Clinical Trials Group. In AYA-designated trials for the Network led by any Group, all Groups (Adult and Pediatric in the NCTN) must participate so that there is adequate & appropriate monitoring of children in clinical trials, but Adult Groups should ensure that membership on the DSMB has appropriate oversight if they lead AYA trials.

NIH policy requires that children must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling reasons not to include them as described at: http://grants.nih.gov/grants/funding/children/children.htm

For cancer clinical research, Network Groups conducting research in adult cancers can provide a rationale for not including children because the majority of children with cancer in the US are already accessed by a Network Group devoted to pediatric cancer research, so that requiring inclusion of children in the proposed adult trials would be both difficult and unnecessary (since the research question is already being addressed in children by the pediatric network) as well as potentially as well as potentially counterproductive since fewer children would be available for the pediatric Network study if other studies were required to recruit and include children.

Application Components – Special Issues: RFA-CA-17-057

Special Issues:

❑ Resource Sharing Plans are provided ONLY in Overall Component

❑ Data Safety Monitoring Plans and PHS Inclusion Enrollment Report are provided ONLY in the Administrative Core Component

❑ NO Appendix Materials are allowable under the research plans of any Component, including the Overall Component

❑ Although both Resource Sharing Plans & Data Safety Monitoring Plans must be provided in the application, prior to funding of an award, these plans (and any updates to the plans) will also need to be reviewed & approved by NCI/DCTD program staff prior to funding of an award to ensure they are in compliance with current NCI/NIH regulations; changes may be required by NCI/CTEP prior to funding of an award.

Application Components – Special Issues: RFA-CA-17-057

Special Issues:

❏ The Project Narrative is required only for the Overall Component (as per the RFA, it should not be included in the Other Component Cores)

❏ Key Personnel and Performance Sites for each Component should follow the instructions in the RFA/User Guide for NIH Grant applications

Budget Issues - General: RFA-CA-17-057

Budget (Overall):

❑ The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover. No Common Budget Outline is requested or required as per the prior Type 1 applications for the NCTN RFAs. Budgets should be provided for a 6-year project period.

❑ *A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.*

Budget (Other Components):

❑ Budgets are required for each of the other Components of the Application (i.e., Administrative Core, Statistics Core, and Data Management Core). The budget for each Core should be as representative as possible (e.g., capitation in the Member Site Core) with general cross-cutting budget items located in the Administrative Core.

Budget Issues – Overall & Administrative Component: RFA-CA-17-057

❑ Overall Component & Administrative Core: The total budget for the SDMC should be appropriate to support a reasonable level of all functions to cover the scope/# of trials and patient accrual anticipated using the prior funding period as a guide.

❑ In the Administrative Core narrative, the applicant can explain how the level of support required across the various Cores is modified by the complexity of the trials being supported in addition to the number of patient enrollments by accrual type (e.g., a higher level of infrastructure support may be needed for more complex trials).

❑ *PD/PI Effort Commitment in the Administrative Core.* The minimal effort commitment for the Contact PD/PI must be 1.8 person-months per year. The effort commitment for the other PDs/PIs (if multiple) must be a minimum of 1.8 person-months per year. These effort commitments cannot be reduced in later years of the award. Salary does not need to be attachment to these commitments in certain applications/situations.

Budget Issues – Administrative Component: RFA-CA-17-057

❑ *Travel Expenses.* Applicants must budget travel funds for two persons (two PDs/PIs or one PD/PI and an additional senior investigator) to attend one NCTN Leadership Management Committee in-person meeting per year in addition to other travel expenses. Applicants should also budget travel funds for one to two persons to attend an annual in-person meeting on NCTN SDMCs and an in-annual in-person meeting for special NCTN initiatives related to statistics and/or data management.

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

Review Criteria – RFA-CA-17-057

❑ Reviewers will review the entire application (all Components and Sections)

❑ Reviewers access the application against the Review Criteria in the RFA

❑ Reviewers will provide an overall impact score for the **entire** Network Group Statistics and Data Management Center or SDMC (Overall component). In addition, assigned reviewers will provide individual "criterion scores" for the Overall criteria but not for the other components.

❑ All other components of the SDMC (i.e., Administrative Core, Statistics Core, and Data Management Core) will be evaluated but each will receive only one overall adjectival (not numerical) rating

Terms of Award – RFA-CA-17-057

❑ In addition to standard terms of award under NIH Grant Policy, the RFA sets out other Terms of Award, including compliance with the following for for PDs/PIs of the Statistics and Data Management Center Awards:

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

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

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

- NCI/DCTD CRADA agreements

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