# Pre-Application Webinar for NCTN Canadian Collaborating Clinical Trials Network 2017 FOA

# RFA-CA-17-058

NIH NATIONAL CANCER INSTITUTE

**November 6, 2017**

# Pre-Application Webinar Topics – RFA-CA-17-058

1. Overview of Application for RFA

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

3. Application Components
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   - Special Issues & Attachments

4. Budget Issues

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# Overview of Application for RFA-CA-17-058 (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

   In addition, State Department approval will be required for the NEW project period for all Canadian participating sites included in the application that enroll patients.

# Special Eligibility for RFA-CA-17-058

| 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**<br><br>**Only current NCTN Canadian Collaborating Clinical Trials Network (CCCTN) awardees supported under RFA-CA-12-504 are eligible to apply**<br><br>**(i.e., new applications must come from the current grantee institution)**<br><br>**Each organization can submit only 1 application under this FOA** | **PDs/PIs for this application cannot overlap with PDs/PIs on applications for:**<br><br>**Group Operations Centers**<br>**Group Statistics & Data Management Centers**<br>**Lead Academic Participating Sites**<br>**RT/Image Core Services Center**<br><br>*However, an individual who is designated as a PD/PI on the application for the CCCTN can, if appropriate, be listed as key personnel in an application for the Network Radiotherapy and Imaging Core Services Centers (RFA-CA-17-060), but not on applications for the other RFAs listed above.* |

# Application Components – RFA-CA-17-058

| U10 Components<br>(Research Strategy Sub-sections) | Page Limits | # of Attachments for Components<br>(Brief Titles of Attachments) |
|---|---|---|
| Overall Component<br>A. Significance<br>B. Innovation<br>C. Approach<br>D. Progress Report (does not replace annual report) | 12 pages | N/A |
| Administrative Core Component<br>A. Organizational Leadership and Structure<br>B. Collective Management & Collaborative Research | 12 pages | 2 Attachments<br>1-Auditing Policy and 2-Conflict of Interest |
| Clinical Trials Development & Member Site Core Component<br>A. Clinical Trials Development Program<br>B. Member Site Program | 12 pages | 11 Attachments<br>1-Key Leadership Staffing, 2-Important Trial Primary Scientific Achievements, 3-Other Important Trial Achievements, 4-Accrual by Trial Phase by Group Members,5-Accrual by Major Cancer Category and Trial Phase by Group Members, 6-Accrual by Major Cancer Category and Trial Phase for All NCTN Trials Led by the Canadian Collaborating Network, 7-Operational Timelines Trial Development,8-Operational Timelines Trial Completion, 9-Operational Timelines Trial Completion, 10-Summary of Audit On-Site Activity by Group Members, and 11-Group Constitution and By-Laws for Site & Investigator Membership |
| Statistics & Data Management Core Component<br>A. Structure<br>B. Approach<br>C. Training | 12 pages | 7 Attachments<br>1-Key Standard Operating Procedures, 2-Model Statistical Analysis Template, 3-Current NCTN Trials Supported, 4-Key Data Management and Monitoring Policies and Procedures for Clinical Trials, 5-Key Procedures to Ensure Security and Confidentiality of Patient Data, 6-General Data Quality and Timeliness for NCTN Trials, and 7-Data Quality and Data Timeliness for Serious Adverse Events on All NCTN Trials Led by the Canadian Collaborating Network Group |

# Core Sections (Not OVERALL Component) – RFA-CA-17-058

**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)**

# Core Sections (Not OVERALL Component) – RFA-CA-17-058

**PHS 398 Research Plan (XXX Core)**

**Specific Aims:**
**Research Strategy & Sub-sections:**
**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-17-058

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 & Attachments: RFA-CA-17-058

**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 & Attachments: RFA-CA-17-058

**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; the Clinical Trials Development & Member Site Component is the section in which all the Groups participating sites should be listed that enroll patients on trial

# Application Components – Special Issues & Attachments: RFA-CA-17-058

**Attachments Related to Accrual:**

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

# Application Components – Special Issues & Attachments: RFA-CA-17-058 – May Not Be Applicable to CCCTN Application

## Attachment Related to Canadian Member Accrual:

- This attachment allows the US Network Group to show reviewers the accrual from its Canadian Members on trials the it LEADS but for which the accrual was credited to the Canadian Collaborating Clinical Trials Network because the CCCTN held a CTA (equivalent to IND) for the trial in Canada – applicants can use this information to address review criteria related to collaboration within/across the Network.

## Information Related to Trials that are Officially Co-Led:

- There are a few NCTN trials that are co-led by more than 1 Group (i.e., official co-management of the conduct of the trial). Accrual and efforts on these trials for the Group that is not the lead operations/statistical center for the trial can be listed as a separate line item at the bottom of the accrual attachments and referred to in the text to address review criteria related to collaboration within/across the Network.

# Budget Issues - General: RFA-CA-17-058

## 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, Clinical Trials Development & Member Site Core, and Statistics & Data Management Core). The budget for each Core should be as representative as possible (e.g., capitation in the Clinical Trials Development & Member Site Core) with general cross-cutting budget items located in the Administrative Core.

# Budget Issues – Overall Component: RFA-CA-17-058

- The total budget for the CCCTN should be appropriate to support a reasonable level of total patient accrual (i.e., patient enrollment numbers by types of accrual) anticipated using the prior funding period as a guide.
  - *However, in the budget narrative of the Administrative Core, the applicant can explain how the level of non-capitation infrastructure 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) and the needs to provide regulatory support under Health Canada for NCTN Trials*
- Funds for tumor banks, correlative science research, and/or reference laboratories are not supported under the NCTN Program and should not be included in the application. Also, the NCI does not support costs associated with routine patient care as a budget expense under this FOA.

# Budget Issues – Administrative Component: RFA-CA-17-058

- *PD/PI Effort Commitment.* Minimal effort commitment for the Contact PD/PI must be 1.8 person-months per year. 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.

- *Travel Expenses.* Applicants must budget travel funds for 3 persons (3 PDs/PIs or 1 PD/PI and 2 additional senior investigators) to attend 1 NCTN Leadership Management Committee in-person meeting per year in addition to other travel expenses. Applicants should also budget travel funds for 1-2 persons from CCCTN Administrative office to attend an annual in-person meeting on special NCTN initiatives. Applicants should also budget travel funds for 1-2 persons from the CCCTN Statistics/Data Management (SDMC) office to attend an annual in-person meeting of the NCTN SDMCs as well as 1-2 persons from the CCCTN SDMC to attend an annual in-person meeting for special NCTN initiatives particularly related to statistics and/or data management.

# Budget Issues – Administrative Component: RFA-CA-17-058

*Other Expenses.* Applicants must include in the budget appropriate expenses to cover support for the Data Safety Monitoring Board activities and auditing activities.
NCI does not support costs associated with routine patient care as a budget expense under this FOA.

# Budget Issues: Clinical Trials Development & Member Site Core: RFA-CA-17-058

- *Quality Assurance Activities.* Applicants may include funding to cover quality assurance functions associated with clinical trials (i.e., trials that the CCCTN leads) when approved by NCI/DCTD in study protocols such as central pathology review to confirm diagnoses, central review/reads of radiographic images, study team review to determine protocol compliance with dose administration and dosage modification of agents, and study team review of adequacy of protocol-specified surgical procedures may be assessed (e.g., through review of operative notes, study-specific surgical forms, and pathology reports) by the Network Group study team for the trial.

- CCCTN budgets should not include scientific services related to development of innovations in advanced imaging or radiotherapy treatments unless it is a specific, essential component of the Network Group's overall research strategy and it was explicitly funded for a Network Group in the previous funding period/award for the Group (i.e., ECOG-ACRIN for Imaging; NRG for RT treatments).

# Budget Issues – Capitation Funding: RFA-CA-17-058

*General level of "per-case management" funding (capitation funding) for Member Sites:*

NCTN provides general total cost support for different types of accrual for member sites depending on accrual type per the "total cost amounts" per category to be sent to the Groups participating sites as listed below (excluding LAPS site and NCORP sties)

$2,250 to $3,250 for each patient enrolled on treatment trials (screening on study **plus** intervention)

$500 for "screening only" accrual on tx or primary imaging trials (i.e., patient does not go onto intervention)

$1,250 for base interventional accrual on primary imaging studies

$500 for 1 patient biospecimen collection per enrollment on a treatment or primary imaging trial

*To justify the budget, the applicant needs to provide an "Accrual Input # Table or Narrative" in the budget narrative detailing the # of patients expected to be accrued in the "screen only" category for tx and/or imaging trials, intervention category for tx trials, intervention category for primary imaging trials, and 1 patient biospecimen collection for each enrollment on a tx or primary imaging trial by category site type. The applicant should use the prior funding period as a guide for reasonable estimates of future patient enrollments by accrual type & site category type with appropriate justification for any significant changes in anticipated levels of patient enrollments.*

# Budget Issues – Capitation Funding: RFA-CA-17-058

- "Per-case management" funding may be provided out of the Member Site Core capitation budget for collections of radiologic images (not costs of the actual imaging) **but only for NCI/DCTD approved integral and/or integrated imaging studies embedded in NCTN trials** and the collection must be coordinated through the Network Radiotherapy and Imaging Core Services Center.

- QA for radiotherapy interventions in NCTN trials is performed by the Network Radiotherapy and Imaging Core Services Centers (i.e., is not a supportable cost item in Operation Center grants)

- "Per-case management" funding may be provided for biopspecimens collected for NCI/DCTD approved integral and/or integrated studies in embedded NCTN trials as well as for optional biospecimen collections for future unspecified research if approved by NCI/DCTD.

*The applicant should use the prior funding period as a guide for reasonable estimates of future patient enrollments by accrual type with appropriate justification for any significant changes in anticipated levels of patient enrollments.*

# Budget Issues – Additional Capitation Funding: RFA-CA-17-058

❑ *Additional Capitation Considerations for CCCT Member Sites:*

Since the CCCTN is not eligible to be a NCI Division of Cancer Prevention (DCP) NCORP Research Base (not eligible as the CCCTN is not a U.S. organization), funding for site capitation for quality of life (QOL) sub-studies embedded into NCTN treatment and primary imaging studies is provided through the NCTN award.

In addition, funding for site capitation for select DCP cancer control studies/DCP NCORP trials can be provided through the NCTN award via a collaboration between DCP and the Cancer Therapy Evaluation Program (CTEP) with prior approval by the NCTN Program Director. An estimate of the site capitation needed for CCCTN sites participating in embedded Quality of Life studies and DCP cancer control studies/DCP NCORP trials should be provided by the applicant in the budget narrative for all capitation in the budget for this Core.

# Budget Issues – Statistics & Data Mgt Core: RFA-CA-17-058

- *Other Expenses for Statistics & Data Management Core:*

Applicants must include in the budget appropriate expenses to cover support for the preparation of data sets for applicable trials for the NCTN/NCORP Data Archive, and coordination activities with the associated NCTN Group Ops 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 that involve the CCCTN.

# Review Criteria – RFA-CA-17-058

- 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** Canadian Collaborating Clinical Trials Network or CCCTN (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 NCCTN (i.e., Administrative Core, Clinical Trials Development & Member Site Core, and Statistics & Data Management Core) will be evaluated but each will receive only one overall adjectival (not numerical) rating

# Terms of Award – RFA-CA-17-058

- 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 CCCTN Award:
  - 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