Suggestions for Organizing Information for a CCOP Application

GENERAL INSTRUCTIONS

In preparing a CCOP application, you must follow the instructions provided in the **RFA CA-08-015** (*Community Clinical Oncology Program*) and the *Application for a Public Health Service Grant* **(PHS-398)** (11/2007) available at: http://grants.nih.gov/grants/forms.htm and its accompanying packet of forms.

You should refer to **RFA CA-08-015** and the **PHS-398** (11/2007) **Part I, II and III** for complete instructions.

NOTE: The PHS 398 is organized into three distinct parts, each of which is available as a separate file in MS Word and PDF versions. Applicants will need to use all three parts of the instructions to prepare a complete and acceptable application.

The PHS 398 instructions include:

Part I: *Instructions for Preparing the Application*
Part II: *Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*
Part III: *Policies, Assurances, Definitions and Other Information*.

The suggestions and sample tables provided in this document "Suggestions for Organizing Information for a CCOP Application" are provided as a supplement to the PHS-398 (11/2007), NOT A REPLACEMENT. These suggestions and tables are not mandatory, however may help the applicant provide all the information required by the RFA while remaining within the page limitations (**see RFA-CA-08-015, Part II**, Section IV.2., Content and Form of Application Submission). Following these suggestions may assist reviewers in their evaluation of the applicant=s resources and capabilities. The tables provided with in this document may be included in the application as part of the Resources, Progress Report and Human Subject Research sections, as appropriate.

Requirement of DUNS Numbers on NIH Applications - Use of the Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is required when applying for Federal grants or cooperative agreements. See NIH Guide Notice dated August 14, 2003 and the DUNS Q&A (MS Word) document for more information.

Other Support should NOT be submitted with the application. If this information is included in the application, the application may be returned to the applicant organization WITHOUT peer review. See PHS 398 (11/2007) **Part III** (*Policies, Assurances, Definitions, and Other Information*), **Section 1.7 - Just-in-Time Policy**. Do NOT confuse "**Research Support**" with "**Other Support**." Although they sound similar, these parts of the application are very different. See **Part III (***Policies, Assurances, Definitions, and Other Information).*

Appendix: See PHS 398 (11/2007) **Part I** (*Instructions for Preparing and Submitting an Application*), **Section 5.7 - Appendix**, for detailed instructions. Include all pertinent information mentioned in RFA-CA-08-015.

Application Due Date: The application **due date** is indicated in RFA-CA-08-015. The standard receipt dates referenced in the PHS 398 **DO NOT apply** to applications submitted in response to RFA-CA-08-015.

Sample Tables: To assist the applicant in providing information sufficient to permit adequate review of certain areas and also maintain clarity and brevity, the following sample tables are provided as suggested formats.

Sample Table 1	-	Components
Sample Table 2	-	Affiliates
Sample Table 3A	-	Participating Physicians
Sample Table 3B	-	Non-Physician Investigators (e.g.: PhD=s)
Sample Table 4	-	Personnel
Sample Table 5	-	Number of Newly Diagnosed Cancer Patients by Site
Sample Table 6A	-	Accrual to NCI Approved Cancer Treatment Clinical Trials
Sample Table 6B	-	Accrual to All Other Cancer Treatment Clinical Trials
Sample Table 6C	-	Accrual to NCI Approved Cancer Prevention/Control Clinical Trials
Sample Table 7A	-	Cancer Treatment Accrual (Progress Report)
Sample Table 7B	-	Cancer Prevention/Control Accrual (Progress Report)
Sample Table 8	-	Research Base Affiliation(s)
Sample Table 9	-	Projected Accrual to NCI Approved Cancer Prevention/Control Clinical Trials during the Next Year

NOTE: **There is no Sample Table for Projected Accrual to NCI Approved Cancer Treatment Clinical Trials**. Applicants should provide a narrative description of their plans for accruing to NCI-approved cancer treatment trials through their affiliated Research Bases.

NOTE: These tables should be included in the application in Resources, Progress Report and/or Human Subjects Research sections, as appropriate. If tables are included in Section 1 through 7, these will count against the page limit as referenced in RFA-CA-08-015.

NOTE: With respect to the PHS 398 page limitation, each of the Tables 1 through 9 counts as **one page**, even though an applicant may include multiple pages for one or more of these Tables (e.g. 8 pages of Table 1 will count as 1 page against the page limitation referenced in the RFA-CA-08-015).

All applicants are advised to complete ALL of the Sample Tables **except** for **Sample Tables 7A and 7B.** These two tables are for **renewal** applications only, as these tables address portions of the required progress report.

PHS 398 - Part I
Instructions for Preparing and Submitting an Application

There is no specific Form Page for the **Research Plan** – Use Continuation Page.
The **Research Plan** should include sufficient information needed for evaluation of the project. Refer to the instructions as provided in RFA-CA-08-015 under **IV.2**. **Content and Form of Application Submission**, sections 1-7 (Note: These sections substitute for Part I - PHS 398, Section 5.5 Items 2-5).
For all other sections under Part I -PHS 398 **Research Plan**, Section 5.5 Items 1 and 6-17 (where applicable) follow the instructions provided in the PHS 398.

Suggestions for Organizing Information for a CCOP Application

Section 1: Progress Report

An application from a currently funded CCOP group (a renewal application) must include a progress report. NOTE: new CCOP group applicants should insert "Not applicable" in this section.

The **progress report** should at a minimum, consist of:

- A summary of CCOP group activities and accomplishments, including annual accrual over the funding period, See Table 7A and Table 7B.
- A plan for continuing to meet prevention and control accrual requirements including plans for follow-up of participants from the large prevention trials;
- An evaluation of CCOP group performance by affiliated CCOP Research Base(s); and
- A complete description of how the applicant has met the special cooperative agreement terms and conditions of the award

Section 2: Catchment Area

Describe the proposed patient catchment area.

- Include a map of the patient catchment/service area, designating counties or zip codes from which approximately 80% of the cancer patients will be drawn.

- Describe the geographical area from which patients will be drawn. Include the demographics (age, race, sex, etc.) for the cancer patient population.

- Estimate the percent of oncologists in the service area who will be participating in the CCOP.

- Describe cancer care resources available in the service area that are not a part of the CCOP application (e.g., hospitals, clinics, physicians, cancer centers, medical schools, cooperative group affiliate program satellite hospital).

- Estimate the percent of the catchment/service area population that participates in HMOs or PPOs.

Section 3: Accrual Requirements

- Describe your participation in treatment and cancer prevention/control clinical trials during the most recent funding period, or for new applicants, the last 3 years.

- Provide data on the number of patients in active follow-up on NCI-approved treatment clinical trials, if applicable.

- Enumerate the patient accrual for each physician, either a current CCOP member or a newly proposed member, to cancer treatment clinical trials. Narrative explanation may be attached, if needed, to fully document your experience. Indicate whether the clinical trial was funded or sponsored by

- NCI cooperative groups, cancer centers, public health departments, the American Cancer Society, or others. See Sample **Table 6A and 6B** which are intended to reflect the accrual activity by individuals of the CCOP.

- Enumerate the accrual for each physician, either a current CCOP or a newly proposed member, to cancer prevention/control clinical trials. See **Sample Table 6C**. Describe your experience in cancer prevention/control research and related activities.

- Describe in detail two examples of NCI-approved cancer prevention and control clinical trials you intend to use from your affiliated Research Bases.

- **New applicants** must provide implementation plans for at least two examples of NCI-approved cancer prevention/control clinical trials that utilize an intervention.

- Describe the outreach activities conducted to attract minority participants.

Section 4: Team Organization and Qualifications

- A designated Principal Investigator (PI) is required. In addition, a designated candidate for replacement of the PI should be named to assure continuity in the event of resignation of the PI. The qualifications and experience of both must be described, specifically documenting their ability to organize and manage a community oncology program that includes cancer prevention/control/ treatment clinical trials and related activities, as well as experience in accruing patients/participants to clinical trials.

- Each application should propose a committed multidisciplinary professional group appropriate for its expected clinical trial participation.

- Is there a history of previous working relationships among some or all of the proposed participating physicians? If so, describe the following:

  < previous patient practice relationships (e.g., referral, partnership, group practice, cross coverage);

  < previous experience of some or all of the investigators in working together as a group in clinical trials (e.g., common Research Base, IRB, data management).

- If the CCOP has more than one component/affiliate (see sample Table 1 and Table 2 for definitions), provide a diagram of the CCOP components indicating distances between components/affiliates (including administrative office and shared resources) and location of proposed personnel.

  < Describe the relationship of components/affiliates to each other and to the CCOP headquarters.

  < Provide information on how the CCOP (physician and staff) will be organized and directed to facilitate participation in treatment and cancer prevention/control clinical trials. Include an organizational chart of how the group will function. Describe procedures for assuring implementation of the organizational plan.

< Describe plans for communication among physicians and components/affiliates and incentives for participation.

Section 5: Affiliations with Research Bases

- Describe previous working relationships with proposed Research Bases, if applicable.
  - < Include information on committee memberships and chairmanships as well as studies chaired.
  - < If one or more components participated as cooperative group affiliate program satellite hospital, specify the years.
  - < List the current Research Base affiliation(s) or, for new applicants, the proposed Research Base affiliation(s). A suggested format is shown in **Sample Table 8**.
- Discuss the Cancer Treatment Clinical Trials the CCOP proposes to accrue to through its affiliated Research Bases. NOTE: There is no Table format for treatment trials.
- Cancer Prevention and Control Clinical Trials the CCOP
  - < List the cancer prevention and control clinical trials to which the CCOP intends to recruit participants. See **Sample Table 9** for suggested format.

Section 6: Quality Assurance and Investigational Drug Management

- Describe the process for Data Management, including:
  - Who will have overall responsibility for data management;
  - Source of records (e.g., hospital, office, clinic, registry);
  - Who will be responsible for registering patients/subjects on study;
  - How the information will flow (provide flow chart);
  - Who will be responsible for information entry on primary patient record and on study forms (e.g., RN, MD, data manager, secretary);
  - Who will be responsible for collecting and sending material (e.g., pathology slides, port films, etc.) to the Research Base if required by a clinical trial; and
  - What records (e.g., study flow sheets, forms, reminder slips) if any, will be placed on the patients charts.
- Describe the proposed quality assurance mechanism(s) for treatment and cancer prevention /control clinical trials. Who will have overall responsibility for quality control?
- Describe in detail the data management operations within and between component/ affiliates, investigators, and the central CCOP administrative office (if applicable).
- Will data be transmitted in batch form or as acquired to an intermediary institution/

central office of the Research Base(s)? Will this submission procedure be the same for each Research Base?

- Are computers to be used for data management (e.g., data file, reminder system, clinical trial data entry, transmittal to Research Base computers)? Are there provisions for electronic data transfer?
- How will NCI/FDA requirements for control of investigational drugs be met?
- If applicable, describe the involvement of oncology nurses/data personnel in clinical trials not funded by the proposed CCOP award.

PHS 398 (Part I) - Section 5.5 – Items 8 through 11

Create a section entitled "**Protection of Human Subjects**"

< See PHS 398 **Part II** Section 3. (*Instructions for Preparing the Human Subjects Section on Protection of Human Subjects*) Scenario F: Human Subjects Research Involving a NIH-Defined Phase III Clinical Trial

<

The majority, if not all, CCOP applicants should follow the instructions and provide the information outlined under Scenario F.

The following provisos will most likely apply to CCOP applicants for the following sections under Section 4.

Section 4.1.5 – **Data Safety and Monitoring Plan**

A CCOP applicant is not directly responsible for the formulation of data safety and monitoring plans and/or boards. However, the CCOP applicant must discuss its requirement to follow the data safety and monitoring plan(s) for each of the Research Bases with which it is affiliated. The application should describe how the CCOP implements the Research Base(s) data safety and monitoring plan(s).

Section 4.2 – Inclusion of Women and Minorities

The CCOP applicant would address the points under this heading from the perspective of overall accrual to protocols available to the CCOP, as opposed to on a protocol by protocol basis, since a CCOP accrues to multiple protocols under the auspices of this grant.

Section 4.2.1 – Additional Instructions & Requirements When NIH-Defined Phase III Clinical Trials are Proposed

A CCOP applicant must include a narrative in this section that explains that they participate in NIH-defined phase III, accessed through their Research Bases, but are not involved in the design and/or analysis of these trials, nor does the CCOP have a complete data set on any clinical trial in which it participates. Therefore, this additional requirement is not relevant or applicable to the CCOP application.

Section 4.3 – Target/Planned Enrollment Tables for Reporting Race and Ethnicity Data

A. New Applications –

A new applicant should complete the **Target/Planned Enrollment Form** by providing the estimated number of enrollments by gender and ethnicity/race that the CCOP anticipates enrolling during the first year of funding as a CCOP. The applicant may use one table for Treatment Trials and one table for enrollments to Cancer Prevention and Control protocols, or combine the enrollments for both in a single table. Indicate under Study Title what data is being presented in the table, i.e. Treatment and/or Cancer Prevention and Control. Provide the period covered in the space entitled "Protocol Number."

B. Renewal Application and Progress Report –

A CCOP applicant should complete the **Inclusion Enrollment Report** by reporting enrollments to NCI-approved protocols that have occurred over the 3 to 5 year funding period leading up to the submission of the renewal application. The applicant may use one table for Treatment Trials and one table for enrollments to Cancer Prevention and Control protocols, or combine the enrollments for both in a single table. Indicate under Study Title what data is being presented in the table, i.e. Treatment and/or Cancer Prevention and Control. Provide the period covered in space entitled "Protocol Number."

A renewal CCOP must also complete a **Target/Planned Enrollment Form**. Follow the same instructions as outlined above for New Applications.

Section 4.4 – Inclusion of Children

- For CCOP applicants that include a pediatric component, provide the information as outlined under Part II, Section 4.4 of the PHS 398 Instructions.

- If children are excluded from the research, present an acceptable justification for the exclusion. See Part II, Section 4.4 – Justification for Exclusion of Children, Item 4.b. "The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network."

PHS 398 (Part I) - Section 5.5

Item 17 – Resource Sharing Plan(s)

17(a) Data Sharing Plan:

CCOP applicants should include a brief paragraph describing how the CCOP shares its data with its affiliated Research Bases and/or through other mechanisms, if applicable. In addition, describe the process the CCOP follows to protect the rights and confidentiality of patients/participants.

NOTE: The Research Base is responsible for describing its data sharing plans because the Research Base is the entity that receives complete data set(s) for the trials they develop, manage and ultimately publish.