Suggestions for Organizing Information for a CCOP Research Base Application

GENERAL INSTRUCTIONS

In preparing a CCOP Research Base 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 Suggestions for Organizing Information for a CCOP Research Base Application are provided as a supplement to the PHS-398 (11/2007), NOT A REPLACEMENT. These suggestions and tables are not mandatory, however, they may help the applicant supply all the information required by the RFA while remaining within the page limitations (see **RFA-CA-08-015**, Part II, Section IV.2.B. Content and Form of Application for CCOP Research Base Award).Following this suggested format may assist reviewers in their evaluation of the application=s resources and capabilities. The tables provided in this format 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.

TABLES SUMMARIZING PROTOCOL ACTIVITY AND CLINICAL SITES

To assist the applicant in providing information sufficient to permit adequate review of study activity and study sites and also maintain clarity and brevity, the following sample tables are provided as suggested formats.

Protocol Activity Tables

Sample Table 1 -	Accrual to NCI Approved Cancer Treatment Trials available for use by CCOP
Sample Table 2a -	Accrual to NCI Approved Cancer Prevention and Control Trials conducted by your Research Base for use by CCOP and your members/affiliates, and other Research Base members/affiliates (if for Inter-group Studies)
Sample Table 2b -	Accrual to Inter-group NCI Approved Cancer Prevention and Control Trials sponsored by other Research Bases for use by your members/ affiliates
Sample Table 3 -	Cancer Prevention and Control Concepts Approved by NCI for Protocol Development
Sample Table 4 -	Cancer Prevention and Control Concepts under Development

Clinical Site Tables

Sample Table 5 -	CCOP Affiliations
Sample Table 6 -	Member/affiliate participation in Cancer Prevention and Control
Sample Table 7 -	APrevention Members@
Sample Table 8 -	Institution audit schedule for Prevention Trials, large-scale and other

NOTE: With respect to the PHS 398 page limitation, each of the Tables 1 through 8 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).

NOTE: **New applications** are advised to complete all of the attached Sample Tables. Although the tables are not required, they may help the reviewers in their evaluation of the application. Since new applicants have not worked with CCOPS in the past year, they may provide information on treatment accruals from their members and affiliates as an indication of their potential for future CCOP treatment accruals. See **Sample Table 1.** Likewise, new applications may present information regarding cancer prevention and control clinical trials even though these are not NCI approved. See **Sample Tables 2, 3, and 4**.

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 Part II, Section IV.2.B. **Content and Form of Application for CCOP Research Base Award**, sections 1-6 (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.

Section 1: Progress Report

The Progress Report, at a minimum, should include:

- Summary of CCOP Research Base activities and accomplishments over the funding period, with a clear presentation of yearly accrual (separately for treatment and cancer prevention/control) from affiliated CCOPs;

- Progress in implementing NCI approved cancer prevention/control clinical trials;

- Complete description of how the applicant has met the special cooperative agreement terms and conditions of the award;

- Clear presentation of annual accrual to each NCI approved prevention/control clinical trials for CCOPs and CCOP Research Base members and affiliates;

- Provide the data on enrollment of women/men and on ethnicity/race of research participants during the previous funding period.

- Status of prevention/control clinical trials under development (i.e. Concepts and Protocols – see definition of these documents on Table 3 and 4);

- If a **renewal** application has currently funded "prevention member(s), the application must include a progress report addressing how the member(s) have contributed to the goals of the CCOP Research Base in relation to cancer prevention research. Include data on accruals to chemoprevention trials lead by the CCOP Research Base applicant, if applicable. Describe contributions to the following areas that apply: pre-clinical studies on the path to chemoprevention protocol(s); chemoprevention protocol(s) development; ancillary studies to prevention trials; other research activities that contribute to the CCOP Research Base's cancer prevention program.

- CCOP Research Base applications that include funding for an ongoing large-scale prevention trial(s) (e.g., Study of Tamoxifen and Raloxifene, (STAR)) should include a progress report that outlines the major milestones for the trial(s) during the funding period (i.e., three to five years).

Section 2: Clinical Trials Design and Implementation.

- Describe the organizational structure for conducting cancer prevention and control research. Indicate responsibilities of the cancer control committee (or its equivalent) to the CCOP Research Base, and the role of the CCOPs, cooperative group affiliate programs, group members, and other affiliates on the committee. Indicate the relationship of the cancer control committee (or its equivalent) to disease site and modality committees.

- State the broad, long-term objectives of the cancer prevention and control research program.
- Provide the scientific rationale for the proposed cancer prevention and control clinical trials. Specifically identify the gaps that the research is intended to fill. Outline the methodology to be used to accomplish the specific aims of the research. Discuss the process by which priorities in cancer prevention and control research are identified, developed, and implemented within the CCOP Research Base.

- Outline the organizational process for development and implementation of cancer prevention and control clinical trials.

- Describe in detail at least two examples of cancer prevention and control clinical trials, including underlying hypotheses, study design, and implementation plan.

Section 3: Accrual Requirements.

- Each application must demonstrate that the proposed Research Base can accrue at least 50 participants annually from CCOP and/or member/affiliate institutions to NCI-approved **prevention/control** clinical trials designed by the CCOP Research Base. An established Research Base is expected to have exceeded the stated minimal number of accruals and have a credible plan for maintaining or increasing accrual throughout the funding period.
- For treatment clinical trials (if applicable), the application must demonstrate that the proposed Research Base can accrue at least 50 patients from CCOPs annually to the NCI-approved treatment clinical trials designed by the CCOP Research Base. An established Research Base, participating in treatment clinical trials, is expected to achieve a higher number of accruals annually.
- A **new** application must demonstrate that the proposed Research Base can develop a selection of treatment clinical trials (**if applicable**) and cancer prevention/control clinical trials to meet the accrual minimums by the end of the first competing project period.

Section 4: Team Organization and Qualifications

- Describe the qualifications and experience of the designated Principal Investigator.

- Demonstrate the availability of the appropriate professionals with relevant expertise to design and implement the Research Base's proposed clinical trials research agenda.

- Describe experience in conducting multi-institutional cancer treatment (if applicable) and/or prevention/control clinical trials.

- Describe the organizational structure of the CCOP Research Base. If there is more than one functional unit (e.g., administrative, operations, statistical), indicate the leadership in each.
- Describe the stability of the functional unit within the organizational structure, as well as the relationship and integration of the functional unit with other functional units in the CCOP Research Base.

- Provide an organizational chart showing the relationship(s) between scientific and administrative units, vis-a-vis the conduct of cancer treatment and/or prevention/control clinical trials.

- Describe the relationship of the CCOP Research Base to any other parent organization (e.g., fiscal agent).

Section 5: Membership

- Describe the relationship of the CCOP Research Base to investigators and institutions (e.g., CCOPs, cooperative group affiliate programs, member institutions and affiliates) contributing to clinical trials.

- Describe the relationship of physician investigators to main member institutions and affiliate institutions.

- Describe the proposed relationship to CCOPs. Include how the CCOPs will be integrated into the activities and decision-making processes of the CCOP Research Base organization. Address the CCOP's scientific and administrative contributions to the Research Base organization.

- If applicable, include proposals for specific non-CCOP member institutions for consideration as "prevention members." Use **Table 7** to list the prevention members included in the application. Refer to the RFA for further details on the information to address in the application for "prevention member(s)."

Section 6: Quality Assurance and Data Management

- Describe procedures for ensuring and assessing patient eligibility and availability. Describe eligibility checks, registration, and quality control procedures for all data (e.g., medical oncology, surgery, pathology, radiation therapy, cancer prevention and control studies).

- Describe methods of on-site auditing or monitoring for data verification and assurance of compliance with regulations for the protection of human subjects (IRB approval and informed consent) and for investigational drug accountability.

- Describe mechanisms for periodic review of performance (qualitative and quantitative) by the CCOP Research Base and criteria for continued affiliations. If mechanisms are different for cancer treatment and prevention/control, describe these differences.

- Include a budget for auditing and quality control activities with complete justification for each budget item.

- Provide a list of Institutions and their audit schedule using **Sample Table 8** (see directions for which institutions to include on the sample table) for large-scale prevention trials (e.g., the Selenium and Vitamin E in Prostate Cancer Trial (SELECT)); and/or other prevention trials that involve institutions that are NOT an NCI Clinical Cooperative Group treatment trial institution.