

Suggestions for Organizing Information for a CCOP Research Base Application

In preparing a CCOP Research Base application, you must follow the instructions provided in the RFA CA-05-014 and the *Application for a Public Health Service Grant* (PHS-398) (revised 5/2001) available at: <http://grants.nih.gov/grants/forms.htm> and its accompanying packet of forms. The suggestions and sample tables provided in this suggested format are only a supplement to the PHS-398, NOT A REPLACEMENT. However, they may help the applicant to supply all the information required by the RFA while remaining within the page limitations (see Supplemental Instructions in RFA-CA-05-014). Following the suggestions and sample tables may enable the reviewers to evaluate the applicant=s resources and capabilities. The tables provided in this suggested format may be included in the application as part of the Resources, Progress Report and Human Subject Research sections, as appropriate.

NOTE: Requirement of DUNS Numbers on NIH Applications - Effective October 1, 2003, use of the [Dun and Bradstreet](#) (D&B) Data Universal Numbering System (DUNS) number will be 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.

NOTE: Other Support should NOT be submitted with the application. If this information is included in the application, the application will be returned to the applicant organization WITHOUT peer review. See pages 43-44 of the PHS 398 (rev. 5/01) instructions

GENERAL INSTRUCTIONS

Although formatting and submission information is provided in the PHS-398 (rev.5/01), some of the requirements are repeated in these suggested format instructions to emphasize the importance of the submission information in preparing your application. Please refer to the RFA CA-05-014 and the PHS-398 (rev. 5/2001) for complete instructions.

- X Prepare the application single-sided and single-spaced, using the PHS 398 RTF or PDF form/format pages as provided. The print must be clear and legible. Use standard size, black letters that can be clearly copied. The PHS 398 RTF and PDF Form pages as provided are acceptable by NIH. All other sections of the application (e.g., Biographical Sketch, Introduction, and Research Plan) **must conform** to the specifications as outlined on page 3 of the PHS 398 (rev. 5/01) instructions under the heading **FORMAT SPECIFICATIONS**. You may substitute computer-generated facsimiles for government provided forms: however, they must maintain the exact wording and format of the government forms, including all captions and spacing. You also may create pages similar to the format pages provided in the PHS 398 (rev. 5/01) and the tables in the suggested format (Tables 1 through Table 8) but these pages must include the requisite information.
- X Include all pertinent information in the text and tables. **DO NOT** use appendices for any material that all reviewers need to see because the appendices will not be reproduced for all the reviewers. See PHS 398 (rev. 5/01) pages 29-30, I. Preparing Your Application, 9. Appendix for more details.
- X **DO NOT** submit photographs, oversized documents, materials that do not reproduce well, or Institutional public relations-type documents.
- Include a table of contents (see Form Page 3), so that reviewers can identify each part of the application by page number (See PHS 398 (rev. 5/01) page 11, 3. Research Grant Table of Contents)
NOTE: Do not include unnumbered pages and do not use suffixes, such as 5a, 5b.

CCOP Research Base APPLICATION DUE DATE

- X Submit the applications **by July 14, 2004**, COB (5:00 pm).
- X Affix RFA label to bottom of face page.
- X Late applications will not be accepted. Receipt dates listed in PHS-398 (rev. 5/01) II. Submitting Your Application on pages 32-33 **do not apply** to receipt of applications in response to RFA-CA-05-014.

REVISED (AMENDED) APPLICATIONS

An unsuccessful applicant from the previous year=s competition is a revised (amended) application that **MUST** include an Introduction of not more than three pages that summarize the substantial additions, deletions and changes to the application. The Introduction must also include responses to the criticisms and issues raised in the summary statement. (See **PHS-398 (rev.5/01), I. C. 8. Research Plan, page 15-16**). NOTE: Only two revised (amended) versions of an application are allowed. The two-year restriction on the receipt of the amended applications has been eliminated: <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-041.html>

COMPETITIVE CONTINUATION APPLICATIONS

An application from a currently funded CCOP research base is a competitive continuation and must include a progress report (see **PHS-398 (rev. 5/01), I. C. 8. page 17**). The progress report, at a minimum, should include:

- X a summary of research base activities and accomplishments over the funding period, with a clear presentation of yearly accrual (separately for treatment and cancer control) from affiliated CCOPs;
- X progress in implementing NCI approved cancer prevention and control clinical trials;
- X a complete description of how the applicant has met the special cooperative agreement terms and conditions of the award;
- X a clear presentation of annual accrual to each NCI approved prevention and control clinical trial for CCOPs and research base members and affiliates;
- X a summary of participation in cancer prevention and control research by members and affiliates;
- X a report and table on the enrollment of women and men and on the race and ethnicity of research participants during the last year (**see pages 30-31, PHS-398**); and
- X the status of concepts and protocols under development.

NEW APPLICATIONS

New applicants are advised to complete all of the attached Sample Tables. Although these are not required, reviewers may interpret their absence as an elusive response or lack of data. Since new applicants have not worked with CCOPs in the last year, they may provide treatment accrual activity from their members and affiliates as an indication of their potential level of CCOP treatment accrual

(see **Sample Table 1**). Similarly, cancer prevention and control protocols may be presented by new applicants even though not approved by NCI (see **Sample Tables 2, 3, and 4**).

SPECIFIC INSTRUCTIONS

The following suggestions for **Section I. C. 7. and 8. (pages 15-20)** are listed in the same sequence as the instructions in the PHS-398 (rev. 5/01).

RESOURCES

Use the Resources Format Page (or create pages similar to the format page with the requisite information) and instructions provided in PHS-398 (rev. 5/01) and integrate the following format suggestions to describe Resources (**Section I. C. 7. page 15**).

Type of Research Base

Indicate organizational type and research focus of application:

- X clinical trials cooperative group (NCI-funded) **for cancer treatment *and* prevention and control research;**
- X clinical, consortia, or comprehensive cancer center (NCI-funded) **for cancer treatment *and* prevention control research;**
- X clinical, consortia, or comprehensive cancer center (NCI-funded) **for *only* cancer prevention and control research.**

Organization of Research Base

- X Describe the organizational structure of the 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 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 and control clinical trials.
- X Describe the relationship of the research base to any other parent organization (e.g., fiscal agency).

§ Limit to two pages

RESEARCH PLAN

There is no Form Page for the Research Plan. The research plan should include sufficient information needed for evaluation of the project. Follow the instructions provided in PHS-398 (rev. 5/01) and integrate the following format suggestions to describe the Research Plan (Section I. C. 8. pages 15-19).

Preliminary Studies/Progress Report

X Past Experience

- < If applicable, describe experience in conducting multi-institutional cancer treatment and prevention and control clinical trials during the last 5 years.
- < Limit to three pages

Research Design and Methods

- X If applicable, describe the relationship of the research base to investigators and institutions (e.g., CCOPs, cooperative group affiliate programs, member institutions and affiliates) contributing to research projects.
- X Describe the relationship of physician investigators to main member institutions and affiliated institutions.
- X Describe the proposed relationship to CCOPs. Include how the CCOPs will be integrated into the activities and decision-making processes of the research base organization and address the CCOP's scientific and administration contributions to the research base organization.
- X Limit to four pages.

Proposed Development and Implementation

- X Outline the organizational process for development and implementation of cancer treatment and/or prevention and control research.
- X Limit to three pages.

Cancer Prevention and Control Research

- X Describe the organizational structure for conducting cancer prevention and control research. Indicate responsibilities of the cancer control committee (or its equivalent) to the 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.

- X State the broad, long-term objectives of the cancer prevention and control research program.
- X Provide the scientific rationale for the proposed cancer prevention and control research and specifically identify the gaps which 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 research base.
- X Describe in detail at least two examples of cancer prevention and control protocols, including underlying hypotheses, study design, and implementation.
 - If applicable, include proposals for specific non-CCOP member institutions for consideration as "prevention members." Use **Table 8** to list the prevention members included in the application. Refer to the RFA Application Procedures **2. Research Base Applicants d. paragraph 5**, for further details on the information to address in the application for "prevention members."
 - For applicants with currently funded "prevention member(s), include a progress report that addresses how the member(s) have contributed to the goals of the research base in relation to cancer prevention research. Include data on accruals to chemoprevention trials led by the 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 research; other research activities that contribute to the research base's cancer prevention program.
 - Research base applicants 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).
- X If applicable, describe the research base's participation in cancer prevention and control research studies that are supported through other federal administrative and funding mechanisms such as research project grants (R01s) and/or contracts, **see Sample Table 2c**.

Quality Control and Monitoring

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).

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

- X Include a budget for auditing and quality control activities with complete justification for each budget item.
- X 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 Study of Tamoxifen and Raloxifene (STAR)); and/or other prevention trials that involve institutions which are NOT a Cooperative Group Treatment trial institution.

TABLES SUMMARIZING PROTOCOL ACTIVITY AND CLINICAL SITES

To assist the applicant in providing material sufficient to permit adequate review of study activity and study sites while maintaining clarity and brevity, we have included the following sample tables as suggested formats for providing specific information.

TABLES SUMMARIZING PROTOCOL ACTIVITY AND CLINICAL SITES

Protocol Activity Tables

- Sample Table 1 - Accrual From NCI Approved Cancer Treatment Protocols Available for Use By CCOP
- Sample Table 2a - Accrual From NCI Approved Cancer Prevention and Control Protocols Conducted By Your Research Base for Use By CCOPs and Your Members/Affiliates, and Other Research Base Members/Affiliates (if for Intergroup Studies)
- Sample Table 2b - Accrual From Intergroup NCI Approved Cancer Prevention and Control Protocols Sponsored By Other Research Bases for Use By Your Members/ Affiliates
- Sample Table 2c - Participation in Cancer Prevention and Control Research Studies sponsored by Other Federal and Administrative Funding Instruments (e.g., research project grant (R01), contract).
- 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

Data-Sharing Plan

All applicants must address their data-sharing plan in their application. Data sharing pertains to both published and unpublished but complete data sets. Investigators should refer to the NIH Guide: Final NIH Statement on Sharing Research Data (<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>) and http://grants.nih.gov/grants/policy/data_sharing/) for guidance on addressing this application requirement.

Human Subjects Research

- Create a section heading Human Subjects Research immediately following the last entry in the Research Design and Methods section.
 - < Address the involvement of human subjects and protections from research risk relating to their participation in the purposed research plan, Include a discussion of potential risks to research participants posed by data sharing and steps that are taken to address those risks. See the Table Guidance for Preparing the Human Subjects Research Section on page 19 of the PHS 398 (rev. 5/01). Research base applicants should refer to scenario C for preparing this section. Refer to Data and Safety Monitoring Plan section below.
- Create a section entitled “Protection of Human Subjects.” See pages 20-21 of the PHS 398 (rev.5/01) instructions for the four criteria that need to be addressed in this section.
 - < Provide verification of completion of education on the protection of human research participants for all investigators involved in the design or conduct of research involving human subjects. Refer to the following URL address for further guidance: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>

Women and Minority Inclusion in Clinical Research

- Create a section entitled “Inclusion of Women,” and a **separate section** entitled “Inclusion of Minorities. These sections must follow immediately after the Human Subjects Research section. See pages 22-24 of the PHS 398 (rev. 5/01) instructions. Note the additional information to be provided for applications that involve NIH-defined phase III clinical trials on page 24 of the PHS 398 (rev. 5/01) instructions.

Inclusion of Children

- Create a section heading entitled Inclusion of Children. This section should immediately follow the Women and Minority Inclusion in Clinical Research section.
 - < For applicants that include a pediatric component, the plan for including children should be described. See the PHS 398 (rev, 5/01) instructions on page 26 for added guidance on information to include in your description.
 - < If children will be excluded from the research, the applicant must present an acceptable justification for the exclusion. For the applicants that do not include a pediatric component see Justifications for Exclusion of Children pages 26-27 1. b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network.

Data Safety and Monitoring Plan

- Create a section heading entitled “Data and Safety Monitoring Plan.”
 - < Describe the research base applicant’s data safety and monitoring plan(s) for clinical trials. For applicants involved in both cancer treatment and prevention and control research, specify differences in the data and safety monitoring plan(s) for treatment and prevention and control trials, if such differences exist. See pages 27-28 of the PHS 398 (rev. 5/01) instructions for guidance completing this section of the application. In addition, the NCI has developed a document: Data and Safety Monitoring Guidelines: Summary A guide to the formulation of DSM plans for all phases of cancer clinical trials, in accordance with NIH requirements that is available at: http://www.cancer.gov/clinical_trials

(NOTE: A detailed Data Safety and Monitoring Plan must be submitted to the applicant’s Institutional Review Board and subsequently to the funding Institute and Center for approval prior to accrual of subjects.)

- < A cancer center CCOP research base, if applicable, may supply the cancer center’s approved institutional plan in the human subjects section of the application and describe how the CCOP research bases studies are integrated into the cancer center’s plan. Cancer center CCOP research base involved in treatment and cancer prevention and control trials should specify differences, if these exist, in monitoring plans for treatment trials versus prevention and control trials.