

**PART III: FORMATTING INSTRUCTIONS FOR NEW
AND COMPETING CONTINUATION CCSG
APPLICATIONS**

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PART III: FORMATTING INSTRUCTIONS FOR NEW AND COMPETING CONTINUATION CCSG APPLICATIONS

This part provides formatting instructions that supplement those on the Grant Application Form PHS 398 (rev.5/01). It is in the particular interest of applicants that the review of complex grant proposals be as trouble-free as possible. Adherence to these instructions will greatly assist peer reviewers in identifying sections of the application and in matching them with the corresponding review criteria listed in Part II, 5.0 of these guidelines.

In general, all pertinent information needed for evaluation should be included in the body of the application; however, applicants should be as concise as possible. Material not essential to making a center's best case for funding should not be included, since it dilutes the main message and distracts reviewers from the major points of the application. If the applicant wishes to submit appendix materials, see part III, section 15.0.

Page Limitations. These limits apply only to the narrative parts of each section. This includes descriptive abstracts, budget justifications, objectives, goals, rationale, accomplishments, tables, figures, charts, etc. This does not include budget pages, biographical sketches, publication lists or lists of grants. Please also note that page limits are, by definition, maxima and are not meant also to suggest the minimum length of sections.

1.0 Face Page

The face page of the Grant Application Form PHS 398 (rev. 5/01) should be completed as indicated in the application kit. The "principal investigator" is the cancer center director; the "applicant institution" is the fiscally responsible institution of which the cancer center is a part.

2.0 Description, Performance Sites, and Key Personnel

A description, limited to the space provided on page 2 of the PHS 398 form, should provide a summary of the CCSG-related organization and research programs of the cancer center, and a brief description of the request for support through the CCSG. A list of performance sites and key personnel should also be provided in accordance with the PHS 398 instructions.

3.0 Table of Contents

This should contain correct pagination for all major sections and subsections of the application.

4.0 Overall Description of the Cancer Center

Limit 20 pages. This section should provide reviewers with a general perspective on center activities. A brief history and broad overview of the center, especially its research efforts, serve to place the entire application in context. A simple map best illustrates the geography of the center, the location of its major activities, and the physical relationship

of any affiliated institutions to the main campus. This is also the place to summarize the center's major scientific thrusts, the principal research opportunities that it is trying to exploit, and how the various scientific efforts fit together in the center. A brief discussion of several of the most important discoveries occurring in the center during the last period of support will help reviewers understand what the center's investigators consider their most important achievements. This section should also briefly discuss general plans for the future development of the center. More specific information about future plans can be presented in other sections of the application, e.g., the Planning and Evaluation section can reflect decisions made for developing new program areas, and the plans for use of pilot project funds or recruitment funds in the Developmental Funds category can reflect efforts to strengthen a particular scientific area. After reading this section, a reviewer previously unfamiliar with the center should have a clear grasp of what the center is, what it does, what the center considers its most important recent discoveries, and what priorities the center has for future development.

5.0 Consolidated Budget Request

Using the budget forms and instructions in the PHS 398, prepare a consolidated budget for the "First 12-month Budget Period" and the summary budget for the "Entire Proposed Budget Period."

6.0 Essential Characteristics of the Cancer Center

Limit 20 pages.

6.1 Cancer Focus

Refer to Part I, 4.1 and Part II, 5.2.3.1.

6.2 Institutional Commitment

Refer to Part I, 4.2 and Part II, 5.2.3.2. It is helpful to include a schematic showing the center's position within the institution(s) in relation to other organizational components (e.g., schools, departments, institutes, or the equivalent).

6.3 Center Director

Refer to Part I, 4.3 and Part II, 5.2.3.3.

6.4 Organizational Capabilities

Refer to Part I, 4.4 and Part II, 5.2.3.4. A diagram(s) is useful in illustrating a center's programmatic structure, administrative organization, advisory groups and decision-making committees and processes.

6.5 Facilities

Refer to Part I, 4.5 and Part II, 5.2.3.5.

6.6 Interdisciplinary Coordination and Collaboration

Refer to Part I, 4.6 and Part II, 5.2.3.6.

7.0 Standard Cancer Center Information

These Summaries (see Attachment for instructions and formats) itemize for easy reference the center's research programs, shared resources, base of funded research projects, patient information, clinical research protocols, and comparison budget.

- Summary 1 - Cancer Center Senior Leaders, Research Programs, Members, and Shared Resources
- Summary 2 - Active Funded Projects
- Summary 3 – Reportable Patients/Accrual to Therapeutic Protocols
- Summary 4 - Clinical Research Protocol Information by Anatomic Cancer Site
- Summary 5 – Summary and Comparison of Current and Requested CCSG Budgets

8.0 Research Programs

Limit 25 pages per program on average; centers that include most or all clinical research in one Program may exceed the page limitation for this Program only.

Refer to Part I, 8.0 and Part II, 3.1 and 5.2.1.and 5.2.2

- **Title page** of the Program with the name(s) of the Program Leader(s) and the Program Code (used in Summaries 1 and 2 of the Standard Cancer Center Information Summaries).
- A brief **description** of the Program using page 2 of the PHS 398 Form.
- A **budget** for the percent effort of the first and future years for the Program Leader(s) using the standard budget pages provided in the PHS 398 form (Note: a level of effort must be included for each Program Leader whether or not salary is requested). Refer to Part II, 3.2.1 for further guidance on level of effort for Program Leaders. Refer to Part II, 3.2.5 for requesting administrative support for Program Leaders.
- A **budget narrative justification** based on the specific role of the Program Leader(s) in facilitating the discovery process and promoting interdisciplinary research important to cancer. Refer to Part II, 3.2.1.
- **Biographical sketches** of Program Leader(s) Use the PHS 398 Form. Note that the form includes information on positions and honors, selected peer-reviewed publications, and research support. Information on other support beyond that required in the biosketch should NOT be submitted with the application.
- A list of the **externally funded research projects** of the Program by member, project and funding source, separated into two categories: “peer-reviewed” and “non peer reviewed” (See Part I, 8.3 and Part II, 3.1.1). If the Program has a clinical orientation, reference can be made to Form 4 of the Standard Cancer Center Information Summaries for more detailed information about individual clinical protocols.

- The **members** of the Program in alphabetical order, with their departmental and institutional affiliation as well as their academic rank (or equivalent). Highlight any members of the program who are proposed to receive staff investigator salary support by indicating for each person the percent effort for which CCSG support is being requested.
- The **scientific goals** of the Program and how the interests, expertise and research approaches of the Program members facilitate their achievement.
- The most significant **scientific accomplishments** of the Program and the ways in which the cancer center facilitated or enabled these accomplishments.
- A selected list of Program-related **publications** from the last project period. Indicate those that particularly illustrate the inter- and intra-programmatic collaborations.

9.0 Non-programmatically Aligned Research Members

No more than 2 pages. List the non-aligned members in alphabetical order and include their departmental affiliations, areas of expertise and research interests, in a few sentences. If a significant proportion of the membership (i.e., greater than 10%) is not aligned with any of the center's research Programs, describe the strategies used to take advantage of their scientific expertise in furthering the research objectives of the center.

10.0 Descriptions, Budgets, and Narrative Justifications for Individual CCSG Components

Using the forms and instructions in the PHS 398 form, prepare 1) a description (where appropriate), 2) a budget for the "First 12-month Budget Period," and 3) a summary budget for the "Entire Proposed Project Period" for each allowable budget category for which funds are requested as outlined below in Part II, 10.1 – 10.9. You do not have to provide narrative justifications for individual Program Leaders (Part II, 10.2), since this information will have already been included under the "Research Programs" section of the application (see part III, 8.0), and need not be repeated here. A simple consolidated budget for Program Leaders should be included in this section.

10.1 Senior Leadership

No more than 1 page per senior leader. See Part II, 3.2.1 and 5.2.4. Prepare a description and a consolidated budget of percent efforts for all Senior Leaders and narrative justifications that carefully describe their roles. Each narrative should be followed by a biographical sketch (PHS 398 Form).

10.2 Program Leader of Research Programs (budget pages only)

See Part II, 3.2.1 and 5.2.1. Provide only a single consolidated budget that lists all Program Leaders in the center and their percent efforts. This is merely a consolidation of the separate budgets provided and justified in part III, 8.0. DO NOT provide any narratives.

10.3 Staff Investigators

No more than 1 page per staff investigator. See Part II, 3.2.2 and 5.2.11. Prepare an overall description, and a consolidated budget. Provide a separate short narrative justification and a biographical sketch for each staff investigator. The narrative should specify the formal research program(s) of the Center in which the staff investigator participates.

10.4 Program Planning and Evaluation

No more than 5 pages. See Part II, 3.2.3 and 5.2.5. Provide an overall description and a consolidated budget. Provide a narrative justification for each planning and evaluation activity. The narrative should summarize how past CCSG funds were used, what was accomplished to improve and develop the cancer center, and how future needs will be met with the requested budget. While budgetary support for development of scientific Programs is not allowable in the CCSG, plans for developing such Programs may be included in this section. If the center employs an outside advisory group, include a consolidated list of these individuals with titles and institutional affiliations and attach their biographical sketches. Discuss recommendations made by the external advisory group, any actions taken in response to those recommendations, or reasons for not responding.

10.5 Developmental Funds

No more than 15 pages. See Part II, 3.2.4 and 5.2.6. Prepare an overall description and a composite budget that includes all developmental fund categories being requested and explain how they will be linked to the strategic and programmatic priorities and scientific opportunities of the center. Also provide individual budgets by category with separate narrative justifications. Narratives should summarize how past CCSG developmental funds were used, what was accomplished with them and how the new request will be used to meet future needs. If a pilot project program is proposed, describe how the projects are reviewed for scientific merit and selected for funding.

10.6 Administration

No more than 5 pages. See Part II, 3.2.5 and 5.2.10. Provide a description budget and narrative justification. The administrative budget request and narrative should be limited to and justified in terms of the specialized research needs of the cancer center and not be duplicative of parent institution(s) responsibilities.

10.7 Shared Resources

No more than 15 pages for each shared resource, on average. Note: centers present resource requests in various ways. Some prefer to group several core components into a single categorical request (e.g., Immunology, Cell Biology). The 15-page limitation is intended to accommodate bundled requests of this kind. Requests for most individual core resources should require much less than the 15-page limit). See Part II, 3.2.6 and 5.2.9. Appropriate description, budget information, data and narrative justifications should be prepared for each resource. The biographical sketch of the key resource director(s) or manager(s) should follow the narrative justification.

In the narrative descriptions for each shared resource, include a description of the

resource including the services and technologies provided and their importance in relation to the scientific needs and objectives of the cancer center. Describe the qualifications of the resource director(s) and the competence of key technical staff; include a biosketch of the resource director(s). Describe the center's policies about operation and use of the shared resource, e.g., access, priorities, limitations and cost management strategies such as chargeback systems. Discuss the center's consideration of the cost-effectiveness of the resource relative to other options for obtaining the service, such as outside vendors, when applicable, and the approach used to evaluate the current extent of use by peer-reviewed, funded center investigators, and projected increase in use, if applicable, based on the scientific needs of the center. If CCSG support is requested for an institutional resource, describe the leverage this support will provide for the cancer center.

Provision of operational costs and usage data for each shared resource over a recent 12-month period is necessary to ensure that reviewers can make a complete evaluation. Use of a table or a chart to present the following information greatly facilitates the review of shared resource requests:

- total operating budget of the resource from all sources; and amount and percentage of the total operating budget being requested from the CCSG
- the extent of usage by each of the major users in terms of the service(s) provided (e.g., number of nucleotides synthesized), as well as the percent of the total usage it represents
- sum of the use and percentage of the total use for each of two categories of users: (1) cancer center investigators with peer-reviewed funded research projects and (2) cancer center investigators without peer-reviewed funding, and non-center member users
- estimated total capacity of the resource if it were operating full-time, i.e., at 100 percent capacity; and the total output or productivity of the shared resource over the 12-month period

All shared resources critical to the clinical research needs of the center (e.g., biostatistics, centralized protocol management office) should be presented last, so they can be reviewed in sequence with the next sections, "Protocol Review and Monitoring System" and "Protocol-specific Research Support."

10.8 Protocol Review and Monitoring System (PRMS)

No more than 10 pages exclusive of list of protocols. See Part I, 9.4; Part II, 3.2.7 and 5.2.7.

- **Description, Budget and Justification.** Include a description, a budget, and a narrative justification.

- Describe the **criteria for selection of the membership** of the committee. List the members of the committee and their expertise. The biographical sketches of these individuals should be included at the end of this section.
- Describe the **procedures for scientific review and scientific monitoring** of cancer clinical trial protocols. Describe the criteria and process for submission of institutional clinical trial protocols to the committee for review and approval; the process for review of all cancer clinical research protocols of the institution; the review criteria that are used to assess scientific rationale, study design, expected accrual rates, adequacy of biostatistical input and feasibility for completion within a reasonable time period; and the criteria used for monitoring ongoing institutional protocol research to evaluate scientific progress, including reasonable accrual rates, to ensure that the scientific aims of the study can be completed. Describe the criteria for terminating a clinical protocol. Describe whether the committee has ever terminated any protocols, and for what reason.
- Describe the **process and criteria used for prioritizing** the activation of cancer clinical protocols at the institution with respect to scientific merit and patient availability.
- Describe PRMS **operations relative to the Institutional Review Board (IRB)** approval process with emphasis on the complementarity of the two entities and absence of overlap or duplication.
- Provide a list of all **Institutional protocols** (i.e., studies that have not received external review) that have been reviewed by the PRMS for scientific merit in a recent 12-month period. List those protocols that were approved and activated, approved but not yet activated, deferred for revision, and disapproved. Indicate for the same 12-month period how many protocols in the institution were monitored for progress and performance and list those that were closed, along with the reason for closure. Peer reviewers will select a sample of the listed protocols for detailed review prior to the site visit. Protocols should not be included in or appended to the CCSG application. For approved, activated protocols, provide descriptive information about the protocol including target accruals and accruals to date using the format provided in Standard Cancer Center Information, Summary 4, Clinical Research Protocol Information.

10.9 Protocol-Specific Research Support

No more than 4 pages. See Part II ,3.2.8 and 5.2.8. Provide a description, a budget and a narrative justification for why these funds are needed. Funds in this category are restricted to support of a core group of research nurses and data managers for conduct of high priority, innovative, feasibility and phase I clinical research protocols. The budget should be based on the number and complexity of these protocols.

11.0 Inclusion of Minorities and Women in Clinical Trials (NIH Policy)

No more than 4 pages. See Part II, 4.1 and 5.2.12.

- **Demographics.** Provide summary information showing the national demographics of the patient population by ethnic categories and subcategories and by gender. Provide similar demographic breakdowns for the cancer patient population in the primary catchment area of the center, as well as for the cancer patient population treated at the cancer center.
- **Accrual.** Complete Parts A and B of the “Inclusion Enrollment Report Table”, found in the Form PHS 398 (rev 05/01). Provide summary accrual information from the most recent 12-month period by ethnic categories and subcategories and by gender in the following two areas: (a) the therapeutic clinical trials conducted at the cancer center, and (b) the NON-therapeutic trials conducted at the cancer center. Relate this information to the demographic information provided above.
- **Deficiencies and Corrective Actions.** If there are any proportional deficiencies in the accrual of women and minorities to therapeutic and non-therapeutic trials relative to the opportunities as defined by the demographics of the center’s catchment area, note:
 - any general policies of the **institution** designed to help with this problem
 - unavoidable circumstances that impede accrual of women and minorities (e.g., a high proportion of non-eligible patients)
 - actions planned or being taken by the **center**, based on careful analyses of the population, which demonstrate a clear effort to correct deficiencies that are potentially avoidable
- **Projected Accrual of Minorities.** Using the “Targeted/Planned Enrollment Table” found in the PHS 398 (5/01 version), report proposed subpopulations for those **phase III studies** that utilize CCSG resources in any way and are not funded by any other PHS grant mechanism. If you do not have any phase III trials that meet this criterion, please include a sentence indicating that.

The table of composite data for all institutional phase III studies should be accompanied by:

- A list of the individual study titles on which the projected data are based. Indicate which listed study is anticipated to be the largest, the cancer site to be studied in that trial, and the number of subjects expected to be accrued to that study.
- A narrative discussing how the projected accruals relate to the demographics of the catchment areas and approximately how many trials of what size are aggregated.

12.0 Inclusion of Children in Clinical Trials

No more than 4 pages. See Part II, 4.2 and 5.2.13

13.0 Data and Safety Monitoring

No more than 4 pages. See Part II, 4.3 and 5.2.14

Include only a summary of the DSM Plan within the text of the application. If funding is being requested for DSM activities, separate budget and justification pages must be provided. To support the request, the applicant should provide:

- A general description of DSM functions, including the workload related to evaluation, auditing, and monitoring of various types of institutional studies, and studies supported on competitive grants (e.g. R01s).
- A description of the committees involved in DSM processes and the biographical sketches of the members of these committees.

14.0 Data Sharing

Not subject to page limits. See Part II, 4.4.

Provide a short description of the Center's institutional approach for adhering to the data-sharing policy, as well as specific data sharing plans for any research conducted directly with CCSG funds (i.e., pilot projects conducted with developmental funds, feasibility or early phase trials conducted with Protocol Specific Research Support) or core components serving as research resources (e.g., array analysis cores, family registries, etc.). Since this section is not peer-reviewed, include it at the end of the required components of the application, just prior to the appendices. If you are requesting a budget for data-sharing activities (e.g., data archiving), include the budget and justification with this section.

15.0 Appendices

After the application has been submitted, the applicant should contact the Scientific Review Administrator (SRA) to discuss the inclusion of any appendix materials that are important to peer review. Only materials approved by the SRA will be included in appendices and used by peer review.

16.0 Review Materials to be Available at the Site Visit

- Biographical sketches of all (research) cancer center members. A complete set of biographical sketches facilitates the review particularly if it is made available to the Scientific Review Administrator for use during the pre-site visit meeting of reviewers.
- Institutional protocols that have been reviewed by the center's Protocol Review and Monitoring Committee.
- Log books or other records of use for all shared resources.

- Minutes or reports of external and internal advisory committees, retreats, etc., involved in the planning and evaluation process for the center.
- An updated Summary 2, Existing Funded Projects from the Standard Cancer Center Information, and using the same format, and if desired, a separate list of grants and contracts pending peer review, approval and funding. It is suggested that these items be made available to the SRA for use during the pre-site visit meeting.
- The complete institutional Data and Safety Monitoring Plan.

This document can be viewed or downloaded online in its entirety and is available at the Cancer Centers website at the following address:

<http://cancer.gov/cancercenters/>

The specific address for Part III of the guidelines is as follows:

http://cancer.gov/ccsg_competing_3.html