

Policies and Guidelines Related to the Cancer Center Support Grant

IV Instructions for Non-Competing Continuation Applications February 2005

These instructions supplement those provided in the “U.S. Department of Health and Human Services Public Health Service Non-Competing Grant Progress Report” (PHS 2590, rev. 9/04) instructions. Per PHS policy a continuation application and progress report must be submitted for each continuing year of the grant **by two months** prior to the beginning date of the next budget period. It is the responsibility of the applicant to obtain the appropriate forms and instructions (<http://grants.nih.gov/grants/forms.htm>).

The completed, signed original progress report and one copy (with required signatures) must be submitted to the centralized mailing address below:

Division of Extramural Activities Support, OER
National Institutes of Health
6705 Rockledge Drive, Room 2207, MSC 7987
Bethesda, MD 20892-7987 (for regular or US Postal Service express mail)
Bethesda, MD 20817 (for other courier/express mail delivery only)
Phone Number (301) 594-6584

Grantees may access a website (http://era.nih.gov/userreports/pr_due.cfm) to determine when a progress report is due. The list is updated on or around the 30th of each month. In addition to this website, email reminders are sent to the principal investigator.

The information provided in the Cancer Center Support Grant (CCSG) continuation application serves as a basis for continued support, and is used to monitor scientific and programmatic progress and to ensure that public funds are used appropriately within all NCI//NIH/PHS guidelines and regulations. The narrative portions are particularly useful in demonstrating the importance of the NCI-designated cancer centers to the Department of Health and Human Services, the public, and Congress.

Formatting Instructions for Non-Competing Continuation Applications

Face Page: Complete the face page as described in the PHS 2590 (rev. 9/04) instructions.

Table of Contents: Provide headings with correct page references.

Detailed Budget for Next Budget Period: Complete an overall budget as described in the PHS 2590 Form (rev. 9/04). You must also provide a separate detailed budget for each component (e.g., senior leaders, program leaders, developmental funds, shared resources, etc.) in the **same sequence used in your competing application**. For the overall and separate budgets, provide a budget justification **only** for those line items and amounts that represent a significant change from those previously recommended. This requirement includes changes in any effort for key personnel.

Biographical Sketch: Provide a biographical sketch for all new key personnel added since the last submission.

Other Support: Provide active support information for key personnel only.

Director's Scientific Overview:

- **Scientific Progress and Plans**
Broadly discuss progress over the current year, noting any important changes in key personnel, scientific Programs, shared resources, and/or institutional commitments that have enhanced the scientific capability and productivity of the center. Discuss next year's plans for developing any new scientific directions and/or taking advantage of new research opportunities. Highlight the most significant **published** scientific accomplishments that you believe should be considered by the NCI when reporting to its advisory groups and to Congress.
- **Major Scientific Accomplishments**
Please prepare **in lay language** a description of **three to five major scientific accomplishments** occurring in your center during the current reporting period, and their potential significance to cancer prevention, diagnosis, and treatment.

Standard Cancer Center Summaries: The summaries listed below should be submitted annually with the non-competing continuation application. Specific instructions for the summaries are found in a separate guidelines section entitled, "Attachment: Formatting for Standard Cancer Information Summaries." This document may be viewed or downloaded at <http://cancercenters.cancer.gov/downloads.html>.

Cancer Centers must also submit an electronic copy of their summary information, in a format compatible with Cancer Centers Branch database, directly to the Cancer Centers Branch at the same time the application is submitted. Electronic information should be sent to ccsgdata@mail.nih.gov.

Summaries to be included in the application and sent electronically include:

Summaries 1A, 1B, 1C, 1D
Summaries 2A, 2B
Summary 3
Summary 4

Progress Reports: Provide a brief progress report for each component to accompany the budget request and justification; these should be in the same sequence used in your competing application. Where relevant, discuss how the **major** concerns identified in the last summary statement are being addressed.

- Describe the scientific progress and achievements for the current year for each *Research Program*, emphasizing the **most significant published scientific accomplishments**, and indicate **how the center has facilitated** these accomplishments. Please highlight those accomplishments of direct or potential importance to cancer. In addition, discuss plans for the development of new scientific capabilities, directions, and opportunities, if any, and their potential impact on the goals and objectives of the Program. Include a selected list of program-related publications of the current year, highlighting those that illustrate inter- and intra-programmatic collaborations.
- Describe how the *Program Planning and Evaluation* activities of the center helped the center achieve its scientific goals and objectives in the current year and how they will be used to enhance the strategic development of the center's scientific objectives in the next year. Specifically elaborate on the important recommendations of the External Advisory Boards (EAB) during the past year and plans for

their implementation. Note any changes in the membership of the committee and indicate each new member's area of expertise and the institution to which he/she belongs.

- For any proposed changes in *Staff Investigators*, follow the guidelines in Part II, Section 7.3, and Part III, Review Criteria.
- Fully describe how funds in various sub-categories of the *Developmental Funds* budget were used in the current year, highlighting for each subcategory those activities that benefited and enhanced the strategic development of the center's scientific capability. Discuss any recommendations of the EAB for developmental fund use and provide a detailed description of how developmental funds will be used in the coming year.
- For each *Shared Resource*, report any major changes made in the resource's scientific and/or technical capabilities and usage, including those planned for the next year, and briefly discuss the importance of these changes on the scientific productivity of the research activities it serves.
- Describe the status of pilot/early phase I research protocols supported in the current year by the *Protocol Specific Research* component and indicate which protocols have led to the next level of studies (e.g., phase II) and/or have received external peer reviewed support.
- Indicate and highlight revisions or modifications in the *Data and Safety Monitoring Plan* since the last review of the plan.
- In accordance with the NIH policy, the application should include a *Data Sharing Plan* if applicable (e.g., pilot projects in developmental funds category, phase I studies conducted with the resources of the Protocol Specific Research component, a shared resource that serves as a final repository of data, etc.).
- Under a separate heading, provide a progress report for any *Supplements* to the Cancer Center Support Grant as required by the Terms of Award for that supplement. Please include data on accrual of women and minorities according to the PHS categories.

Checklist: Complete the checklist in accordance with PHS Form 2590 instructions (rev. 9/04). Ensure that program income and expenditures (e.g., from shared resource charge backs or other sources) is reported here.

General Considerations for all Budget Requests and Justifications

Requirement of Notification (via Letter and/or Type 5 application): The grantee is required to notify the Grants Management Office (GMO) in writing if the PI or key personnel specifically named in the Notice of Grant Award will withdraw from the project entirely, be absent from the project during any continuous period of 3 months or more, or reduce time devoted to the project by 25 percent or more from the level that was approved at the time of award (for example, a proposed change from 40 percent effort to 30 percent or less effort). NIH must approve any alternate arrangement proposed by the grantee, including any replacement of the PI or key personnel named in the NGA.

The request for approval of a substitute in a key personnel position should include justification for the change, the biographical sketch of the individual proposed, other sources of support and any budget changes resulting from the proposed change.

Expanded Authorities: Cancer Center Support Grants are administered under the provisions of Expanded Authorities as specified in the following excerpt from the NIH Grants Policy Statement:
http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600128.

In addition to the above- referenced summary of authorities routinely granted to all NIH awards, NCI has elected to provide automatic carryover authority to its Cancer Center Support Grant (P30) awards. The following language is cited from the NIH Grants Policy Statement for those awards subject to expanded authorities but excluded from Streamlined Non-Competing Award Process (SNAP):

“For those awards subject to expanded authorities but excluded from SNAP, the FSR must specify the amount to be carried over. The notification must be provided under item 12, “Remarks,” on the FSR. When a grantee reports a balance of unobligated funds in excess of 25 percent of the total amount awarded, the GMO will review the circumstances resulting in the balance to ensure that these funds are necessary to complete the project, and may request additional information from the grantee, including a revised budget, as part of the review.”

If the NCI determines that some or all of the unobligated funds are not necessary to complete the project, it may reduce the level of funding for the current or subsequent budget periods.

Center directors have considerable flexibility to move funds between CCSG components in response to changing needs and opportunities. In accordance with the PHS 2590 instructions, a detailed budget justification must be provided for items and amounts that represent a significant change from that previously recommended.

Prior Approval Requirement by the NCI: The following kinds of requests require NCI approval and should be submitted separately from the non-competing continuation application.

- The creation of a *new budget category* (e.g., a new shared resource) from within the committed levels on the award statement that would constitute a change in scope and normally be subject to peer review evaluation.
- Any requests for *additional funding* beyond that committed in the Notice of Grant Award (NGA). Applicants should note that requests of this nature are approved only under exceptional circumstances.
- Replacement or other changes in time commitment of the Principal Investigator (as described above under “Requirement of Notification.”).

Funding Policies: In years of significant budgetary constraint, NCI funding plans will spread the impact over their entire Centers program (non-competing as well as competing grants) to reduce the adverse impact on those institutions that happen to compete during a difficult year. If funds become available in future years, funds may be restored.

This document can be viewed online or downloaded in its entirety at the following address:
<http://cancercenters.cancer.gov/downloads.html>.