**SUPPLEMENTAL GUIDELINES FOR PREPARING A
NON-COMPETING APPLICATION FOR**

*COMPREHENSIVE MINORITY INSTITUTION/
CANCER CENTER PARTNERSHIP (U54)*

INTRODUCTION

These supplemental instructions are provided in addition to Form PHS 2590 (rev. 5/01), "Progress Report for a Public Health Service Grant" for Non-Competing Grant Progress Report which is required each year in order to receive continuing support. In general, please refer to the Specific Instructions for completing the Face Page; Detailed Budget for Next Budget Period; Budget Justification; Biographical Sketch; and Other Support Form Pages of PHS 2590 (rev. 05/01).

Additional guidance and requirements pertinent in the preparation of a U54 Comprehensive Minority Institution/Cancer Center Partnership (MI/CCP) progress report for a Non-Competing Continuation application is provided below.

GENERAL ISSUES

The NCI advocates flexibility in the use of U54 to achieve the objectives of the MI/CCP and will administer these grants with a view towards that end. Nevertheless, it is important to highlight and explain changes in the component budget that differ from the approved peer reviewed budget levels of the original competing application. **Areas requiring explanation, justification and NCI approval are as follows:**

1. Any proposed increase or decrease in the level of effort of key personnel.
2. Substitution of key personnel with persons not previously peer reviewed (e.g., Principal Investigators, Project/program Leaders, Administrative Coordinators).
3. Redistribution of dollars between components within a U54 cooperative agreement (NOTE: this is encouraged in a MI/CCP when more promising opportunities than those originally proposed).
4. Redistribution of the budget between U54 partners within the $1.5 million direct cost cap (NOTE: this is the time to consider redistribution if the objectives of the partnership can be achieved better by placing more of the total budget in the Cancer Center or MSI grant).
5. New research projects/programs not included in the competing application and not peer reviewed (NOTE: this is encouraged, especially in the use of developmental funds, however, NCI must approve these projects/programs before they can be activated).
6. New resources and infrastructure not previously peer reviewed.
7. New recruitments not previously peer reviewed.

8. Changes in institutional commitment leadership (e.g., Presidents, Deans, Departmental Chairs) and/or resources (e.g., release time, laboratory/core space) (NOTE: requires new Letters of Commitment).

PROGRESS REPORT SUMMARY

The Progress Report Summary portion of the continuation application of PHS Form 2590 is not specifically tailored to the unique objectives of the MI/CCP grant. Non-Competing Progress Reports for U54 MI/CCP cooperative agreements should follow the outline and numbering system shown below. Continuation pages may be used as necessary:

1. Combined Director's Overview

The Director's Overview is an important section and should be the same in each progress report in which the Co-Principal Investigators must address the following issues:

A. <u>Response of Summary Statement Concerns</u>: This section should include a response to the specific concerns and recommendations offered in the Summary Statement of the competing application. This section should be no longer than two pages.
B. <u>Scientific Leadership and Administrative Core</u>: This section should include information about the following:
  o Describe how the Co-PIs interacted with each other and the Program Steering Committee (PSC) during the initial budget period.
  o Describe the different ways in which the members of the MI/CCP team worked together and exchanged ideas during the initial budget period.
C. <u>Planning and Evaluation Core</u>: This section should include the following discussions for both the initial budget period and the next budget period:
  o Describe the process used for and list the participants who were involved in the prioritizing and selection of any new pilot projects/programs for implementation and their potential to be successful in the acquisition of preliminary data.
  o In chronological order list the internal processes (e.g. workshops, retreats, seminars, etc.) purposes, the participants and outcome of each that took place during the initial budget period.
  o Include the PSC report and include any new priorities affecting the distribution of MI/CCP funds based on the progress of existing projects/programs and results obtained from the use of developmental funds.
  o Describe how the developmental funds are being used in a flexible manner to explore new opportunities and how the MI/CCP sets priorities in the use of developmental funds.
  o Describe how developmental funds have stimulated new collaborative interactions with scientists within the MI/CCP institutions.

- Describe any special efforts to recognize unique opportunities based on cancer incidence and mortality rates of minorities in the community/region of the MI/CCP through interactions with individuals, organizations and institutions within the community.
- List all planning activities anticipated to take place during the next budget period.

In all of the above the intent should be to explain how the team of MI/CCP scientists are functioning as a partnership for pursuing research objectives using integrated, innovative, and flexible strategies and maximizing the unique capabilities of MI/CCP support in achieving program objectives.

2. Developmental Core

Projects and Programs (unique to each U54 partner)

For each pilot and/or full project/program, the Co-leaders should briefly describe the following:

- *Specific Aims.* Briefly describe the specific aims of the project/program as actually funded and if applicable, describe how the aims differ in scope from those stated in the original, competing application, because of Scientific Review recommendations and/or budgetary modifications made by NCI. If the aims have not been modified, state this.
- *Studies and Results.* Describe the studies directed toward specific aims during the current budget year and the results obtained. Include positive or negative results associated with each specific aim that are important to the hypothesis being tested. If technical problems were encountered in carrying out this project, describe how your approach was modified.
- *Significance.* Emphasize the significance to the scientific field and/or their potential impact on minority health, training, education and outreach in a reasonable time span. For pilot training programs, please use the NRSA Additional Budget Page 2 to provide trainee information requested.
- *Plans.* Summarize plans to address the following:
    1. Include any important modifications to the original aims and objectives. Include any projects/programs that were either dropped (with explanation) or completed (with outcome).
    2. Include a clear timeline and the plans of each pilot projects/programs to become competitive grant applications (e.g. RO1s; T32s; R25Ts).
    3. Include those projected to become full project/program.
    4. List in tabular form grant applications, as a product of this U54, that have already been submitted, where and when submitted, and whether pending, funded or not funded.
    5. Address any changes involving research using human subjects and/or vertebrate animals.

- *Publications/Presentations.* List and provide one copy of each publication not previously submitted. List the complete citation of all publication/presentations not previously reported. This includes manuscripts submitted or accepted for publication. Report only those publications/presentations resulting directly from this grant. State if there have been no publications.
- *Project-Generated Resources.* If the research supported by this grant resulted in data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information available to be shared with other investigators, describe the resource and how it may be accessed.

Complete items A and B on Form 2590 Page 5 if the research involves Human Subjects or Vertebrate Animals. Please read and follow the instructions on pages 9 -11 of PHS 2590 for studies involving <u>Vertebrate Animals</u>, <u>Human Subjects</u> and <u>Women and Minority Inclusion in Clinical Research.</u>

3. *Resources/Infrastructure* (unique to each U54 partner)

Describe the status of all fully operational resources as described in the competing application and/or the progress in establishing the resource or infrastructure. Describe the current use of the resource by the participants in the partnership and how the high-quality of the operation of each resource described in the original competitive application is being maintained and how it furthers the priorities and objectives of the partnership. Discuss structural, organizational, logistical, and administrative changes in the resource; problems that have developed in the operation and the plans to improve the resource in the next budget period (no more than 750 words plus tables, etc., as needed).

4. *Recruitment* (unique to each U54 partner)

Briefly describe the recruitment process and outcome. Explain how each individual, whether recruited from within or outside the institution fulfills the priorities of the partnership, the nature of the position, the location of the individual and the institutional commitment for stability and resources to promote success. If junior investigators, describe how the individual(s) are being mentored to pursue an independent and competitive career in cancer research. Describe any plans for further recruitment in the next budget period.

5. *Summary of Peer-Reviewed Publications and Grant Applications*

It is important to maintain a clear commitment to using the U54 to generate peer-reviewed publications and peer reviewed funding. This is the primary goal of the U54. The Co-Principal Investigators must provide a table that summarizes the following as a result of the U54 partnership:
- Publications in peer reviewed journals

- o Submitted (when/where submitted, authors, title)
  - o Published (when/ where published, authors, title)
- Peer reviewed research grants (R03s, R01s, P01s, U01s, P50s)
  - o Submitted: (grant number, Principal Investigator(s), title)
  - o Pending: (grant number, Principal Investigator(s), title)
  - o Awarded: (grant number, Principal Investigator(s), title)
- Peer reviewed training Programs (T32s, K12s, R25Ts)
  - o Submitted (grant number, Principal Investigator(s), title)
  - o Pending: (grant number, Principal Investigator(s), title)
  - o Awarded: (grant number, Principal Investigator(s), title)
- Other Peer reviewed grants (R25Es, outreach, ACS, etc)
  - o Submitted (grant number, Principal Investigator(s), title)
  - o Pending: (grant number, Principal Investigator(s), title)
  - o Awarded: (grant number, Principal Investigator(s), title)