Instructions for the Cancer Center Support Grant Non-Competing Progress Reports

The information included in the non-competing Progress Report is used to monitor scientific and programmatic progress and to ensure that public funds are used appropriately.

The instructions here supplement those provided in the U.S. Department of Health and Human Services Public Health Service Non-Competing Continuation Progress Report PHS 2590 Revised 06/2009 instructions; http://grants.nih.gov/grants/funding/2590/2590.htm.

Non-Competing Continuation Progress Reports and eData files must be submitted two months (60 days) prior to the start of their next budget period. One paper copy of the non-Competing Continuation Progress Report, signed by a University Business Official, should be mailed to the 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

A signed, PDF copy of the Progress Report should be submitted via email to the Office of Grants Administration Grants Specialist and the Office of Cancer Centers Program Director.

Contents

Face Page:

1. Complete the face page as described in the PHS 2590 (rev. 06/2009) instructions

   http://grants.nih.gov/grants/funding/2590/2590.htm

2. IRB Approval Date:

   a. Provide the current IRB approval date

   b. If the CCSG is not reviewed by the IRB, consider using one of these two formats:

      i. OMB No. 0990-0263: http://www.hhs.gov/ohrp/assurances/forms/of310.pdf

      ii. A letter from the Institution's IRB stating that informed consent (and HIPAA research authorization) must be obtained from subjects or their legally authorized representatives and documented prior to research involvement

Table of Contents:

Provide headings with correct page references.

Detailed Budget for Next Budget Period:

1. Complete an overall budget as described in the PHS 2590 Form (rev. 06/2009)

   http://grants.nih.gov/grants/funding/2590/2590.htm

2. 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 (Type 2).

3. The following kinds of requests require NCI approval and should be submitted separately from the non-competing continuation application.

   a. Key personnel whose effort has changed more than 25%: provide a budget justification and rationale.

i. In general, key personnel include members of the Center's Senior Leadership Team including the Center Director.

b. Budget categories that have changed more than 25% from the previous year: provide a budget justification and rationale

i. Developmental Funds and Supplement Funds cannot be moved to another budget category without written permission of the NCI
ii. CCSG funds in other categories may be moved into any peer-reviewed portion of the grant that received an Excellent, or better, rating during the most recent Competing Application (Type 2) grant review.

Biographical Sketch:

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

Other Support:

Provide updated, active, Other Support documents for key personnel.

Standard Cancer Center Data tables:

Include the following Data Tables with the paper/ PDF Progress Report:

1. Data Tables 1A, 1B, 1C, 1D
2. Data Table 2B

Submit the following Data Tables electronically to ccsgdata@mail.nih.gov concurrently with the non-Competing Continuation Progress Report.

1. Data Tables 1A, 1B, 1C, 1D
2. Data Tables 2A and 2B
3. Data Table 3
4. Data Table 4

References:

1. The Data Guide: http://cancercenters.cancer.gov/documents/CCSGDataGuide508C.pdf

2. The Electronic Data Guide: http://cancercenters.cancer.gov/documents/CCSGElectronicDataGuide-eData508C.pdf

Director's Scientific Overview:

Not to exceed 8 pages

For each of the elements below, describe the Center's activities for the past 12 month funding period:

1. Highlight your Center's most significant, published, scientific accomplishments. Include their potential significance to cancer prevention, diagnosis, and/ or treatment

2. Broadly, discuss the Center's progress and describe any important changes to:

    a. Key personnel

    b. Research Programs

    c. Shared resources

3. Describe any updates or accomplishments related to the Six Essential Characteristics of Cancer Centers; Facilities, Organizational Capabilities, Transdisciplinary Collaboration and Coordination, Cancer Focus, Institutional Commitment, and the Center Director

4. Briefly describe the vision and general plans for the future scientific development of the center

5. If you are a consortium center, clearly outline any changes to the consortium

Senior Leadership:

2 pages

1. Provide any updates or changes to the Senior Leadership personnel. Discuss how these changes have impacted the Center.

2. What have the Senior Leaders accomplished in the past year in relation to:

    a. Establishing a vision for the center and addressing overall center goals, policies, and operations.

b. Fostering basic discovery and advancing scientific findings?

c. Enabling a focus on cancer research applicable to the center's catchment area?

d. Establishing a process for integrating the training of biomedical scientists and health care professionals into programmatic research efforts?

Planning and Evaluation:

Not to exceed 2 pages, exclusive of External Advisory Committee (EAC) member list and biosketches

1. Summarize how past CCSG Planning and Evaluation funds were used. Include what was accomplished to improve and develop the cancer center and how future needs will be met with the requested budget.

2. Discuss recommendations made by the EAC, any actions taken in response to those recommendations, or reasons for not responding.

3. Discuss any changes to the internal evaluation processes for reviewing:

    a. Institutional and CCSG-supported shared (and clinical) resources

    b. Developmental fund usage

4. Discuss the development of future scientific Research Programs

Exclusions:

1. Provide a consolidated list of EAC members with titles and affiliations

2. Include the biosketches of new EAC members

Developmental Funds:

Not to exceed 4 pages

1. Summarize how past CCSG developmental funds were used and what was accomplished with them (e.g., establishment of a new shared resource; number of recruitments, areas of expertise, and contribution to the Center; interim salary and research support for Center Members; number and description of pilot projects resulting in peer-reviewed funding; description of purchased shared resource services; and role and contributions of funded staff investigators)

2. Discuss any recommendations of the EAC and/ or an internal advisory body for developmental fund use and provide a description of how developmental funds will be used in the coming year.

3. Describe how the funds are linked to the strategic and programmatic priorities and scientific opportunities of the center. If pilot projects are proposed, describe how the projects are reviewed for scientific merit and selected for funding.

4. Are any of the funds being used to support research at a foreign site?

Administration:

Not to exceed 2 pages

1. Provide any updates or changes to the:

    a. Sources of funding for activities of the administrative office, including the CCSG

    b. Roles and functions of administrative staff members

    c. Relationship of the center (*e.g.*, level of support, overlap of functions, and authorities) to other offices within the parent institution, such as the central grants office and clinical and other pertinent entities.

Research Programs:

Not to exceed 4 pages/ Research Program, exclusive of publication list

1. Discuss any changes in Program Leaders and/ or Program Membership

2. Describe the scientific progress and achievements of the Research Program during the last twelve months. Emphasize the most significant published scientific accomplishments and indicate how the center has facilitated these accomplishments. Provide citations for accomplishments discussed.

3. Describe any scientific findings by Center investigators that have been enhanced by collaborations across other mechanisms (*e.g.*, grants for SPOREs, Phase I/II consortia, program projects, and NCTN). These include collaborations with members from other Research Programs at your Center and collaborations with external partners at other institutions and industry.

4. As appropriate to the type of Program, include examples of how the research relevant to the catchment area is being addressed, *e.g.*, problems affecting racial and ethnic minorities, rural

residents, women, children, elderly, persons of low socioeconomic status), cancer sites of high incidence/mortality, environmental exposures, behavioral factors, or other issues .

5. Describe how the Program's use of the Shared Resources and other services has strengthened their Research Program

6. For consortium centers, describe any changes to the integration of the scientific activities among members from all institutions included in the Research Program.

7. Include future plans for new scientific capabilities, directions, and opportunities, and their potential impact on the goals and objectives of the Program.

Exclusions:

1. Include a list of twenty-five program-related publications of the current year. Highlight those that illustrate inter-and intra- programmatic collaborations or other multi-institutional collaborations.

    a. PubMed Central (PMC) ID numbers are required 1) for all publications that are funded directly through the CCSG via developmental or Early Phase Clinical Research Support funds, 2) those publications that use CCSG-supported shared resources, and 3) those with NIH support through other mechanisms. Divide the publications list into 2 parts, those with a PMC ID (i.e., meeting the criteria above) and those without.

        i. http://www.pubmedcentral.nih.gov/
        ii. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html
        iii. http://publicaccess.nih.gov/

Shared Resources:

2 pages/ Shared Resource

1. Discuss any changes to roles or functions of Resource Leadership

2. Report any major changes made in the resource's scientific and/or technical capabilities. Discuss the importance of these changes on the scientific productivity of the research activities it serves.

3. Include any changes in the proportional to use by investigators within the cancer center that have cancer-related peer-reviewed funding

Clinical Protocol and Data Management:

1 page

1. Discuss any changes to the centralizing, managing, and reporting process
2. Discuss any changes to the timeline of CPDM processes related to trial initiation and completion
3. Discuss any changes to the quality control functions and training services offered by the CPDM
4. How has your Center's DSMP undergone any changes? (Yes/ No)
    a. Indicate its last revision date
    b. If your Center's DSMP has changed, submit a tracked and clean version of your Center's DSMP plan under a separate cover to Dr. Henry Ciolino at henry.ciolino@nih.gov

Protocol Review and Monitoring System (PRMS):

1 page, exclusive of membership roster

1. Discuss any changes to the PRMS's authorities and processes for initiating, reviewing, prioritizing, monitoring and terminating all cancer clinical research protocols

Exclusions:

1. List the members of the PRMS committee, their title, and their expertise.

Early Phase Clinical Research Support:

1 page, exclusive of the list of studies

1. Discuss any changes in the process used for prioritizing studies
2. Describe the proposed uses of EPCRS funds for the coming project period (e.g. areas to be supported and examples).

Exclusions:

1. List all studies supported with EPCRS funds over the last 12 month project period.

    Include the investigator name, project name, phase, anatomic site (if applicable), duration, and outcome or impact (e.g., led to peer-reviewed funding for a later phase

trial, a publication, a revised scientific approach, identification of investigational agents for further development or novel probes, etc.).

Inclusion of Minorities and Women in Clinical Research:

1 page

1. Discuss any changes to the accrual of women and minorities to interventional therapeutic, non-therapeutic trials, and to non-interventional studies
2. Discuss any changes to and the effectiveness of the plans and processes for monitoring and improving recruitment.

Inclusion of Children in Clinical Trials:

1 page

1. Discuss any changes to plans recruitment of children.

Human Subject's Research:

1 page

1. Was the research approved by the full IRB panel or an Expedited Review panel?

Data Sharing Plan:

1 page

1. Discuss any changes to your Center's Data Sharing plan

Human Embryonic Stem Cells:

1 page

1. Does the Progress Report propose a change in the use of human embryonic stem cells?

Biohazards:

1 page

1. Are there any biohazards involved?

Checklist:

1. Complete the Type 5 Checklist as described in the PHS 2590 Form (rev. 06/2009)

   http://grants.nih.gov/grants/funding/2590/2590.htm

All Personnel Report:

1. Complete the All Personnel Report as described in the PHS 2590 Form (rev. 06/2009)

   http://grants.nih.gov/grants/funding/2590/2590.htm

Supplements:

Not to exceed 2 pages/ Supplement, exclusive of grant and/ or publication list

1. The supplement number (i.e. CA123456-03S1 or CA97654-43S2)
2. The "common" name of the supplement (i.e. "CTRP or CURE")
3. Issue date of the supplement's NGA
4. Does the Center expect there to be any carry forward funds into the next budget period?

   If so, what is the proposed end date for the supplemental work to be completed and the funds to be spent?
5. State the goals of the supplement
6. Describe the scientific progress and achievements made towards the goals of the supplement during the last twelve months. Emphasize the most significant published scientific accomplishments and indicate how the center has facilitated these accomplishments. Provide citations and PMCID numbers for accomplishments discussed and grant applications submitted as appropriate.
7. Address any supplement-specific progress requirements included in the FOA