Policies and Guidelines Relating To the P30 Cancer Center Support Grant

(For applications submitted on or after January 25, 2013)

National Institutes of Health/ DHHS
National Cancer Institute
Office of Cancer Centers

6116 Executive Blvd.
Bethesda, MD 20892-8345
http://cancercenters.cancer.gov/

September 25, 2012

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SECTION 1. PHILOSOPHY & POLICIES

1.1 BACKGROUND

The National Cancer Act officially established the Cancer Centers Program in 1971.The legislation was based on the report of a congressional committee, which concluded that a formalized cancer centers program would provide a unity of purpose, a centralized platform for sharing concepts and resources, and a management structure necessary to achieve progress toward the goal of preventing and curing cancer. The Act grandfathered in twelve existing centers that were already receiving support through diverse NCI grants and contracts and authorized the establishment of additional centers. It also implemented a standard funding mechanism (the P30 Cancer Center Support Grant or CCSG) and guidelines, and created an administrative and organizational home for the program at the NCI.

1.2 PURPOSE

Based on this early legislation, qualified applicant institutions receive the CCSG award and accompanying NCI designation for successfully meeting a spectrum of rigorous competitive standards associated with scientific and organizational merit. While CCSG requirements have evolved over the years, the grant continues to support research infrastructure that enhances collaborative, transdisciplinary research productivity. CCSG grants provide funding for formalized cancer research Programs, shared research resources, scientific and administrative management, planning and evaluation activities, development of new scientific opportunities, and centralized clinical trial oversight and functions.

Although the CCSG does not directly fund the wider range of activities at cancer centers, an NCI-designated Cancer Center links state-of-the-art research and care, thus perpetuating the translational continuum. To decrease cancer incidence and mortality among populations within its catchment area[1], including minority and underserved populations, it also establishes partnerships with other health delivery systems and state and community agencies for dissemination of evidence-based findings.

Over the past several decades, the number of NCI-designated Cancer Centers has grown extensively – today they are in a variety of organizational settings across the United States. An NCI-designated Cancer Center is a local, regional, and national resource, directly serving its community and, through the knowledge it creates, the nation as a whole.

[1] The catchment area must be defined and justified by the center based on the geographic area it serves. It must be population based, *e.g.* using census tracts, zip codes, county or state lines, or geographically defined boundaries. It must include the local area surrounding the cancer center

1.3 FEATURES OF AN NCI-DESIGNATED CANCER CENTER

A Policy of Inclusion: An NCI-designated Cancer Center capitalizes on all institutional cancer research capabilities, integrating cancer related programs in basic laboratory; clinical; and prevention, cancer control and population-based sciences into a single transdisciplinary cancer center research enterprise across departmental, school, and institutional boundaries. A major test of both institutional commitment and the quality of center leadership is to strengthen and unite all major areas of research present within the institution(s), and to harmonize research with education, service, and care.

Excellence in Cancer Research: All NCI-designated Cancer Centers excel in cancer research. Successful cancer centers have scientifically rigorous research, supported by peer-reviewed grants from the National Institutes of Health (NIH) and other sources and organized into formal collaborative cancer-focused Programs (for a definition of Program as it relates to the CCSG, see Section 2.8).

Education and Dissemination: Cancer centers integrate training and education of biomedical researchers and health care professionals, including those from underserved populations into their programmatic research efforts, thereby furthering the scientific mission of the center. Centers also disseminate their medical advances as rapidly as possible via professional and public education and partnerships with public health or clinical service delivery systems, thus ensuring benefit to patients, professionals, and the general public.

1.4 THE SIX ESSENTIAL CHARACTERISTICS OF NCI DESIGNATED CANCER CENTERS

A successful NCI-designated Cancer Center demonstrates strength in six essential characteristics. Together these characteristics maximize its scientific potential and produce a whole that is greater than the sum of its parts:

- **Facilities:** Physical facilities dedicated to the conduct of cancer focused research, and to the center's shared resources, and administration, are appropriate and adequate for the task.
- **Organizational Capabilities:** The center takes maximum advantage of institutional capabilities in cancer research, engaging in appropriate planning and evaluation of Center strategies and activities. It also has a process for integrating education and training of biomedical researchers and health care professionals, including those from underserved populations, into programmatic research efforts. In addition to addressing research questions of broad applicability, it uses its available expertise and resources to address cancer research within the catchment area[1].
- **Transdisciplinary Collaboration and Coordination:** Substantial coordination, interaction, and collaboration, both among center members from a variety of disciplines and between center members and investigators in other institutions, enhance and add value to the productivity and quality of research. As appropriate to the nature of the research, centers facilitate transition of scientific findings through the translational

continuum, via coordination of research across NCI and other funding mechanisms and through collaborations with other partners.

- **Cancer Focus:** The center members' grants and contracts, as well as the structure and objectives of its formal research Programs, demonstrate a clearly defined cancer research focus.
- **Institutional Commitment:** The center is a formal organizational component of the institution, with sufficient space, positions, and discretionary resources to ensure its stability and fulfill the center's objectives. The center director has authorities appropriate for managing the center and furthering its scientific mission. The institution recognizes team science in its promotion and tenure policies.
- **Center Director:** The director is a highly qualified scientist and administrator with leadership experience and expertise appropriate for establishing a vision for the center, advancing scientific goals, and managing a complex organization. He or she is effective in using institutionally designated authorities to manage the center and advance its scientific objectives.

1.5 TYPES OF CENTERS

Cancer centers have developed in many different organizational settings, reflecting considerable diversity in the size and complexity of their research emphases. Whether organized as a freestanding center, a center matrixed within an academic institution, or a formal research-based consortium under centralized leadership, all centers are peer-reviewed by the same scientific, organizational, and administrative criteria. There are two types of NCI-designated cancer centers:

- **Cancer Centers** have a scientific agenda primarily focused on basic laboratory; clinical; and prevention, cancer control, and population-based science; or some combination of these components. All areas of research are linked collaboratively. While not all basic findings require a translational endpoint, basic laboratory centers develop linkages with other institutions that will foster application of laboratory findings for public benefit where appropriate.
- **Comprehensive Cancer Centers** demonstrate reasonable depth and breadth of cancer research activities in each of three major areas: basic laboratory; clinical; and prevention, control and population-based science. Comprehensive cancer centers also have substantial transdisciplinary research that bridges these scientific areas. They are effective in serving their catchment area[1] as well as the broader population, through the cancer research they support. They integrate training and education of biomedical researchers and community health care professionals into programmatic efforts to enhance the scientific mission and potential of the center.

1.6 MAJOR RESEARCH AREAS OF CANCER CENTERS AND TYPES OF INTERACTIONS

An NCI-designated cancer center should feature vigorous interactions across its research areas, facilitating collaboration between basic laboratory; clinical; and prevention, control and population-based science investigators and the formal research Programs of which they are a part. The organizational approach should serve the science of the institution, with reasonable breadth and depth of cancer-focused scientific faculty and dedicated research facilities.

In addition, centers should ensure that they are both fostering basic discovery and, as applicable, facilitating transition of scientific findings through the translational pipeline (*i.e.*, basic to pre-clinical and early clinical development, then to Phase III trials or other types of definitive studies appropriate to the nature of the research). Discoveries may be advanced through NCI and other peer-reviewed translational science and clinical trial funding mechanisms (*e.g.* grants for SPOREs, program projects, phase I/II consortia, and the NCI National Clinical Trials Network or NCTN) and other collaborative strategies, including external partnerships. All centers are encouraged to establish collaborative links that maximize productivity and result in appropriate application of findings. The form and extent of these activities may vary, based on the type of center.

Depending on center type, the major research areas may include:

- **Basic Laboratory Research:** Centers use their base of support to promote breadth and depth in basic laboratory research and transdisciplinary collaborations among investigators in basic discovery and other research areas, both within the Center and with other external partners.
- **Clinical Research:** Cancer Centers engage in a broad spectrum of clinical studies with diverse forms of sponsorship. A Cancer Center is a major source of innovative investigator-initiated clinical studies that can be exported to NCI's NCTN or other appropriate externally peer-reviewed funded mechanisms. Clinical studies involve relevant laboratory research whenever possible. Cancer centers foster translation between the laboratory and clinic, conduct early proof-of-principle clinical trials and lead, and/or participate in, NCI's NCTN trials (including studies of rare cancers). They also participate in trials initiated by industry and other external partners.
- **Prevention, Control, and Population Science Research:** While cancer centers may not be able to conduct research in all aspects of prevention, cancer control, and population science, and no one area is required, they demonstrate depth in grant support across several thematic areas (*e.g.*, epidemiology, primary prevention, early detection, health services, dissemination, palliation, and survivorship). They also demonstrate appropriate collaborative links to other research areas within the center and with external partners.

1.7 CONSORTIUM CENTERS

NCI supports consortium centers in which investigators from distinct scientific institutions partner together to contribute actively to the development and actualization of the cancer

research agenda; these formalized relationships have the potential to both strengthen the science of the center and further extend the benefits of cancer research. Partnerships between research institutions serving special populations or located in geographic areas not currently served by an NCI-designated Cancer Center are particularly encouraged.

Three basic principles apply to consortium arrangements in the context of the NCI designation:

- **Each member institution adds strategic value to the research mission of the cancer center, *i.e.*, holds a portfolio of peer-reviewed cancer related research grants that contribute to the center's scientific goals.** The terms applied to these research partnerships may vary, *e.g.*, some centers may refer to the arrangement as a research affiliation, rather than a consortium. Consortium centers in the CCSG context are clearly distinguished from other types of partnerships, however, such as clinical networks or affiliations with community hospitals designed primarily for the purpose of enhancing clinical trial accrual or expanding the center's patient base.
- **At the time of application for a CCSG, the partnering institutions already function as one cohesive cancer center.** Their research must be integrated (as evidenced by a history of collaboration, including joint grants and publications) and mechanisms must exist for including geographically dispersed members in programmatic activities. Common fundraising and a joint Internal Review Board for evaluation of all cancer research across the partner institutions are encouraged, but not required.
- **A formal, written agreement is in place to ensure the stability and integration of the consortium partnership.** The agreement should include:
    - A process for resolution of differences at the highest levels of institutional leadership.
    - A single Protocol Review and Monitoring System and Data and Safety Monitoring Institutional Plan governing cancer clinical trial protocols across all partner institutions.
    - An integrated planning and evaluation process that enables achievement of the center's research goals, (*e.g.* identification of future recruitment needs, shared resources; and other activities).
    - Ongoing, tangible institutional commitments to the cancer center from all consortium partners. Such commitments should be appropriate to the nature of the consortium and may be demonstrated in a number of ways, including financial and in-kind contributions based on agreed upon formulas, housing and funding of cancer center cores, accrual to center-wide trials, active representation and engagement of members in Cancer Center Programs and committees, etc.
    - Full eligibility for membership in formal scientific Programs and leadership positions in the center
    - Reasonable access to shared resources for all members.
    - Center director oversight of CCSG-supported shared resources, including those located in partner institutions.

1.8 BUDGET AND FUNDING POLICIES

Time Limitations: CCSG awards are for periods of up to five years.

Some Restrictions on Allowable Budgets: Requested and/or awarded funds may not duplicate or replace costs normally included in the institution's indirect cost base or services and benefits normally provided by the institution (*e.g.*, purchasing, personnel, and other ancillary services) to other departments, schools, or institutes. CCSG funds should not be used to compensate for NIH/NCI administrative reductions of active awards, or to pay for shortfalls in funded research projects. They cannot supplement or offset any patient costs, even those directly related to clinical research protocols.

Renewal (Type 2) Applications - Size of Direct Cost Budget Request (Interim Policy): Renewal applications with an existing direct cost award equal to or greater than $6,000,000 are capped at their current direct cost budget level. Renewal applications below this level may request a direct cost budget of $1, 000,000, regardless of the prior award level, or 10% above the direct costs in the last year of their non-competing project period, whichever is greater. The budget in subsequent years may receive cost-of living adjustments, depending on the NCI policy in effect for the fiscal year.

Larger budget increases should be requested only under exceptional circumstances (*i.e.*, first recompeting application after a no-cost extension or reduced award). OCC program staff should be consulted prior to submission of such a request. Centers should clearly describe the unique circumstances leading to a larger budget request and provide compelling justification.

See Funding Policies, below, for information on awards.

New (Type 1) Applications: Budget requests from a center with no current CCSG grant should not exceed $1,000,000 direct costs for year one (the budget in subsequent years may receive cost-of living adjustments, depending on the NCI policy in effect for the fiscal year). The cap on the budget request for a first-time application is predicated on the limited track record of the applicant organization. The NCI may consider an exception to the cap in cases where a prior CCSG award was phased out due to a non-fundable priority score.

Resubmissions: Resubmission applications must include an introduction addressing the previous peer review critique (Summary Statement). The time limit on resubmission applications is 37 months from the date of the original submission; after that time, the application must be submitted as new. See the NIH policy on resubmission (amended) applications (http://grants.nih.gov/grants/guide/notice-files/not-od-09-003.html NOT-OD-09-003, NOT-OD-10-140 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-016.html).

Revisions: These applications support a significant expansion of the scope of the P30 CCSG. The parent award must be active at the time of the revision application and no-cost extensions, where applicable, must be in place. The project director/principal investigator (PD/PI) must be the same as that for the parent award. Revisions to the P30 CCSG are accepted only in response to targeted NIH funding opportunity announcements listed in the NIH guide and must undergo peer review.

Administrative Supplements: Depending upon the availability of funds, the NCI will consider administrative supplements to CCSGs to pursue important, short-term scientific opportunities that need immediate attention or could not be initiated and sustained through the normal, competitive grant process (*e.g.*, R01s). Interested centers should contact the program director of their grant to inquire about availability of such funds.

Funding Policies: Peer review plays a major role in assessing the merit and budget justification of new, renewal, resubmission, and targeted revision applications. Actual award levels, however, are dependent upon the overall NCI Fiscal Year budget and the budget established specifically for the Office of Cancer Centers. Additional factors that may influence funding levels for cancer centers include the scientific priorities of the NCI, the entry of meritorious new centers into the program and the need to ensure representation of underserved populations. As award levels are determined by multiple considerations, actual funding may not be concurrent with requested or peer-approved budgets, *i.e.*, actual funding may increase, decrease, or remain stable even when the merit of the application is high or exceptional circumstances exist.

Applications not selected for an award may receive no funding (new, renewal, resubmission, or targeted revision applications) or phase-out funding (renewal applications). During a period of phase-out funding, the center can submit a resubmission application addressing the concerns of peer review.

Non-competing (Type 5) applications are paid in accordance with NCI policies established each fiscal year. In years of significant budgetary constraint, funding plans may spread the impact over the entire program (non-competing as well as competing grants). If funds become available in future years, restorations may be considered.

Carryover of Unobligated Funds: CCSGs are administered under the provisions of NIH Terms of Award (http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch8.htm). Requests for carryover of unobligated funds will be reviewed by NCI to ensure funds are necessary for completion of the project; additional information, including a revised budget, may be requested from the grantee as part of this review. If it is determined that some or all of the unobligated funds are not necessary to complete the project, the NCI may take one of several actions: 1) use the balance to reduce or offset funding for a subsequent budget period, 2) restrict the grantee's authority to carry over future unobligated balances, or 3) a combination of items 1 and 2, above. The Federal Financial Report must specify the amount to be carried over. Any amount not specified for carryover may be used to offset the award in a subsequent budget period.

Re-budgeting: Cancer centers have flexibility to move funds between budget areas in response to changing needs and opportunities. With the exception of restricted categories, such as developmental funds, the center director may increase any budget area rated at least excellent by up to 25 percent over the peer-approved level without prior NCI approval. Re-budgeting of funds into areas rated less than excellent by peer review requires prior NCI approval. To ensure appropriate peer review, centers may establish new components (*i.e.*, research Programs, shared resources not currently supported by CCSG developmental funds, etc.) only at the time of a renewal (T2) or competitive revision application.

NIH Policy Relative to Program Income: Income realized from grant-supported activities (*e.g.*, from CCSG supported shared resources) must be reported in the budget/financial statements accompanying annual progress reports and on the annual financial status report, in accordance with NIH Grants Policy. The "additive cost alternative" will apply to the first $25,000 of program income. Unless approved for use otherwise, program income in excess of $25,000 will be deducted from the next year's award.

SECTION 2. ELIGIBILITY REQUIREMENTS, PRE APPLICATION CONSULTATIONS AND INSTRUCTIONS FOR SUBMISSION

2.1 BACKGROUND

The NCI awards P30 CCSGs to qualified applicant institutions that have successfully met a series of competitive standards associated with scientific and organizational merit. The purpose of a CCSG is to foster meritorious science and productive interactions within institutions that already have a substantial cancer-related research base. The application and supporting materials should be presented in sufficient detail to convince peer reviewers that all requests for resources are justified.

2.2 ELIGIBILITY REQUIREMENTS

- Only research institutions in the U.S. are eligible to apply.
- Only one CCSG application per institution may be submitted.
- An applicant institution must have a base of at least $10,000,000 in annual direct costs of peer-reviewed, cancer-related funding. If the cancer center is a consortium of institutions, the funding base of the center will be the sum of the funding bases of all participating institutions.
- **Sources of Support That May Be Included for Determining Eligibility to Apply for a CCSG are:**
    - *NCI* peer-reviewed grants, cooperative agreements, and contracts: R00, R01, R03, R15, R18, R21, R24, R25, R33, R37, R41, R42, R43, R44, R55, R56, P01, P20, P30s other than the CCSG, P50, SC1, SC2, U01, U10, U19, U54, U56, T32, K and F series awards and N01s (excluding SEER and other N01s funding materials, services, or research resources).
    - *Other NIH Institutes and Approved Funding Organizations*. Submit non-NCI support information to determine the eligibility of applicants for a CCSG *only* if the applicant's NCI support is below the minimum. Peer-reviewed, cancer-relevant grants and research contracts from other NIH institutes, and a number of other approved funding organizations can be included. An updated list of approved organizations is available at http://cancercenters.cancer.gov/documents/NCIApprovedFundingOrganizations508C.pdf

TABLE 2-1. KEY DATES IN GRANT APPLICATION, REVIEW AND FUNDING PROCESS

Letter of Intent	July 25	November 25	March 25
Pre-application Consultation	Sept-Nov	Jan-Mar	May-Jul
Application Due Date	January 25	May 25	September 25
Site Visit	May-Jun	Sept-Oct	Jan-Feb
Review Committee Meeting	Aug	Dec	Apr/May
NCAB Meeting	Sept/Oct	Jan/Feb	May/June

2.3 LETTER OF INTENT AND PRE-APPLICATION CONSULTATION

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NCI staff to estimate the potential review workload and plan for the review.

By the date listed in Table 2-1, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Name, address, and telephone number of the PD(s)/PI(s)
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

The LOI should be sent to:

Director, Office of Cancer Centers
National Cancer Institute
National Institutes of Health
6116 Executive Blvd, Suite 700, MSC 8345
Bethesda, Maryland 20892-8345 (for Express mail, use Rockville, M20852)
Tel: 301.496.8531
Fax: 301.402.0181

In addition, a pre-application consultation with NCI staff is highly recommended. Pre-application consultations are conducted via an in-person meeting or videoconference. The consultation should be scheduled well in advance of the application receipt date. NCI staff will respond to questions, clarify the intent of the guidelines, discuss strategies for preparing a competitive application and funding trends, and describe the peer-review process.

The following are specific examples of items that help NCI staff understand the plan of the first-time applicants:

- Background and responsibilities of the cancer center director and the key senior leaders of the center.
- Diagram showing the reporting, programmatic, and advisory structure of the center; its relationship to the organizational structure of the institution as a whole; and a list of external advisory board members.
- How the center expects to meet the six essential characteristics of an NCI-designated cancer center.
- Proposed scientific Programs and their projected leadership.
- List of all active peer-reviewed, approved research grants, cooperative agreements and contracts, grouped by the formal scientific Programs that will form the total research base of the cancer center, preferably in Data Table (Summary) 2 format.
- List of active clinical research of the center, preferably in Data Table (Summary) 4 format.

2.4 INSTRUCTIONS FOR SUBMITTING THE CCSG APPLICATION

Where to Send the Application: Submit one original and three copies of the CCSG application to the Center for Scientific Review (CSR), NIH, according to the instructions in the PHS Form 398 (rev. 06/09) kit. For a new, renewal, resubmission, or competitive revision application, enclose a cover letter naming the NCI staff person who agreed to accept the application for consideration.

At the same time you submit the application to CSR, please send two complete copies to the NCI at the address below to facilitate scheduling and determination of whether additional information is needed for the review. The NCI address is:

Referral Officer
National Cancer Institute
National Institutes of Health
6116 Executive Blvd, Room 8004, MSC 8329
Bethesda, Maryland 20892 – 8329 (for Express mail, use Rockville, MD 20852)
Tel: 301.496.3428
Fax: 301.402.0275

Acceptance of the Application: A Scientific Review Officer (SRO), located in NCI's Division of Extramural Activities oversees the peer-review process. Between submission and the completion of the peer review process, direct all communication to the SRO responsible for the CCSG review. The SRO supervises the review process to ensure a technically competent and unbiased review. While the application is in review, the SRO may consult NCI program staff on program policies and guidelines.

Upon receipt of an application, the SRO conducts a thorough review of the submitted materials with attention to the following elements:

- **Conformity with Guidelines:** Applications should exhibit the general organizational, administrative, and operational structure of cancer centers and request allowable and appropriate costs as per these guidelines.
- **Format:** Applications should be prepared in conformity with the PHS Form 398 (rev. 06/09) instructions to facilitate review of the submission.
- **Completeness of Required Information:** The applicant should ensure that all essential information is presented completely and unambiguously, to facilitate the quality and consistency of the review.

If an application is deficient in the elements above, depending upon the magnitude of the problem, the responsible NCI staff may:

- Defer the application to a later review cycle
- Return the application to the applicant without review

Modifications after Submission:

Only modifications of the application, as defined by NIH revised policy on submission of late grant application materials prior to initial peer review can be accepted. Post-submission grant application materials are those submitted after submission of the grant application but prior to the initial peer review. This option is not to be used to correct oversights/errors discovered after submission of the application; see NIH revised policy for details (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-115.html).

Acceptable post-submission materials include:

- Revised budget page(s), (*e.g.*, change in budget request due to new funding or institutional acquisition of equipment).
- Biographical sketches (*e.g.*, change in senior/key personnel due to the hiring, replacement, or loss of an investigator).
- Letters of support or collaboration resulting from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator.
- Adjustments resulting from natural disasters (*e.g.*, loss of an animal colony).
- Adjustments resulting from change of institution (*e.g.*, PI moves to another university).
- News of an article accepted for publication (a copy of the article should not be sent).

Unacceptable post-submission materials include:

- Updated Specific Aims or Research Strategy pages.
- Late-breaking research findings.
- New letters of support or collaboration that do not result from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator.

A request for major modifications may result in deferral by the SRO to the next round of receipt and review.

Inquiries about the Application after Submission: Before completion of NCI Subcommittee-

A Review (see Part III, NCI Subcommittee-A Review) direct inquiries to the SRO, who is responsible for all aspects of the peer review process.

After completion of the NCI review, address questions to the responsible program director in the OCC or, for fiscal questions, the Grants Management Specialist.

Applicants may not contact any member of the site visit team or NCI Subcommittee-A about the review.

2.5 Formatting Instructions and Review Criteria for Specific Components of New and Competing Continuation CCSG Applications

These formatting instructions supplement those of the PHS Form 398 (rev. 06/09). Adherence to these instructions will assist peer reviewers in identifying sections of the application and in matching them with the corresponding review criteria.

Page Limits: These apply only to the narrative parts of each section including descriptions, objectives, goals, rationale, accomplishments, tables, figures, charts, etc. They do not include budget pages; budget justifications; biographical sketches; references or publication lists; tables on clinical trial accrual, or lists of grants. Page limits are not meant to suggest the optimal length of sections.

2.5.1 Face Page

The "Project Director/Principal Investigator" is the cancer center director or designee; the "Applicant Institution" is the fiscally responsible institution of which the cancer center is a part.

2.5.2 Description, Performance Sites, and Key Personnel

Provide a description, limited to the space provided on page 2 of the PHS Form 398 (rev.06/09); of the CCSG-related organization and formal research Programs of the cancer center, and of the request for support through the CCSG. Provide a list of performance sites (including hospitals) and key personnel as per PHS Form 398 (rev. 06/09) instructions.

2.5.3 Table of Contents

Include for all major sections and subsections of the application.

2.5.4 Consolidated and Summary Budget Request

Prepare per PHS Form 398 (rev. 06/09) instructions.

2.5.5 Resource Section: Supportive Data (Standard Cancer Center Summary Information, No Page Limit)

These data tables (see 2013 CCSG Data Guide) for instructions and formats) itemize the center's formal research Programs, shared resources, base of funded research projects, patient information, clinical research protocols, and a comparison of current and requested budgets.

- **Data Tables (Summaries) 1a, b, c, and d** list the Center's senior leadership (*e.g.*, cancer center director, deputy director, and associate directors), leadership of the proposed Programs and shared resources, and cancer center membership.
- **Data Table (Summary) 2a** lists all active cancer-related projects competitively funded by sources external to the fiscally responsible institution of which the cancer center is a part, as of the date of preparation of the data table. Grants are listed alphabetically by PD/PI in two parts – active, funded peer reviewed research and training projects and active non-peer reviewed research and training projects.
- **Data Table (Summary) 2b** provides a consolidated list of the funding by category. Together with Data Table 2a, it indicates the size and scope of the funded research base of the center.
- **Data Table (Summary) 3** provides cancer registry data regarding the numbers of patients newly diagnosed and treated at the cancer center and the number placed on treatment studies by cancer site during a recent 12-month period. (Note: Data Tables 3 and 4 may not correlate and should not be cross-referenced.)
- **Data Table (Summary) 4** lists clinical research protocols open at the center during a recent 12-month period, sorted by Program, category of research, sponsor, and PD/PI. (Note: Data Tables 3 and 4 may not correlate and should not be cross-referenced.)
- **Data Table (Summary) 5** lists the current (last full non-competing year) and requested CCSG budgets in each CCSG budget category. See the section on Budget and Funding Policies in Part I for guidance on request limits.

2.6 HISTORY AND DESCRIPTION OF THE CANCER CENTER SPECIFICALLY DESCRIBING THE SIX ESSENTIAL CHARACTERISTICS OF THE CANCER CENTER

2.6.1 Director's Overview (limit of 12 pages)

Provide a short history and overview of the cancer center, especially its research activities. Briefly describe the most important research accomplishments during the last period of support and the vision and general plans for the future scientific development of the center. If you are presenting a consortium center, clearly outline the contributions of each institution, and the history, objectives, and benefits of the consortium arrangement.

2.6.2 Six Essential Characteristics of Cancer Centers

Describe specifically the structure of the cancer center with respect to:

Facilities (limit of six pages):

Centers are more successful in establishing an identity if they have a distinct physical location. Not all members of the cancer center need be physically located in facilities controlled exclusively by the center; however, location of members across program areas (basic laboratory; clinical; and prevention, control, and population-based science) in close physical proximity enhances shared use of resources and facilitates scientific interactions. Even if proximity is impossible, center shared resources and other services should still be reasonably accessible to all members.

In your application, discuss the size and other characteristics of the physical facilities dedicated to cancer research, center shared resources, and administration. Provide a map that illustrates the main location of the center's research and administrative activities, and the physical relationship of any consortium institutions to the main campus. Indicate how the center facilitates access to shared resources and other services (*i.e.*, Clinical Protocol and Data Management).

The following review criteria apply to this characteristic (merit descriptor):

- How adequate and appropriate are the center's space and physical facilities to its identity, objectives, and activities?
- How is reasonable access to shared resources and other services and resources facilitated for all members?

Organizational Capabilities (limit of 12 pages):

A center should have an overall programmatic structure that effectively promotes collaborative scientific interactions both within the institution and with external partners. It should take maximum advantage of the institution's cancer research capability (this is particularly important to explain when the center includes multiple participating institutions in a consortium arrangement), as well as an efficient and cost-effective administrative organization with clear lines of authority. It should sponsor or participate in education and training of biomedical researchers and health care professionals, including those from underserved populations, and have a process for integrating these activities into programmatic research efforts (the nature and range of these activities may vary by type of center). In addition to scientific questions of broad applicability, it should use its available expertise and resources to address cancer research within the catchment area[1] (See Section 2.8.5).

While a formal written strategic plan is not required, methods used by the center to obtain effective internal and external advisory committee input, set priorities, make decisions, and evaluate center plans and activities should be established and clearly documented, including those for determining and sustaining individual membership in the center.

Using the above description, discuss the organizational structure, capabilities, and processes of the center.

Consortium centers should include a discussion of how differences are resolved among partners and how planning and evaluation processes are integrated to meet the strategic goals of the center, including those for clinical trials, faculty recruitment, and other research activities. A

copy of formal written agreements documenting specifics of consortium arrangements and commitments relative to CCSG requirements should be made available at the site visit.

The following review criteria apply to this characteristic (merit descriptor):

- How effective is the center in taking full advantage of institutional capabilities in cancer research, and in fostering scientific interactions and joint initiatives among programmatic elements and with external partners?
- How successful is the center in establishing an efficient and cost effective administrative organization with clear lines of authority?
- How effective are strategic planning and evaluation processes for the conduct of center activities, including use of external and internal cancer center advisory bodies?
- In addition to addressing scientific questions of broader applicability, is the center organized to apply its expertise and resources to cancer research relevant to the catchment area[1] it serves?
- How appropriate is the center's process for integrating training and education of biomedical researchers and health care professionals, including members of underserved populations, with programmatic research efforts?
- For consortium centers, how adequate are the mechanisms in place for ensuring:
    - Differences can be resolved among consortium institutions?
    - An integrated planning and evaluation process that enables achievement of the center's research goals?
    - The partnership is stable, as evidenced by a history of research integration and the provisions of formalized agreements?
    - All members have reasonable access to shared resources and other services, participate in scientific Programs, and may assume leadership positions in the center, even if partner institutions are geographically dispersed?

Transdisciplinary Collaboration and Coordination (limit of 12 pages):

An actively functioning center promotes innovative and interactive research opportunities through the formation of formal research Programs, comprised of groups of investigators who share common scientific interests and goals and participate in competitively funded research and in publications and other interactive activities. Inter- and intra-programmatic collaborations are important, as well as collaborations with external partners. These activities maximize the potential of the institution, whether small or large, to conduct transdisciplinary and translational research.

Movement of scientific findings through the translational pipeline (*i.e.*, basic to pre-clinical and early clinical development, then to Phase III trials or other types of definitive studies appropriate to the nature of the research) is also critical. NCI and other peer-reviewed translational science and clinical trial funding mechanisms (*e.g.*, grants for SPOREs, multi-investigator R01s and program projects, phase I/II consortia, and the NCI National Clinical Trials Network) are important avenues for advancing discoveries originating in the center, and coordination of research across these mechanisms is strongly encouraged. Collaborative strategies may involve investigators within the cancer center, investigators in other centers, industry, or other partners.

The form and extent of these activities may vary, based on the type of Center, but all Centers are encouraged to establish collaborative links that result in appropriate application of findings, *i.e.*, not all transdisciplinary research is translational.

In this section, summarize the center's major scientific strengths, its principal research opportunities, and the transdisciplinary coordination and collaboration between cancer center members, including inter-and intra-programmatic collaborations and those involving consortium institutions. Provide a brief description of how the center fosters transdisciplinary collaboration through collaborative research projects, joint publications, retreats, working groups, colloquia, joint seminar series, and other types of meaningful interchange that cement interactions around related or common goals. The type and balance of activities will vary from center to center. Discuss how productivity and quality of translational research in the center are enhanced by these collaborations and the mechanisms used by the center to promote interactive research opportunities. Describe strategies that have promoted appropriate movement of findings through the translational and clinical continuum both within and outside the Center, including coordination across NCI and other translational science and clinical funding mechanisms.

Consortium applications also should document the integration of research Programs and activities across the partner institutions, as well as cross-institutional access to center resources and participation and leadership in Programs.

The following review criteria apply to this characteristic (merit descriptor):

- How effective is the center in promoting transdisciplinary and/or translational collaborations among basic laboratory; clinical; and prevention, cancer control, and population science cancer center members?
- To what extent have collaborations within and among (intra- and inter-programmatic) Programs added value to cancer related scientific activities?
- How effective is the center in moving scientific findings forward to cancer-related endpoints appropriate to the nature of the research, through internal collaborations and/or external partners?
- For consortium centers, how adequate are mechanisms to ensure that:

    Research is integrated across partner institutions, as evidenced by programmatic structure and objectives, joint publications and grants and other transdisciplinary, cross-institutional activities?

Cancer Focus (limit of six pages):

A clearly defined scientific focus on cancer research is demonstrated via the center members' grants and contracts, by the structure and objectives of its formal Programs, and the collaborations between laboratory researchers and other investigators more directly concerned with application of research knowledge. NCI recognizes that cancer-relatedness should be a matter of flexible interpretation (*e.g.*, as with studies of basic mechanisms or of conditions or behaviors that influence a range of diseases), but the center should be prepared to demonstrate how the scientific research it supports through the CCSG is linked to cancer.

Based on the description above, discuss how the projects in the center's peer reviewed, funded research base and the collaborations between center investigators support the objectives of its cancer research Programs and reflect a scientific cancer focus.

The following review criterion applies to this characteristic (merit descriptor):

- What are the breadth, depth, and significance of the cancer-related research base, as judged by the structure and objectives of the Programs, peer-reviewed research support, collaborative publications, and other activities of center members?

Institutional Commitment (limit of 12 pages):

The NCI designation lends stature to an institution by attracting patients, industry research support, and philanthropy. The NCI substantially invests in cancer centers and expects similar commitment of the institution(s) to the center. Commitments of parent institutions to the cancer center generally include the following:

- An organizational status for the cancer center that is comparable or superior to that of departments.
- Funding from the institution and consortium partners.
- Research, clinical, and administrative space and positions.
- Measures that ensure other institutional leaders (deans, hospital presidents, and department chairs) will provide the long-term stable support necessary to accomplish strategic cancer center objectives.
- Joint control, at a minimum, with department chairs over faculty recruitments to the cancer center.
- A well-defined plan for a change in directorship and for continuing institutional commitment to support of the cancer center.
- Recognition of participation in team science in formal institutional policies, including those related to promotion and tenure.
- Authority of the center director:
    - As comparable or superior to that of department chairs, with appointments to decision making committees relevant to the cancer center and formally codified authorities.
    - Over specific research and resource space and equipment dedicated to the cancer center for the enhancement of center research capabilities.
    - Over inpatient and outpatient clinical research facilities and the appointment and evaluation of individuals critical to linking oncology care to clinical research.
    - Over faculty appointments to the cancer center, and of their periodic review for continued membership.
    - Over central discretionary funds (*e.g.*, philanthropic funds, facilities and administrative costs, and clinical revenues).

- In consortium centers, director oversight for integration of scientists in collaborating institutions into the research Programs of the center and CCSG-supported shared resources.

This section of your application should discuss the institutional commitment relative to the above description.

Include a letter signed by the Dean and Hospital President or other appropriate institutional officials documenting specifics of institutional commitment both for the long-term future of the center and for this award period.

The stability of a consortium is demonstrated via provisions of formal written agreements, the record of tangible contributions of each consortium institution to the cancer center, and the provisions of formal agreements.

The following review criteria apply to this characteristic (merit descriptor):

- To what extent has the institution (and consortium partners, where appropriate) met prior commitments and provided resources to ensure that the center reaches its full potential?
- How appropriate are resources committed to the center by the institution and any consortium partners for the next project period (*e.g.*, return of indirect costs, endowment income, and clinical income), and the processes for determining how funds will be used?
- For matrix centers, is there evidence that cancer center status is at least equivalent to that of an academic department and that other institutional leadership (department chairs, deans, etc.) provides support for strategic center objectives?
- How appropriate is the director's position within the institution and his/her representation on the decision-making committees relevant to center objectives ?
- How adequate is the authority of the center director over:
  - Appointment of new members and discontinuation of existing members?
  - Appointments of faculty necessary to enhance the research objectives of the center?
  - Inpatient and outpatient research facilities necessary to achieve the center's clinical research objectives (in centers with clinical research activities)?
  - Philanthropy, clinical revenues, or other funding streams?
- What is the adequacy of the institution's plan for dealing with a change in the directorship of the center?
- How well do institutional policies, including those related to promotion and tenure, recognize team science?
- For consortium centers, how adequate are the mechanisms for ensuring the center director has authority over integration of investigators from all partner institutions into the scientific Programs of the center and oversight over CCSG-supported shared resources in collaborating institutions?

Center Director (limit of six pages):

The director should be a highly qualified scientist and administrator with the leadership experience and expertise appropriate for establishing a vision for the center, advancing scientific goals and managing a complex organization. In a consortium, the director should play a major role in advancing the integration of the partner institutions into the research and other activities of the center. He or she should have an appropriate time commitment to the directorship role.

In your application, describe the scientific and administrative qualifications and leadership experience of the center director, as well as his/her time commitment to the center. Discuss activities of the director relative to overall management of the center and use of authorities and resources to advance the center's research mission.

The following review criteria apply to this characteristic (merit descriptor):

- How appropriate are the scientific and administrative qualifications and experience of the director for the center's research activities and objectives?
- How effective is the director in establishing a vision for the center and using authorities to further its scientific objectives?
- How appropriate is the director's time commitment to the center's scientific and management activities?
- For consortium centers, how effective is the director in advancing integration of the partner institutions?

2.7 DESCRIPTIONS, BUDGETS, AND NARRATIVE JUSTIFICATIONS FOR INDIVIDUAL CCSG COMPONENTS

Using the forms and instructions in the PHS Form 398 (rev. 06/09) for each allowable budget category for which funds are requested, prepare:

- A description
- A budget for the first 12 month Budget Period
- A summary budget for the entire Proposed Project Period

The CCSG provides reasonable costs for a great variety of activities clearly related to the research needs of the cancer center. The narrative describing the role and function of requested personnel should clearly justify the stated person months, whether or not you request salary.

The major categories of allowable costs are:

2.7.1 Senior Leadership

No more than one page of narrative per senior leader, plus five additional pages for narrative discussion of how the senior leaders work together.

Individuals in pivotal leadership positions in the center are eligible for salary support for the time and effort they devote to its research activities. Consider the breadth and complexity of the role of each senior leader to determine the appropriate level of effort needed to meet this responsibility (*i.e.*, there is no standard level of effort for all senior leaders).

Prepare a description and a consolidated budget of person months for all senior leaders and narrative justifications that carefully describe their roles. Follow each narrative with a biographical sketch see PHS Form 398 (rev. 06/09).

In a short 5-page description, discuss how the senior leaders have worked together to:

- Establish a vision for the center and address overall center goals, policies, and operations.
- Foster basic discovery and, as appropriate, implement strategies that advance early scientific findings via coordination across NCI and other funding mechanisms and collaborations with other external partners.
- Enable a focus on cancer research applicable to the catchment area[1] served by the center. (See Section 2.8.5)
- Establish a process for integrating the training of biomedical scientists and health care professionals, including those from minority and other underserved populations, into programmatic research efforts. This might include, for example, appointment of an Associate Director or center wide committee to focus on coordination, integration, and monitoring of education and training efforts; regularly scheduled meetings or retreats focused on training; formalized mentoring or career development programs; tracking of training outcomes for junior investigators; development of approaches for recruitment of trainees from underserved populations; and other activities. The range and nature of activities may vary based on type of center.

The form and extent of these activities may vary, based on the type of Center.

The following review criteria apply to this component (merit descriptor):

- How appropriate are the qualifications and effectiveness of each senior leader in relation to his/her role in the research activities of the center?
- How appropriate is the time commitment of each leader to needs and objectives of the center, and to the difficulty and complexity of his/her specific responsibilities?
- How effective is the senior leadership team in:
    - Establishing a future vision for the center and advancing goals and policies relevant to the center's progress?
    - Fostering basic discovery and appropriately advancing scientific findings?
    - Enabling a focus on cancer research relevant to the center's catchment area[1]?
    - Establishing a process for integrating training and education of biomedical scientists and health care professionals into programmatic research efforts?

2.7.2 Leaders of Scientific Research Programs

Budget pages only. Provide only a single consolidated budget that lists all Program leaders in the center and their person months. This is merely a consolidation of the separate budgets provided and justified in Section 2.8. Do not provide any narratives.

2.7.3 Planning and Evaluation (Limit of five pages)

Provide an overall description, a consolidated budget, and a narrative justification for each planning and evaluation activity. Costs of planning and evaluation might include support for the external advisory committee and ad hoc scientific and technical consultants; a seminar series, when the speakers or invited participants also serve as consultants for the center's scientific or administrative activities; retreats designed to stimulate transdisciplinary research opportunities; and the regular assessment of center goals and activities by the senior leadership.

The center should have a formal standing External Advisory Committee (EAC), appropriately balanced for basic laboratory; clinical; prevention, cancer control and population science; and administrative expertise. The EAC should meet at least once yearly, and provide objective evaluation and advice in a consensus report to the center director.

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. Discuss recommendations made by the EAC, any actions taken in response to those recommendations, or reasons for not responding. Provide a consolidated list of EAC members with titles and affiliations and attach their biosketches. Discuss how internal evaluation processes have affected center planning and implementation activities (*e.g.*, of shared and clinical resources, including institutional resources, and developmental funds) over the last project period. Although budgetary support for development of future scientific Programs is not allowable in the CCSG, plans for developing such Programs should be discussed in this section.

The following review criteria apply to this component (merit descriptor):

- How effective are internal advisory and evaluation activities for the development of the center's scientific activities?
- How effective is the center in using the advice of the EAC in advancing its scientific objectives?

2.7.4 Developmental Funds (Limit of 12 pages)

Developmental Funds are the major source of budgetary flexibility in the CCSG and should be linked substantially to the planning and evaluation activities of the center. These funds allow centers to take risks and strengthen weaker scientific areas. They also provide opportunities for exploring innovative ideas and new collaborations and technologies to center members.

The cancer center must centrally monitor and evaluate the effectiveness of all developmental funds. These funds can be administered flexibly - dispensed centrally by the director and senior leaders to achieve broad strategic objectives or delegated to individual Program leaders to target

specific scientific objectives. Developmental funds may not pay for training, routine equipment purchases, upgrades for established shared resources, or salary support for Senior or Program leaders or shared resource personnel. Developmental funds are restricted, and may not be rebudgeted to other CCSG categories during the course of the project period.

Prepare an overall description and a composite budget that includes all requested developmental fund categories. Explain how funds are linked to the strategic and programmatic priorities and scientific opportunities of the center, based on planning and evaluation activities. Provide individual budgets by category with separate narrative justifications. Narratives should summarize how past CCSG developmental funds were used, what was accomplished with them (*e.g.*, establishment of a new shared resource, number of recruitments and areas of expertise, and number of pilot projects resulting in peer-reviewed funding) and how the new request will be used to meet the center's strategic goals. If pilot projects are proposed, describe how the projects are reviewed for scientific merit and selected for funding.

Use of developmental funds is restricted to the following:

Recruitment of faculty level scientists in areas of strategic need: Judicious recruitments strengthen weak areas of science and enhance the center's overall research strength. Eligible investigators are: (1) those newly recruited from outside the parent institution, with developmental support beginning at the time of, or very soon after, arrival at the grantee institution. (2) those inside the institution who, whether junior scientists or well established in other scientific areas, are entering the field of cancer research as independent investigators for the first time.

Developmental funds may not be used to support costs associated with the recruitment process itself, training or tuition, or large equipment purchases, but may fund recruitment packages that include the staff needed (*e.g.*, technicians, graduate students, and postdoctoral fellows) to initiate the research program of a new investigator. The duration of support from these funds should not exceed 3 years. This category should provide temporary support permitting a new cancer investigator to establish his/her scientific activities at the new center and achieve independent funding. Developmental funds cannot support established cancer researchers already within the institution.

In your application, explain how these developmental funds were used in the previous 3 to 5 year grant period, specifying which investigators and projects were supported, the rationale for recruiting these investigators relative to the needs of the center, and to what extent these investigators were subsequently productive as evidenced by research grants, publications, and leadership/participation in clinical trials.

Identify the kinds of individuals the center plans to recruit as part of its plans for developing the center. Identification of particular individuals or research plans is not necessary.

Interim salary and research support: The center director may provide partial support for up to 18 months to an investigator who has a reasonable probability of regaining independent research support in the near future. Interim salary and support is independent of any salary funded by the CCSG in the Staff Investigator category. Individuals who are

having chronic difficulty with peer-reviewed grant support, and for whom permanent institutional funds are not available, are ineligible.

Your application should include a description of the process and the criteria used to select investigators for interim support. Peer review at the next competitive evaluation will examine the uses of the interim support category and the success that individuals supported from this category have had in regaining peer-reviewed grant support.

Support of pilot projects that allow center scientists to pursue innovative, high-risk ideas or stimulate high priority research areas (*e.g.*, translational research, research on underserved populations or development of new technologies or methodologies): Centers are encouraged to make these funds accessible to basic laboratory; clinical: and prevention, control, behavioral and population-based research for projects of relatively short duration (*i.e.*, 1-2 years). Pilot projects may be awarded to new or established investigators, preparatory to the development of an application for independent peer-reviewed support, or to take maximum advantage of a unique research opportunity, nurture an innovative idea, stimulate a high priority research area, or encourage cross-disciplinary translational research.

NCI also encourages the development of new technologies that will advance cancer research (procedures, instrumentation, analytical tools, or reagents), *e.g.*, the detection and analysis of molecular signatures of cancer in vitro or in vivo, biomedical imaging, model development, drug discovery, tumor targeting, drug delivery, survey development, and informatics.

Your application should describe the processes for eliciting and reviewing proposals, and list the awardees and their projects for the preceding project period. Describe the outcome of all projects supported by the CCSG through the pilot and technology/methodology development mechanisms (*e.g.*, grant awards, publications, and patents).

If CCSG resources are used in partnership with industrial resources, the cancer center must assure that applicable federal law governs the public availability of any final products of the research.

NIH must track all pilot projects in this category that include foreign components and, if necessary, State Department clearance must be obtained prior to implementation. OCC staff will act as the liaison between the Centers and the NIH Fogarty International Center, which is responsible for coordinating all clearances.

Development of new shared resources: CCSG funds may be used to help develop new shared resources when the center recognizes a need. If the resources are sufficiently developed to be proposed and reviewed as established resources (*e.g.*, a track record demonstrating its viability as a fully functioning shared resource), they should be proposed under the shared resources category. They may not be used for upgrades or routine purchases of equipment.

Describe the planned shared resources, including need, anticipated scope of the services and timeline for development, and potential usage (predicated on member surveys or

other data). Report on the outcomes for funds used for this component in the prior project period, (*e.g.*, of a newly established shared resource).

Purchase of peer-reviewed shared services from other NCI-designated Cancer Centers: Not all NCI-designated Cancer Centers have access within their own institution to high technology or other specialized shared services that may be crucial to accomplishment of research goals, on either a permanent or a temporary basis. Since establishment of such resources may not be economically or scientifically feasible in every institution, sharing of resources across cancer centers is encouraged. Centers may use developmental funds to purchase meritorious, peer-reviewed shared services from within the established shared resources of other NCI-designated Cancer Centers for this purpose.

Based on the scientific goals of the center, your application should briefly describe the anticipated shared resource needs in this category and the research areas to be supported, and identify the NCI-designated Cancer Center shared resource services and the personnel that will provide those services. Where appropriate, report on the outcome of funds used previously for this purpose in the past, *e.g.*, successful grant applications, completion of projects, and publications. Funding should be consistent with CCSG guidelines on shared resources (*e.g.*, need, cost-efficiency, and accessibility), but no specific types of financial arrangements are mandated due to variation in institutional policies, facilities and administrative costs, other pricing structures, and the type and volume of the services that may be required.

Support of Staff Investigators: Members of the center who are important contributors to the scientific, translational, and clinical activities of the center may receive salary support as a Staff Investigator for their specific roles in the center. To qualify, individuals should play a definable and special role in either helping the center achieve scientific objectives above and beyond their own research (Research Staff Investigator), facilitating center-wide clinical activities (Clinical Staff Investigator), or, as part of a larger cancer center effort, furthering center research that focuses on cancer issues for minority and other special or underserved populations (Special Populations Staff Investigator).

Research Staff Investigators must be a /PD/PI or serve a significant leadership role on at least one NCI approved peer-reviewed and funded research-project award and should play a special role in helping the center achieve scientific objectives beyond those of their own individual research.

Clinical Staff Investigators should be instrumental in the development and implementation of the center's clinical activity, including authorship of clinical trials, accrual of patients on interventional trials, and leadership role in NCI National Clinical Trials Network studies.

Special Populations Staff Investigators must have a track record of NCI approved peer-reviewed research focused on minority and other special and underserved populations and should have a special role in advancing center research that focuses on cancer issues for minority and other special or underserved populations.

Prepare an overall description for the component, and a consolidated budget. Identify each Staff Investigator by name and type. There is no limit on the number of Staff Investigators, but choices should be made judiciously and justified by the description of duties. The CCSG guidelines do not prohibit members with other official roles in the Center from receiving additional support as a Staff Investigator, but responsibilities for each role should be clearly distinguished. Provide a separate narrative justification, with a description of duties, and a biographical sketch for each Staff Investigator proposed and clarify how your selection will enable the center to meet overarching scientific and/or clinical objectives. Additional information, (*e.g.*, for Research Staff Investigators and Special Populations Staff Investigators, their research track record and a list of peer reviewed grants on which they serve as PD/PI or serve a significant leadership role; for Clinical Staff Investigators, a list of authored trials, etc.) should also be provided.

Subsequent applications should provide information on accomplishments of Staff Investigators funded in prior cycles.

The following review criteria apply to the developmental funds component (merit descriptor):

- How effective has the center been in using developmental funds to strengthen cancer related science in the prior project period via development of new shared resources, recruitment of new investigators, interim salary and research support, pilot projects, purchase of shared resource services, or funding of staff investigators?
- How effective has the center been in using internal and external advisory bodies to assist in identifying scientific opportunities and needs appropriate for the investment of developmental funds (development of new shared resources and areas of recruitment)?
- How appropriate are plans for use of funds and are they tied to advancement of center strategic goals?

2.7.5 Cancer Center Administration (Limit of 12 pages)

Provide a description, budget and narrative justification. Include the costs necessary for central administration of resources and services required for center research activities, fiscal management of the center, and reporting activities. Because administrative structures differ from center to center, carefully explain and justify requested support.

The CCSG central administrative budget may support an appropriate percentage of the salary of the chief administrator, secretarial and other staff, travel needs of senior leaders and Program leaders in the performance of their center-specific roles, and supplies for the administrative functions of the center.

Funding for a percentage of salary for a staff person to support links with state health departments, other state agencies, or the Centers for Disease Control and Prevention (CDC) also is allowable. Partial salary support for a center informatics lead to further NCI's goals of increased interoperability both within the Center's existing informatics systems and workflows, and between those systems and NCI informatics systems, may be included as well.

Examples of non-allowable costs include non-research educational activities, public relations, fund-raising, and general grant application and manuscript preparation. Matrix centers should not duplicate parent institution responsibilities (*i.e.*,. services normally supported through indirect costs or provided by the institution to other comparable research units such as academic departments).

While organizational structures and functions vary, your application should describe, as appropriate:

- Sources of funding for activities of the administrative office, including the CCSG.
- Qualifications of administrative staff and their roles in governance and decision-making processes at the center.
- 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.
- Roles of center administration in CCSG-related activities, for example:
    - Oversight and management of shared resources, whether center or institutionally managed, *e.g.*, prioritization processes, prices, chargebacks, auditing, user satisfaction measures, and quality control.
    - Faculty recruitment, retention, and tenure/promotion activities.
    - Management of membership processes.
    - Processes for solicitation, receipt, review, award, and monitoring of pilot projects.
    - Space management, including policies on assignment and retention.
    - Arranging and documenting center meetings.
    - Management of philanthropic and other funds.
    - Budgeting, accounting, and expenditure monitoring.
    - Oversight of activities relevant to the CCSG grant application process.
- For consortium centers, how CCSG functions are coordinated across the partner institutions.

The following review criteria apply to this component (merit descriptor):

- How qualified are administrative staff members for their roles?
- As applicable, how effective is the administration in:
    - Oversight and management of shared resources (whether center or institutionally managed)?
    - Budget, accounting, and expenditure monitoring processes, including management of philanthropic and other funding streams?
    - Faculty recruitment and retention processes, including those related to promotion and tenure?
    - Arranging and documenting meetings organized by the center?

- Management of processes related to pilot project solicitation, review and award?
- Management of membership processes?
- Representing the center with institutional offices, including the central grants office, and clinical and other pertinent entities?

- For consortium centers, how effective are mechanisms to ensure efficient administration of CCSG functions across institutions?

2.8 RESEARCH PROGRAMS (LIMIT OF 12 PAGES PER PROGRAM, WITH EXCLUSIONS AS INDICATED BELOW)

2.8.1 Goals

Cancer Centers foster cancer-focused research, in part through the creation of formal scientific research Programs. In the context of the CCSG, a Program comprises the activities of a group of investigators who share common scientific interests and goals and participate in competitively funded research. Programs are highly interactive and lead to exchange of information, experimental techniques, and ideas that enhance the individual productivity of scientists and often result in collaborations and joint publications. Ultimately, the success of Programs is measured by scientific excellence and the emergence of productive collaborations. How this is achieved will vary with the center and the needs of particular Programs; there is no proscribed set or balance of activities for accomplishing these objectives. Formal or informal planning meetings, seminars and retreats, developmental funding of selected pilot projects, new shared resources, or key recruitments may be effective ways of promoting increasing levels of interaction.

2.8.2 Selection of members

Selection of members for a center's Programs is one of the most critical decisions made by leadership. Functional and productive Programs select individuals for their scientific excellence and, just as importantly, for their commitment to work together to further the scientific goals of the cancer center. Some Program members may not hold peer-reviewed grants, but contribute to the research objectives of the center in other important ways (*e.g.*, development and implementation of center's clinical activity, including authorship of clinical protocols, accrual of patients on interventional trials, and leadership roles in NCI National Clinical Trials Network studies), and these contributions should be recognized.

Many Programs in cancer centers involve sustained collaborations with scientists who clearly strengthen and enhance value-added interactions and the scientific productivity of the research but who have no formal appointment within the institutions that comprise the cancer center. Collaborators from other NCI- designated Cancer Centers or research institutions may become center and Program members. While the funded research projects of these members cannot count toward the funding base of the Program, these members may have full access to shared resources and developmental funds.

2.8.3 Characteristics of Programs

Programs should be of adequate size and scientific quality, should exhibit a high degree of interaction, and should be capably led. A Program must have at least five peer-reviewed and funded research projects (*e.g.*, % R01 + % R21 + % U01 = 300%) from a minimum of three separate, independent PDs/PIs to be eligible, however successful programs substantially exceed this minimum. Peer-reviewed, funded research sub-projects of larger grants (*e.g.*, P01s, P50s), but not shared resources, may be counted as separate projects.

The interactive attributes of a Program are documented by collaborative research projects, joint publications, colloquia, joint seminar series, and other evidence of meaningful interchange that cement interactions around related or common goals. Again, the type and balance of activities will vary from center to center. In addition, effective scientific leadership, with a history of cancer-related funding appropriate to the nature of the Program, provides intellectual stimulation, cohesion, focus, and direction.

2.8.4 Definition of Peer-Reviewed, Funded Research Projects for Inclusion in Programs and for Designation of Users in Shared Resources

Peer review as employed by the NIH is the acceptable standard for inclusion of a cancer-related research project within a formal Program. Eligible peer-reviewed grants and contracts, including those formally awarded to individual or multiple investigators, are as follows:

- Research grants, cooperative agreements and research contracts from the NCI including all awards with the following prefixes: R00, R01, R03, R15, R18, R21, R24, R25, R33, R37, R41, R42, R43, R44, R55, R56, P01and P50 sub-projects, P20, SC1, SC2, U01, U10, U19, U54, U56, N01 research contracts and peer-reviewed, funded subcontracts of center members participating in collaborative research. (Note: Shared resources of multi-component grants are not eligible for inclusion)
- Components of NCI National Clinical Trials Networks (*e.g.*, U10s, U19s)
- Individual research studies involving protocols approved by the NCI Cancer Therapy Evaluation Program (CTEP) and funded by NCI.
- Individual research studies involving prevention and control protocols approved by the NCI Cancer Control Protocol Review Committee and funded by NCI.
- Awarded cancer-related research grants, cooperative agreements, and research contracts from other institutes of the NIH (same prefixes as above).

For descriptions of specific NIH funding mechanisms, see http://grants.nih.gov/grants/funding/ac_search_results.htm.

Peer-reviewed, cancer-related support from a number of other NCI program-approved funding organizations can be included. An updated list of approved organizations is available at http://cancercenters.cancer.gov/documents/NCIApprovedFundingOrganizations508C.pdf.

2.8.5 Formatting For Each Program Section

Limit of 12 pages of narrative per Program, excluding title page; description; biosketches; budget; budget justification; and lists of members, funded projects, clinical trials, shared resources and services, and publications. For each Program, please provide the following:

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 description of the Program using page 2 of the PHS Form 398 (rev. 06/09), including:

- The central themes and scientific goals of the Program.
- The number of Program members and the number of departments and schools represented.
- The NCI and other peer reviewed cancer-related support for the last budget year.
- The total number of Program publications and the percent that is intra- and inter-programmatic and/or collaborative with investigators in other institutions. (**Note:** Inter-programmatic publications may be listed in multiple programs, as relevant, but should be included only once in an overall count of interprogrammatic publications).

A budget for person months of the first and future years for the Program leader(s) using the standard budget pages provided in the PHS Form 398 (rev. 06/09). A level of effort must be included for each Program leader even if salary is not requested. Indicate if salaries meet or exceed the NIH salary cap. Programs may also request modest funding for support of scientific activities directly relevant to Program goals, such as small pilot projects, seminar speakers, etc.

A budget narrative justification describing the specific role of each Program leader(s) in facilitating the discovery process and promoting transdisciplinary research important to cancer, and any projected use of funds to support other scientific activities.

Biographical sketches of Program leaders(s) Use the PHS Form 398 (rev. 06/09).

A list of the externally funded, cancer-related research projects (no page limit) of the Program separated into two categories: "peer-reviewed" and "non-peer reviewed" by member, project and funding source, using the format described for Data Table (Summary) 2A. Program leaders should exclude grants focusing on other diseases (*e.g.*, diabetes, cardiology, neurological disease) or address their cancer relevance in the programmatic narrative.

A list of the members of the Program (no page limit) in alphabetical order, with their departmental and institutional affiliation, their academic rank (or equivalent) and their role in the Program (*e.g.* research; development and implementation of the center's clinical activity, including authorship of clinical trials, accrual of patients to interventional trials, and leadership roles in NCI National Clinical Trials Network studies). Information on the latter is especially important for assessment of the transdisciplinary nature of the Program, integration of member activities, and contribution of members to programmatic goals.

A list of shared resources and other services (no page limit) used by program members.

A list of intra- and inter- Programmatic activities and external collaborations (no page limit) *e.g.*, meetings, seminars, significant multi-investigator grants, retreats, and working groups; and other significant collaborative activities with investigators outside of the center.

A selected list of Program-related publications (no page limit) from the last project period. Include only those that have made an important scientific contribution, had a significant effect for patients and the public, or particularly illustrate intra- and inter-programmatic or other multi-institutional collaborations. Publications should represent the broad diversity of Program members. (**Note:** 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. (See also Section 2.20 for links to relevant federal citations.)

A list of the clinical research of the Program (no page limit) using the definitions and format specified in the instructions for Data Table (Summary) 4.

In a 12-page narrative, briefly discuss the following:

How the interests, expertise, and research approaches of the Program members and other collaborators facilitate achievement of the central themes and scientific goals listed in the description above.

The *most significant* scientific accomplishments of the Program within the last full project period, the effect of those accomplishments, and the ways in which they were facilitated by the Center (including access to shared resources). **Note:** Color photos relevant to scientific accomplishments should be included in the appendices.

For clinical and translational Programs, this should include:

- activated interventional clinical trials that are making a difference, *e.g.*, advancing the field or changing medical practice.
- examples of how scientific findings by Center investigators are advanced
    - via translational and clinical funding mechanisms from NCI (*e.g.*, grants for SPOREs, Phase I/II consortia, program projects, and NCTN) and other sources.
    - via collaborations with additional partners, such as other institutions or industry

In addition to questions of broader applicability, and as appropriate to the type of Program, briefly describe how the cancer research relevant to the catchment area[1] is addressed. This may include, for example, a discussion of research focused on cancer health disparities[2] (*e.g.*, problems affecting racial and ethnic minorities, rural residents, women, children, elderly, persons of low socioeconomic status), cancer sites of high incidence/mortality, rare cancers, environmental exposures, behavioral factors, or other issues.

[2] The NCI defines "cancer health disparities" as differences in the incidence, prevalence, mortality, and burden of cancer and related adverse health conditions that exist among specific population groups in the United States.

The following review criteria apply to this component (merit descriptor):

Note: If the program does not meet the minimum requirements for funded projects as discussed in Section 2.8.3, the merit descriptor will be lower.

- What is the overall scientific quality of the Program?
- What is the extent of cancer focus in the peer-reviewed research base?
- How successful is the Program in fostering productive transdisciplinary and/or translational research collaboration among its members, with members of other programs, and with other external partners?
- As appropriate to the type of Program, what is the evidence that research relevant to the catchment area[1] 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 (in addition to research questions of broad applicability)?
- What is the value added by the Center to programmatic efforts in terms of shared resources and other services?
- How appropriate and effective are the Program Leaders in relation to expertise, program management, and time commitment?
- For clinical and translational Programs:
    - How successful is the Program in activating interventional trials that make a difference, *e.g.*, advance the field or change medical practice?
    - How successful is the Program in moving research through the translational continuum, via translational and clinical funding mechanisms of the NCI or collaborations with industry or other partners?
    - Is the Program participating in accrual to, and leadership of, National Clinical Trial Network (NCTN) trials appropriate to its scientific agenda?
    - How appropriate is overall accrual to trials (taking into consideration those with unique accrual targets, *e.g.*, rare cancers, targeted therapies)?
- For consortium centers:
    - What is the evidence for integration of members from all institutions into scientific Programs and leadership positions?
    - What is the evidence that research is integrated across all partner institutions?

2.9 SHARED RESOURCES (LIMIT OF 12 PAGES PER RESOURCE)

2.9.1 Goals

Shared Resources provide access to specialized technologies, services, and expertise that enhance scientific interaction and productivity. The support of centralized shared services for center investigators is intended to ensure greater stability, reliability, cost-effectiveness, and quality control.

The primary beneficiaries of CCSG-supported shared resources and services should be cancer center members with peer-reviewed, funded projects, a standard assuring funds support high-quality research. Support to others is at the discretion of the center director and should be justified by contributions to the overall cancer research objectives of the center (*e.g.*, access by a junior investigator funded by a pilot project).

2.9.2 Budgets

Cancer centers may use CCSG funding to support member's access to either institutionally- or cancer center-managed shared resources, including those integrated through multiple NIH funding sources, such as Clinical and Translational Science Awards. CCSG funding should not be used to establish independent, center-managed shared resources that duplicate institutionally managed resources if the latter provide cost effective, accessible, and quality services. It should also not be used to support shared resources that are offered free of charge to other investigators. If proposed or existing institutional shared resources are not structured to meet cancer center needs, separate shared resources may be supported through the CCSG, but must be rigorously justified. CCSG funding for any shared resource should be proportional to use by investigators within the cancer center that have cancer-related peer-reviewed funding.

The CCSG provides stability for some of the operating costs associated with salary of key personnel operating centralized shared resources and services; small equipment maintenance contracts; service contracts; and minimal supplies. Replacement of small equipment (less than $25,000) also is allowable. Other "variable" costs associated with specific research projects should be supported by other funding sources, *e.g.*, user fees, chargebacks, institutional funds.

No standard approach applies to all shared resources and services. NCI recognizes that virtually all shared resources derive a portion of their operating costs from multiple sources. Centers should justify the proportion of funding allocable to the CCSG in the context of this overall support. The scope of the budget request should be reflective of use of the shared resource by cancer center members with peer reviewed funding.

The primary costs of research are supported by the peer-reviewed, funded grants and research contracts of the center. Consider the elements listed below in developing budgets for shared resources and services as they will be factors in peer evaluation of the budget:

- Need for the resource relative to current and projected use by peer-reviewed funded center members.
- Cost-efficiency, particularly in comparison to other options (*e.g.*, purchase orders or contracts to an outside vendor).
- Stability of the operation and quality of the service.
- Accessibility of the resource or service to qualified member-investigators, including the critical consultative services performed by experts who direct selected shared resources such as biostatistics and informatics.
- Proportion of the total resource operation paid for by the CCSG relative to other sources.

2.9.3 Formatting for the Shared Resource Section

Prepare a description using page 2 of the PHS Form 398 (rev. 06/09), budget and narrative justifications for each resource.

In the section for each shared resource, describe the:

- Major services, technologies, equipment, and expertise provided, and their importance to the scientific needs and objectives of the center (*i.e.*, how the shared resources support the research of the Programs).
- Management structure, *i.e.*, by the center, institution, or other entity.
- Cost-effectiveness of the resource relative to other options for obtaining the service, such as outside vendors, when applicable.
- Qualifications of the shared resource director(s) and the competence of key technical staff; include a biosketch of the resource director(s) and manager(s).
- Use of services (current grant year or anticipated if new), *i.e.*, total number of users, total number and percent of users who are center members with peer reviewed support, and total number and percent of users who are center members without peer-reviewed support. Do not include users from other centers or provide a list of users.
- Policies on operation and use of the shared resource, *e.g.*, access, priorities, hours of operation, staffing, etc., and charge back systems.

The requested budget should reflect realistic needs in terms of support from other sources (*e.g.*, institutional or cancer center support or recovery from chargebacks) and any other specific additional requirements. Provide the following information for the most current grant year and for the proposed period of support.

TABLE 3-1. SOURCES OF SUPPORT FOR SHARED RESOURCES

Income Source	Current Support ($)	Percent of Current Total Budget	Proposed Support - Year 1 ($)	Percent of Proposed Total Budget
CCSG				
Fee for Service/ Chargebacks				
Other				
Total Operating Budget				

After you have completed a section for each individual shared resource, organize the resources into three groupings. Groupings may be based on type of shared resource, *e.g.*, basic, clinical, population science, or any other system you choose. Indicate the chosen group name at the

beginning of each grouping. A fourth grouping 'Other' may be added for shared resources that do not fit easily into the three already identified.

2.9.4 Issues Regarding Unique or Specialized Shared Resources

A center has the flexibility to propose the functions that it wishes to have funded as shared resources. Primary consideration should be given to resources that are critical to a center's research mission. Additional factors may include the needs of past and potential new users, accessibility to cancer center members, and the effectiveness and fairness of the process for setting scientific priorities for their use. While shared resources should never be established for primary use by one or two members, the absolute number of users is of lesser importance than the value of the resource to the science of the center. Some technically sophisticated or unique resources (*e.g.*, x-ray crystallography, preparation of clinical grade gene therapy vectors, proteomics, family ascertainment, health communication, tracking, nutrition support) are not always adaptable to high-volume operation, or may have only a few very specialized users, or be used by only one Program (*e.g.*, population science). Chargebacks may not be relevant for resources such as informatics and biostatistics (see discussion below), and other consultative services not typically charged to grant mechanisms.

Informatics: In cancer centers, informatics expertise and resources are critical shared resource functions. The CCSG may support applications of informatics directed toward cancer research (*e.g.*, the acquisition, maintenance, and integration of database systems for clinical trials or studies in populations; data extraction, storage, and analysis tools for genomics, proteomics, or molecular structure; a database annotating a research repository involving human specimens; and tools that enable sharing of data sets with collaborating investigators in related areas of research). Performance of specific research functions, such as data entry, for individual research projects or clinical trials is excluded. As the interoperability of independently developed informatics systems is an important goal of the research community, informatics development efforts supported by CCSG funds must comply with evolving standards articulated by the NCI, the scientific community, and other standard-setting organizations in the medical and bioinformatics areas.

Biostatistics: Biostatistics is a shared resource central to the mission of most centers, particularly those that perform clinical or population research. Participation by statisticians in many collaborative activities of the cancer center is eligible for CCSG support. Salary support is allowable for participation in cancer-center pilot projects, assistance to center investigators in conceptualizing and developing research projects, analyses for publication, and the development of methodology clearly and closely related to the support of specific projects within the cancer center. The CCSG is not intended to support: 1) independent, investigator-initiated research in statistical methodology, for which statisticians, like other scientists, should be supported by project-specific grants or 2) a significant collaborative role for a statistician on a funded research project, since the this effort would normally be supported by an appropriate time-and-effort allocation as a collaborator on that grant.

The following review criteria apply to all shared resources presented in this component (merit descriptor):

Note: Reviewers should assess whether this is a specialized shared resource as CCSG defined in Section 2.9.4

- What are the quality and cost efficiency of the service provided, and how effective are accessibility policies governing institutional and other specialized shared resources?
- How appropriate are the qualifications of staff and their time commitment?

2.10 CLINICAL PROTOCOL AND DATA MANAGEMENT (CPDM) /CLINICAL TRIALS OFFICE (LIMIT OF 12 PAGES) AND DATA AND SAFETY MONITORING (DSM, LIMIT OF 5 PAGES)

Clinical Protocol and Data Management:

Provide a description, biosketches, budget and narrative justification. Clinical Protocol and Data Management/Clinical Trials Office (formerly a shared resource) provides central management and oversight functions for coordinating, facilitating, and reporting on the cancer clinical trials of the institution(s) that define the center, whatever the study origin (local, industrial, NCI National Clinical Trials Network, or other). As a tool for management of a center's clinical research enterprise, it complements the Protocol Review and Monitoring System. It also provides a central location for cancer protocols, a centralized database of protocol-specific data, an updated list of currently active protocols for use by center investigators, and status reports of protocols. Quality control functions might include centralized education and training services for data managers and nurse; data auditing for tracking of patient accrual, assessment of patient eligibility and evaluability, timely submission of study data, and other study compliance measures; and data and safety monitoring activities that ensure the safety of study participants.

In addition, this component also may support:

- Staff to assist in analysis and reengineering of protocol preparation and revision, and trial activation processes.
- Trial development managers whose primary responsibility is tracking and managing of protocols in development to assure timely completion of all required activities.
- Physician protocol officers, with primary responsibility for assembling scientific and clinical protocol content and coordination and resolution of unresolved scientific and clinical issues in protocol revision.
- Other staff positions that speed protocol preparation, revision, and activation, including those that focus on acceleration/facilitation of collaborative clinical trial activities crossing multiple cancer centers or NCI-funded mechanisms (*e.g.*, SPOREs, National Clinical Trials Network, etc.).
- A partial staff position in the university legal and/or contracting office, with the funded time to be devoted exclusively to negotiating Cancer Center institutional clinical trial agreements.

- Staff with responsibilities relevant to data submissions for the NCI Clinical Trials Reporting Program.

The CCSG allows funding for oversight and quality control for the center's entire cancer clinical trials effort but does not include tasks involved in the actual direct conduct of individual trials (such as data entry). Therefore, the CCSG request for this resource should not duplicate, replace, or make up for reductions in funding provided through the individual grants and contracts supporting the studies.

Briefly discuss the role of the CPDM in relation to management and coordination of the cancer clinical trials of the center, ensuring timely completion and initiation of trials, and conducting effective quality control and training functions. Provide an overview of accrual to interventional clinical trials over the project period preceding the competing renewal application. [**Note:** This is a summary of Standard Cancer Center Data Table (Summary) 4 interventional trial data and the definitions, reporting years, and accrual sites used in Data Table (Summary) 4 apply to the data in this table]. A sample template is below:

TABLE 3-2. ACCRUAL TO INTERVENTIONAL* CLINICAL PROTOCOLS BY REPORTING YEAR (MM/YYYY)* AND SOURCE OF SUPPORT (FOR PRIOR FOUR YEARS OF ACTIVITY)

Reporting Year (Specify mm/yyyy))					Total
National Group					
External Peer Review					
Institutional (investigator initiated)					
Industry					
Total Accrual to Interventional Clinical Protocols					

*Centers also may provide data on accrual to non-interventional clinical studies in a similar format if desired, using Data Table (Summary) 4 data for observational, ancillary, and correlative studies.

The following review criteria apply to the CPDM (merit descriptor)

- How effective is CPDM in centralizing, managing, and reporting on the cancer clinical trials of the center?
- To what extent does CPDM help to assure timely initiation and completion of clinical trial activities?
- How effective are the quality control functions and training services offered by the CPDM?
- How reasonable is overall accrual, based on the nature/type of the individual trials supported?

Data and Safety Monitoring:

In addition to the above, Data and Safety Monitoring (DSM) should be addressed in this section. DSM is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants ("NIH Policy for Data and Safety Monitoring," NIH Guide for Grants and Contracts, http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

DSM functions are distinct and should not be the direct responsibility of the Protocol Review and Monitoring System (PRMS), which oversees scientific aspects of cancer clinical trials. Do not merge these activities and committees.

By NIH review criteria, the peer reviewers will be responsible for determining only whether the DSM plan is acceptable or unacceptable. Peers are expected to define the weaknesses of an unacceptable DSM plan and to reflect any weaknesses in the impact/priority score. The final approval of a DSM plan in its original form or later modified form is the responsibility of the staff of the OCC.

Provide a very brief summary of the Center's DSM plan. Do not include the entire plan within the text but provide a copy at the site visit.

Note: Review of the DSM plan by peers is an NIH requirement, separate from, and unrelated to, the separate review and approval of the plan by NCI program staff.

Funding may be requested for appropriate support staff and supplies. If funding is requested for staffing related to DSM activities, provide a separate budget and justification pages and include a description of: the DSM workload relevant to investigator-initiated studies and studies supported on competitive grants, including evaluation, auditing, and monitoring of patient safety based on phase, level of risk, or other pertinent factors. Do not include DSM activities directly supported on other grants and contracts.

The following review criteria apply to the DSM (acceptable/unacceptable):

- How adequate is the DSM plan in defining the overall structure of the monitoring entity and the mechanisms for reporting adverse events?
- For consortium centers, is there a single DSM plan governing all cancer clinical trials across partner institutions?

2.11 PROTOCOL REVIEW & MONITORING SYSTEM (PRMS, LIMIT OF 10 PAGES EXCLUSIVE OF PROTOCOL LISTING)

Provide a description, budget and narrative justification. A particularly important function for centers involved in clinical research is a mechanism for assuring adequate internal oversight of the scientific aspects of all the cancer clinical trials in the institution or institutions that formally comprise the center (*i.e.*, consortium centers should document that all protocols are reviewed

through a central PRMS). This function is complementary to that of an Institutional Review Board (IRB), which focuses on the protection of human subjects.

The PRMS is not intended to duplicate, or overlap with, the responsibilities of the IRB. Auditing for quality control or safety reasons is not a function of the PRMS. DSM committee functions and PRMS committee functions are separate and distinct from one another and should not overlap. The focus of the PRMS is on scientific merit, priorities, and progress of the clinical protocol research of the center. The PRMS should have the authority to open protocols that meet the scientific merit and scientific priorities of the center and to terminate protocols that do not demonstrate scientific progress. Unique considerations may apply to trials of rare diseases (http://cancercenters.cancer.gov/news/news-announ-comm.html), or targeted therapies, which often do not accrue rapidly. PRMS evaluations do not include quality control concerns, unless the problem is so serious as to make the results of the protocols meaningless.

The PRMS scientifically evaluates and prioritizes all cancer center trials derived and supported from institutional sources, including those originating from other cancer centers, or from industry. However, the PRMS:

- Should not duplicate traditional peer review, which includes peer-reviewed protocols supported by the various NIH mechanisms (*e.g.*, R0ls, U0ls, U10s, P0ls, and P50s, etc.), other approved funding agencies (http://cancercenters.cancer.gov/documents/NCIApprovedFundingOrganizations508C.pdf), and clinical research protocols approved by the NCI's Cancer Therapy Evaluation Program or the Cancer Control Protocol Review Committee. These protocols may receive an expedited administrative review for the purpose of prioritization.

- Is not required to evaluate or prioritize studies dealing with healthy human subjects and the population sciences, *e.g.*, observational and epidemiologic studies.

All trials approved by the PRMS for merit, whether via full or administrative review, have access to CCSG-supported centralized resources such as informatics, biostatistics, and clinical protocol and data management.

The PRMS may elect to perform a 2-stage review in which institutional concepts, without a full protocol, are first reviewed for scientific merit. Concepts approved in this stage are then sent forward for full protocol development. Review of the protocol itself would occur as the second stage. The aims of this 2-stage review are to reduce staff effort in developing protocols of lesser scientific merit, and the timeframe from concept approval to protocol activation.

Budget and Justification. The budget may include appropriate personnel, administrative support, equipment appropriate to the task, and supplies.

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. Scientific expertise from basic laboratory; clinical; and prevention, cancer control, and population-based science should be represented on the PRMS committee. While there may be minimal overlap, committee representation should not duplicate

that of the DSM Committee and the same individual should not chair, or have supervisory responsibility over, both committees.

Describe the procedures for scientific review and scientific monitoring of cancer clinical trial protocols, including:

- 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, biostatistical input and feasibility for completion within a reasonable time period.
- the criteria used for monitoring ongoing institutional protocol research to evaluate scientific progress, including accrual rates, to ensure that the scientific aims of the study can be completed.

Describe the process and criteria used for prioritizing the activation of cancer clinical trial protocols at the institution with respect to scientific merit and patient availability. Describe the input, if any, of disease focused groups, to the prioritization process. Clarify whether a one or two stage review (*e.g.*, full protocol only, or concept then full protocol) is conducted at the PRMS level and provide a prioritization schema.

Discuss the metrics used by the committee to assess the efficiency and timeliness of their activities.

Describe the process, criteria, and authority for terminating a clinical protocol. Discuss whether the committee has terminated any protocols, and for what reason.

Describe PRMS operations relative to the IRB approval process with emphasis on the complementarily of the two entities and absence of overlap or duplication.

If a consortium center, discuss how the PRMS process is governed across the partner institutions.

Provide a subset of data from Data Table (Summary) 4 Clinical Research Protocol Information that includes all institutional protocols (*i.e.*, studies that have not received external review) reviewed by the PRMS for scientific merit or actively monitored for scientific progress in a recent 12-month period (Grant year, January to December [preferred format], or July through June). Add a column to the table to indicate which protocols have been approved and activated, approved but not yet activated, deferred for revision, disapproved, or closed. (For the last column, you may use a coding system, *e.g.*, 1 for approved and activated, 2 for approved but not yet activated, 3 for deferred, 4 for disapproved, and 5 for closed). Provide only the code in effect at the time of table preparation.

Note: In a consortium center, the table should include protocols from all partner institutions.

NCI will request a sample from the list for detailed review prior to the site visit. Do not include or append protocols to the CCSG application.

In addition, provide information for the most recent 3 year period (Grant year, January to December [preferred format], or July through June) on the number of trials reviewed or prioritized by sponsor.

TABLE 3-3. NUMBER OF PROTOCOLS REVIEWED OR PRIORITIZED BY SOURCE OF SUPPORT AND YEAR (FOR MOST RECENT 3 YEARS OF ACTIVITY)

Specify Reporting Year (mm/yyyy)				Total
National Group				
External Peer Review				
Institutional				
Industry				
Total # of Trials Reviewed/Prioritized				

In cases of conditional approval or disapproval of the PRMS, the peer reviewers will clarify in the Summary Statement what steps or changes are needed for full approval, along with any recommendations on timing of re-evaluation by peers. See Section 2.19.

The following review criteria apply to this component (approve, conditionally approve, or disapprove):

- How appropriate are the composition of the committee and the qualifications of its members for ensuring the breadth of expertise necessary to conduct a critical and fair scientific review of all institutional clinical cancer protocols?
- How appropriate are PRMS authorities and processes for initiating, monitoring and terminating all cancer clinical research protocols in the institution(s) comprising the center?
- How appropriate are the criteria and processes for scientific review, taking into account the rationale, and study design, potential duplication of studies elsewhere, adequacy of biostatistical input, and feasibility for completion within a reasonable time?
- How appropriate are processes for ensuring prioritization of competing protocols from all sources and optimal use of the center's scientific resources?
- How adequate are the criteria for monitoring trials to ensure they are making sufficient scientific progress?
- Are the criteria and process for terminating trials that do not meet scientific goals (trials involving rare diseases are excluded) adequate and used appropriately?
- How adequate are metrics for moving trials forward through the PRMS system in a timely fashion?

- If a consortium center, is there a single PRMS governing all cancer clinical trial protocols across the partner institutions?

2.12 EARLY PHASE CLINICAL RESEARCH SUPPORT (EPCRS, FORMERLY PROTOCOL SPECIFIC RESEARCH SUPPORT; LIMIT OF FOUR PAGES, EXCLUDING TABLES AND LISTS OF STUDIES)

Provide a description, budget and narrative justification. This CCSG component provides support for short term, pilot (pre-phase I) and phase I clinical research studies originating from scientific investigators within the cancer center (See http://www.cancer.gov/clinicaltrials/conducting/ncictrp/resources/glossary#p-z for clinical trial phase definitions). Preliminary data generated from these studies, which historically have been rarely funded through other mechanisms, can be used as the basis for application for support of later phase studies through competitive grants or industry. Support is not meant for all early phase trials, for later phase trials, or for studies that do that do not involve testing of an agent or device. Center leadership must prioritize studies for support and oversee these funds, *i.e.*, CCSG funds may not be used for oversight of this component.

These funds may be used for global health studies, but must meet all eligibility criteria listed below. In addition, NIH must track all projects in this category that include foreign components and, if necessary, State Department clearance must be obtained prior to implementation. OCC staff will act as the liaison between the Centers and the NIH Fogarty International Center, which is responsible for coordinating all clearances.

Eligibility criteria are as follows:

- These should be high priority, innovative, pilot and phase 0 or I institutional clinical studies focusing on initial early phase testing of a candidate agent or device for the diagnosis, prevention detection or treatment of cancer.
- Studies must be conceptualized/designed by members of the center's research Programs.
- Studies should typically be of short duration (*e.g.*, 1-2 years).
- Studies receiving support through other peer-reviewed research grants, cooperative agreements, or contracts are ineligible for support through this mechanism. Studies may receive partial support from industry, assuming all other criteria are met.
- The center's PRMS must be approved or conditionally approved by peer review for funding of studies supported through this component.
- Supported studies must be approved by the PRMS.

Funding in these pilot and phase I clinical studies is limited to support of:

- Nurses and data managers for a pilot (pre-phase I) or phase I clinical trial,
- Costs associated with generation of preliminary data through other early phase clinically related activities, for example:
    - Purchase of imaging time for scans related to early phase clinical research

- Support for IND or IDE applications
- Pharmacodynamic studies, *e.g.*, use of sequential or pre- and post- biopsies or assays of activity in peripheral tissues to identify investigational agents deserving full clinical development, clinical evaluation of structurally similar analogues directed at the same molecular target, determination of a dosing regimen for an agent to be used in combination therapy, or development of novel imaging probes that establish mechanism of action in patient samples or provide functional and metabolic information about the effect of a drug on its target.

Provide a listing of all studies supported with EPCRS funds over the last project period, with 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.). Discuss the process used for prioritizing studies for support. Describe proposed uses of EPCRS funds for the coming project period (*e.g.* areas to be supported and examples). Base the budget request on the center's actual and projected clinical study activities, as well as on complexity of these studies.

The following review criteria apply to this component:

- How well do the proposed studies comply with criteria for support outlined above?
- What are the quality and innovation of studies proposed for the coming project period?
- How effective has past CCSG support for this component been in terms of project outcomes?
- How appropriate is the prioritization and selection process for use of funds in this component?

2.13 INCLUSION OF MINORITIES AND WOMEN IN CLINICAL RESEARCH (NIH POLICY):

No more than six pages in total, with Inclusion of Children

It is the policy of the NIH (NIH Revitalization Act of 1993-Section 492B of Public Law 103-43) that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (**http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html**); a complete copy of the updated Guidelines is available at **http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm**.

In your application, provide separate tables for accrual in interventional therapeutic, interventional nontherapeutic, and non-interventional studies (*e.g.*, epidemiologic, outcome, observational).

Reviewers evaluating the section of the application on the inclusion of women and minorities in clinical research will consider separately whether the accrual of women and minorities to interventional therapeutic and non-therapeutic trials and non-interventional studies is proportionate to the cancer patient population in the cancer center's primary catchment area[1]. Reviewers will assess the total picture, taking interventional therapeutic and non-therapeutic clinical trial accrual and accrual to non-interventional studies, in relation to approval/disapproval of gender and minority accrual.

When women or minorities are substantially under-represented in relation to catchment area[1] demographics, the adequacy of the institution's policies, specific activities and a corrective plan become especially critical in convincing peer reviewers that the institution is serious about addressing the problem and is investing the appropriate effort to correct under-accrual. In addition, if the population of the catchment area[1] of the cancer center has limited ethnic diversity, provide a discussion of the institution's efforts to broaden the ethnic diversity of its clinical trial accrual.

Include the following information in this section:

- **Demographics**. Provide summary information showing the demographics of the primary geographic catchment area[1] of the center by ethnic categories and subcategories and by gender, as well as for the cancer patient population treated at the cancer center. Centers also have the option of providing data on demographics of cancer patients in the catchment area[1], if available.
- **Accrual.** Complete Parts A and B of the "Inclusion Enrollment Report Table", found in the PHS Form (rev 06/09). Provide summary accrual information from the most recent 12-month period by ethnic categories and subcategories and by gender in the following o areas: (a) the interventional therapeutic clinical trials conducted at the cancer center, (b) the interventional non-therapeutic trials conducted at the cancer center, and (c) accrual to non- interventional epidemiologic, observational, outcome studies. Relate this information to the demographic information provided above.

The revised PHS Form 398 instructions (rev. 06/09) also require applicants to provide data on the composition of proposed study populations in terms of gender and racial/ethnic groups. For CCSG applications, this requirement is limited to projected accrual to phase III studies that utilize CCSG resources and are not funded by any other PHS grant mechanism. See the PHS Form 398 (rev. 06/09) for table formats for both targeted/planned enrollment and actual enrollment. Please indicate if you have no phase III trials that meet this criterion.

In addition to the above, you may also include information in this section on other underserved populations (*e.g.*, rural, elderly, low socioeconomic status) within the center's catchment area[1] if desired.

Plans for Accrual of Women and Minorities: In this section, all centers should include a description of:

- Any general policies of the parent institution designed to help with recruitment and retention of women and minorities.

- Evidence or data that support unavoidable circumstances impeding accrual and retention 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 catchment area[1], which demonstrate a clear effort to recruit and retain women and minorities and correct deficiencies that are potentially avoidable.

If the accrual of women and minorities is not approved by peers, a grant award cannot be issued until a corrective plan and adequate response to the critique is submitted and approved by NCI.

The following review criteria apply to this component (approval/disapproval):

- How proportional is the accrual of women and minorities to interventional therapeutic, non-therapeutic trials, and to non-interventional studies, based on demographic and accrual data provided?
- How appropriate are plans and processes for monitoring and improving recruitment?

2.14 Inclusion of Children in Clinical Research

Included in six page limit for Minorities and Women above.

The NIH maintains a policy that children (*i.e.*, individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guide-lines" on the inclusion of children as participants in research involving human subjects (http://grants.nih.gov/grants/funding/children/children.htm)

As part of the scientific and technical merit evaluation of the research plan, reviewers will be instructed to evaluate the adequacy of plans for including children (as appropriate for the scientific goals of the research), or justification for exclusion.

The following criterion applies to this component (approval/disapproval):

- How appropriate is the plan for including children in clinical trials, or how acceptable is the justification for excluding children in clinical trials?

2.15 Other Review Considerations

2.15.1 Reviewing Science in the CCSG

Science, not process, is the primary focus of the review. Even when process is to be specifically evaluated, such as with planning and evaluation or use of developmental funds, the criteria for success are the scientific judgment behind, or consequences of, particular actions or decisions. In a CCSG review, assessment of scientific quality differs importantly from the peer review of individual grants. It is not the role of peer review to re-evaluate individual projects that have

already received fundable impact/priority scores. Rather scientific review of a CCSG should seek to evaluate the major issues listed under Overall Impact/ Priority Score of the Cancer Center and individual component review criteria (See Section 2.16).

Assessing Merit Despite Institutional Diversity: The peer-review process will evaluate scientific merit and the value-added by the center across a variety of institutions. NCI encourages peer review to recognize and reward scientific excellence and the diversity of organizational forms. Small institutions compete directly with large ones; centers organized only recently compete against distinguished cancer-research organizations that have existed for decades. Some centers may be comprised of a consortium of scientific institutions. Scientific excellence is not synonymous with large size; smaller institutions may develop a limited number of scientific Programs that capitalize on their specific scientific strengths or special populations. The primary consideration is the merit of the Programs presented not their number or size.

2.15.2 Process for Criterion Scoring

Prior to the site visit, assigned reviewers assigned to criterion scoring will submit to the SRO their criterion scores for the overall application on the five standard review criteria: Significance; Investigator(s); Innovation; Approach; and Environment. These scores will be included in the Draft Site Visit Report and Summary Statement under the heading, Overall Impact/ Priority Score, but in keeping with NIH policy, will not be discussed as part of the review process.

2.15.3 Process for Determining Overall Impact /Priority Score

As part of the evaluation and written critique on the Overall Impact/ Priority Score of the Center, reviewers will discuss and describe the extent to which the overall application meets the five standard review criteria, as delineated under the NIH enhanced peer review process. The evaluation of the five standard review criteria (listed below) will be addressed for the application as a whole along with evaluating additional specific review for the components of the CCSG application. In the Overall Critique, under a subheading, Overall Impact/ Priority Score, the Chairperson will provide a summary that includes an evaluation of the Essential Characteristics and the Overall Impact/ Priority Score review criteria and addresses the five criteria: Significance; Investigator(s); Innovation; Approach; and Environment.

2.16 OVERALL IMPACT/PRIORITY SCORE OF THE CANCER CENTER (MERIT DESCRIPTOR)

2.16.1 Background, Including the 5 Standard Review Criteria

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project (*i.e.*, center application) to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five scored review criteria, and additional review criteria (as applicable for the component proposed).

Ultimately, the application should reflect how the CCSG has influenced Center accomplishments, *i.e.*, if the Center would have reported similar achievements without the benefit of the CCSG, the 'value-added' would be minimal and should be reflected in the overall

impact/priority score along with an assessment of the likelihood for the CCSG to exert a sustained and powerful influence on the cancer research fields highlighted in the Center's application.

Reviewers will consider each of the five review criteria below in the determination of overall impact/priority score. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

2.16.2 Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? What is the overall quality of the science in the center? What has the center contributed to the development of more effective prevention, diagnosis, and treatment for cancer (where appropriate)?

(**Note:** in the context of a P30 Cancer Center Support Grant review, the term 'project' refers to the Center application and 'project aims' refers to the Center's strategic goals.)

2.16.3 Investigator(s)

Are the PDs/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

2.16.4 Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

2.16.5 Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2)

inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed? Does the cancer center add value over and above the separately funded research efforts themselves? Have thoughtful, coherent scientific Programs been assembled and Program members selected to maximize the cancer-related interactive science in the parent institution as a whole? How do the different cancer-related scientific themes in the parent institution fit together in the center?

2.16.6 Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? What impact has the center itself had (or is likely to have) on the quality of the science, the productivity of the scientists, and the transdisciplinary activities of the institution relating to cancer? Have the choices for center membership made by its leaders resulted in a group of excellent cancer-focused scientists who are also committed to productive interactions with one another?

2.17 DURATION

What is the recommended number of years of support?

2.18 APPLICATION AND REVIEW FOR COMPREHENSIVENESS

The determination of whether a cancer center will be designated as "comprehensive" (see page 3 for definition) by the NCI is determined by whether the center fulfills the broad scientific and other requirements for comprehensiveness as described in other components of the application (2.6.2,2.7.1,2.8.5). Unless a center advises the SRO in advance of the review that they choose not to be considered for comprehensiveness, the NCI Subcommittee-A (3.2.3) will evaluate comprehensiveness after merit of the Cancer Center Support Grant application has been determined.

In consortium centers, a comprehensive designation may be based on research in the primary institution alone, or on supplemental strengths of the research in all consortium institutions. Grants of the partner institutions may be counted toward Program eligibility.

The following review criteria apply for determination of comprehensiveness (approve/disapprove):

- How adequate are the depth and breadth of science in each of the three major areas of basic laboratory, clinical, and prevention, control and population sciences?
- What is the degree of evidence for strong transdisciplinary research bridging these sciences?

- How effectively has the center defined the cancer problems relevant to its catchment area[1] and served its catchment area[1], as well as the broader population, via the research it supports?
- How is the scientific mission of the cancer center enabled by training and education of biomedical scientists and health care professionals?

2.18.1 One-time Opportunity to Reapply for Comprehensiveness

A funded grantee that fails to receive the comprehensive designation at the time of NCI Subcommittee-A review may re-apply once during the grant project period. The re-application, which should address reviewer concerns, will be evaluated by the NCI Subcommittee-A. Centers interested in re-application should contact NCI program staff for further information.

2.18.2 Retaining the Comprehensive Designation

If an NCI-designated Comprehensive Cancer Center's competing renewal application meets the scientific standards for comprehensive recognition from the NCI Subcommittee-A, but is voted an impact/priority score that does not merit funding, the center may retain the NCI comprehensive designation only for as long as the NCI maintains the "active" status of the CCSG through administrative actions.

2.19 PEER RE-EVALUATION OF THE PROTOCOL REVIEW AND MONITORING SYSTEM

If the PRMS is conditionally approved or disapproved, staff of the OCC will contact the P30 PD/PI approximately four months in advance of the review date recommended by peer reviewers to discuss the center's readiness for re-evaluation. If the center is ready, staff will forward a request for an application for re-evaluation of the PRMS by the NCI IRG Subcommittee A (see Section III) with accompanying instructions. A funded grantee may undergo re-evaluation of the PRMS only once during the grant project period. Peer reviewers may approve or disapprove the PRMS at the time of re-evaluation; *i.e.*, there is no option for conditional approval.

If the PRMS is disapproved, institutional protocols that have not been peer-reviewed by approved funding agencies or mechanisms may not use CCSG-supported shared resources, the Clinical Protocol and Data Management component, or Early Phase Clinical Research Support funds. Additionally, the Center may not use CCSG funding for Early Phase Clinical Research Support until the PRMS has been re-evaluated and approved. The PRMS must continue to operate under institutional funds until approval is obtained.

2.20 FEDERAL CITATIONS RELEVANT TO CCSG APPLICATIONS (LIMIT OF TWO PAGES)

Use of Animals in Research

Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals:

http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf as mandated by the Health Research Extension Act of 1985

http://grants.nih.gov/grants/olaw/references/hrea1985.htm and the USDA Animal Welfare Regulations (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm) as applicable

Human Subjects Protection

Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Sharing Research Data

Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing)

You must submit a plan for data sharing if the CCSG provides direct support for the generation or storage of research data (*e.g.*, pilot projects supported through developmental funds, early phase clinical trials conducted with funds from Protocol Specific Research Support) or funds shared resources that serve as the final repository of data (*e.g.*, a high throughput DNA array analysis resource, family registries). If you are requesting a budget for data-sharing activities (*e.g.*, data archiving), include the budget and justification with this section.

The adequacy of the proposed data sharing plan will be assessed, but does not factor into the determination of scientific merit or impact/priority score.

Policy for Genome-Wide Association Studies (GWAS)

NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088. For additional information, see **http://grants.nih.gov/grants/gwas/**

Peer reviewers will assess the adequacy of the proposed GWAS plan, but do not include it in their final impact/priority score. Concerns regarding GWAS data sharing plans must be resolved by program staff prior to making awards.

Sharing of Model Organisms

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see **http://grants.nih.gov/grants/policy/model_organism/index.htm**). At the same time, the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh-Dole Act (see the NIH Grants Policy Statement, **http://grants.nih.gov/grants/policy/nihgps_2011/**). Beginning October 1, 2004, all investigators submitting an NIH application or contract proposal are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Provide a short description of the center's institutional approach for adhering to the model-sharing policy, as well as specific model sharing plans for any research conducted directly with CCSG funds (*i.e.*, pilot projects conducted with developmental funds) or components serving as research resources (*e.g.*, mouse model and transgenic mouse shared resources , etc.). The adequacy of plans for sharing model organisms will be considered by reviewers when a competing application is evaluated. An assessment of the plan will be provided in an administrative note, but the overall impact/priority score will not be affected. If you are requesting a budget for model-sharing activities, include the budget and justification with this section.

Links to Other Federal Citations

Access to Research Data through the Freedom of Information Act:

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm

Required Education on the Protection of Human Subject Participants:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

NIH Public Access Policy Requirement:

http://www.pubmedcentral.nih.gov/

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html

http://publicaccess.nih.gov/

Standards for Privacy of Individually Identifiable Health Information:

http://www.hhs.gov/ocr/

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html

Authority and Regulations:

http://www.cfda.gov/

Healthy People 2020:

http://www.health.gov/healthypeople

Loan Repayment Programs:

http://www.lrp.nih.gov/

Human Embryonic Stem Cells (hESC):

http://stemcells.nih.gov/index.asp

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html

http://escr.nih.gov

2.21 APPENDICES (50 PAGES)

At the time of submission, two additional copies of the application and three CD-ROM copies of the appendix materials must be sent to the address below.

Referral Officer
Division of Extramural Activities
National Cancer Institute
6116 Executive Boulevard, Room 8041, MSC 8329
Bethesda, MD 20892-8329 (for U.S. postal Service express or regular mail)
Rockville, MD 20852 (for non-USPS delivery)
Telephone: (301) 496-3428
Fax: (301) 402-0275
E-mail: ncirefof@dea.nci.nih.gov

2.22 REVIEW MATERIALS TO BE AVAILABLE AT THE SITE VISIT

- Biographical sketches of all cancer center members. A complete set of biographical sketches facilitates the review particularly if it is available for use during the presentations.
- An updated Data Table (Summary) 2, Active Funded Projects, sorted by Scientific Program, and in the same format, a separate updated list of grants and contracts pending peer review, approval and funding, sorted by Scientific Program (or listed as XY if applicable).
- An updated Data Table (Summary) 4, List of Clinical Research Studies, sorted by Scientific Program (where applicable) using the definitions and sort order specified in the Data Table (Summary) 4 instructions.

- Updated information on personnel or major services, technologies, and equipment offered in the shared resources (may be provided in the slide book).
- Institutional protocols reviewed by the center's Protocol Review and Monitoring System.
- Copies of the minutes or reports of external and internal advisory committees (*e.g.*, the center's Executive Committee).
- The complete institutional Data and Safety Monitoring Plan.

SECTION 3. PEER REVIEW OF THE APPLICATION

3.1 BACKGROUND

Cancer centers may have a number of appropriate missions—research, education, and care. Nevertheless, the CCSG predominantly supports the research mission of the center. The role of peer review is to assess the extent to which the center has promoted or is likely to promote excellence in research that may lead to a reduction in the incidence, morbidity, and mortality attributable to cancer to persons within their catchment area[1] and beyond. Reviewers also evaluate how well the center's leader-ship, organization, and processes for development and evaluation facilitate scientific productivity, strengthen the institution's research capabilities, and enable its investigators to take advantage of scientific opportunities beyond what would have likely occurred at the institution without the CCSG.

Successful cancer centers:

- Have a strong peer-reviewed research base in cancer-related science.
- Add tangible value to the research base already in place within the institution.
- Meet all six essential characteristics of an NCI-designated Cancer Center.

3.2 TYPES OF REVIEW

CCSG applications undergo peer review under the authority and responsibility of the Scientific Review Officer (SRO). Applications may undergo a site visit; the site visit committees gather information for final evaluation by the NCI Initial Review Group Subcommittee-A (NCI Subcommittee-A or NCI-A, *i.e.*, parent committee). (Criteria for Peer Review of Individual Components and Overall Impact/Priority Score of the Cancer Center are presented in Part II, with the instructions for application.)

If there is a site visit, the SRO contacts the center director in advance of the site visit date to decide on the appropriate length of time for the site visit, discuss the proposed agenda, and coordinate other site visit logistics.

In some circumstances, a grantee may elect not to have a site visit; in this case, the review will be based only on the information in the application, (*i.e.*, "paper" review or Application Only Review, see Section 3.2.2).

Proper review of a center, whether at site visits or at the deliberations of the NCI Subcommittee-A, requires evaluation by peers: scientists with substantial experience, a broad perspective on cancer research, and scientific, organizational, and administrative sophistication. Peers may be drawn from cancer centers or institutions without centers. Reviewers who have not served on at least one center site visit in the last 3 years will undergo an orientation.

3.2.1 Site Visit Reviews

A review team will visit the center to seek clarification and update of the application through presentations and tour(s). The separate administrative review during the site visit will be as short as possible, based on the completeness of the application, to permit center administration to attend the site visit presentations. Site visits usually extend a maximum of 5 hours at the center, depending on the size and complexity of the application and center. Centers are encouraged to present formal scientific Programs in groups rather than individually to allow more time for discussion, and have the option to present shared resource data as part of the slide book (posters are optional), so reviewers can focus more time on the Center's scientific Programs. A written report of the site visit is provided to the applicant, who may submit factual corrections prior to the application's final evaluation by the NCI Subcommittee-A.

3.2.2 Application Only Reviews

Application only reviews are available to funded centers that have had no change in director since the last review and received an impact/priority score of 'Excellent' or better in their prior CCSG review.

The application will be reviewed by a subset of members from NCI Subcommittee-A and will be presented to the full NCI Subcommittee-A for final evaluation. NIH submission policies, including those relevant to application dates and post submission of application materials should be accessed at http://grants.nih.gov/grants/funding/submissionschedule.htm#policy and http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-115.html. (See also Section 2.4, Modifications after Submission.)

Applicants should consult with OCC staff before requesting an application only review.

3.2.3 NCI Subcommittee-A Review

The NCI Subcommittee-A is a chartered review committee of the NIH. After considering the written report of the site visit committee (where applicable), the discussion by the NCI Subcommittee-A members who participated in the site visit, the deliberations of the full committee, and the response of the applicant to the site visit report (where applicable), the NCI Subcommittee-A provides a final merit evaluation and a budget recommendation for the CCSG application in a Summary Statement, which is provided to the P30 PD/PI.

The NCI Subcommittee-A also determines if the criteria for comprehensiveness are met (where applicable) and completes Peer Re-Evaluation of PRMS, where required.

3.2.4 Ad hoc *Review*

Whenever conflict of interest exists within the usual peer review process of site visit and NCI Subcommittee-A, (*e.g.*, an application submitted from the institution of a NCI Subcommittee-A member who is the institution's Cancer Center Director), the SRO will conduct a single step ad hoc review.

3.2.5 National Cancer Advisory Board (NCAB)

The NCAB is the final step in the peer review process. The NCAB may concur with all peer review recommendations, ask for re-review, or make some other recommendations. NCAB approval must precede funding.

Final funding decisions are made in accordance with the NCI's budgets for the OCC during each fiscal year.

SECTION 4. GLOSSARY OF ACRONYMS

ARRA American Recovery and Reinvestment Act

CCSG Cancer Center Support Grant

CPDM Clinical Protocol and Data Management

CSR Center for Scientific Review

CTEP Cancer Therapy Evaluation Program

CTSA Clinical Translational Science Awards

CTSP Clinical Trial Reporting Program

DSM Data Safety and Monitoring

DSMP Data Safety and Monitoring Plan

EPCRS Early Phase Clinical Research Support

GWAS Genome-Wide Association Studies

IDE Investigational Drug Exemption

IND Investigational New Drug

IRB Institutional review Board

IRG Initial Review Group

LOI Letter of Intent

MOU Memorandum of Understanding

NCAB National Cancer Advisory Board

NCTN National Clinical Trials Networks

NIH National Institutes of Health

OCC Office of Cancer Centers

PD/PI Project Director/Principal Investigator

PRMS Protocol Review and Monitoring System

SEER Surveillance, Epidemiology and End Results Program

SPORE Specialized Programs of Research Excellence

SRO Scientific Review Officer