Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Cancer Institute (NCI)
Funding Opportunity Title	**Cancer Center Support Grants (CCSGs) for NCI-designated Cancer Centers (P30)**
Activity Code	P30 Center Core Grants
Announcement Type	Reissue of PAR-12-298
Related Notices	• NOT-OD-16-004 - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015) • NOT-OD-16-006 - Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals (November 18, 2015) • October 19, 2015 - Notice of Correction PAR-13-386. See Notice NOT-CA-15-043. • June 4, 2014 - Notice NOT-14-074 supersedes instructions in Section III.3 regarding applications that are essentially the same. • November 20, 2013 - See Notice NOT-CA-14-008. Notice of Correction to Research and Related Other Project Information (Clinical Protocol and Data Management), Research and Related Other Project Information (Research Programs) & PHS 398 Research Plan (Research Programs).
Funding Opportunity Announcement (FOA) Number	**PAR-13-386**
Companion Funding Opportunity	None
Number of Applications	Only one application per institution is allowed as described in Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.397
Funding Opportunity Purpose	This Funding Opportunity Announcement (FOA) invites applications for P30 Cancer Center Support Grants (CCSGs) for NCI-designated Cancer Centers. CCSGs support two types of cancer centers: 1) Comprehensive Cancer Centers, which demonstrate reasonable depth and breadth of research activities in each of three major areas: basic laboratory; clinical; and prevention, control and population-based research, and which have substantial transdisciplinary research that bridges these scientific areas; and 2) Cancer Centers, which are primarily focused on basic laboratory; clinical; and prevention, cancer control, and population-based research; or some combination of these areas. The purpose of both types of NCI-designated Cancer Centers is to capitalize on all institutional cancer research capabilities, integrating meritorious programs in laboratory, clinical, and population research into a single transdisciplinary research enterprise across all institutional boundaries. Cancer Centers supported through this FOA are expected: to serve as major sources of discovery of the nature of cancer and of development of more effective approaches to prevention, diagnosis, and therapy; to contribute significantly to the development of shared resources that support research; to collaborate and coordinate their research efforts with other NCI-funded programs and investigators; and to disseminate research findings for the benefit of the community.

Key Dates

Posted Date	November 7, 2013
Open Date (Earliest Submission Date)	December 25, 2013
Letter of Intent Due Date(s)	60 days prior to the application due date
Application Due Date(s)	February 10, 2014 and then Standard dates apply, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	Standard dates apply
Advisory Council Review	Standard dates apply
Earliest Start Date	Standard dates apply
Expiration Date	January 8, 2017
Due Dates for E.O. 12372	Not Applicable

**** ELECTRONIC APPLICATION SUBMISSION REQUIRED****

NIH's new Application Submission System & Interface for Submission Tracking (ASSIST) is available for the electronic preparation and submission of multi-project applications through Grants.gov to NIH. Applications to this FOA must be submitted electronically; paper applications will not be accepted. ASSIST replaces the Grants.gov downloadable forms currently used with most NIH opportunities and provides many features to enable electronic multi-project application submission and improve data quality, including: pre-population of organization and PD/PI data, pre-submission validation of many agency business rules and the generation of data

summaries in the application image used for review.

Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*) and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options to submit your application to the agency through Grants.gov. You can use the ASSIST system to prepare, submit and track your application online. You can download an application package from Grants.gov, complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons. Or, you can use other institutional system-to-system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons. Learn more.

Apply Online Using ASSIST Problems accessing or using ASSIST should be directed to the eRA Service Desk.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

This Funding Opportunity Announcement (FOA) invites applications for P30 Cancer Center Support Grants (CCSGs) for NCI-designated Cancer Centers. NCI-designated Cancer Centers serve as major sources of discovery into the nature of cancer and of the development of more effective approaches to prevention, diagnosis, and therapy. They contribute significantly to the development of shared resources that support cancer relevant research and they collaborate and coordinate their research efforts with other NCI-funded programs and investigators.

The objectives of the NCI Centers Program are to foster highly interactive cancer research through support of the following:

- Formal, interactive scientific research programs comprised of investigators with common scientific interests and goals, yielding competitively funded research grants and contracts and productive collaborations;
- Centralized Shared Resources that provide access to technologies, services, and scientific consultation that enhance scientific interaction and productivity;
- Strategic planning and evaluation that further the research agenda of the Center;
- Developmental funding that allows the Center to pursue newly identified priorities, strengthen weaker scientific areas, and explore new collaborations and technologies;
- Centralized Cancer Center administration for resources and services, fiscal management and other supportive activities; and
- Centralized scientific oversight of cancer clinical trials.

NCI support to Cancer Centers is intended to foster excellence in research across a broad spectrum of scientific and medical concerns relevant to cancer. To facilitate discovery and its translation into direct benefit to patients and the general public, the NCI awards CCSGs to institutions that have a critical mass of excellent cancer-relevant scientific research. The CCSG focus on research derives from the belief that a culture of discovery, scientific excellence, transdisciplinary research, and collaboration yields tangible benefits extending far beyond the generation of new knowledge.

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.

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, 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.

NOTE: 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 other geographically defined boundaries. It must include the local area surrounding the cancer center

The NCI recognizes two types of 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 areas. 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, 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.

The Six Essential Characteristics of an NCI-designated Cancer Center

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:

- **Physical Space:** 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.
- **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.

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 and conduct early proof-of-principle clinical trials and lead, and/or participate in, NCI's NCTN trials (including studies of rare cancers). Cancer Centers 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.

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.

Section II. Award Information

Funding Instrument	Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
Application Types Allowed	New Renewal Resubmission Revision The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.
Award Budget	**New (Type 1)** applications should not exceed $1,000,000 in direct costs during the initial, year-one grant period. The budget for years 2-5 of new applications may receive cost-of-living adjustments consistent with the NCI policy in effect for the fiscal year. **Renewal (Type 2)** 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. Funding may be requested for up to five years. Larger budget increases for Type 2 applications should be requested only under exceptional circumstances *(i.e.*, first renewal application after a no-cost extension or reduced award). Scientific/ Research Contacts listed in this FOA 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.
Award Project Period	5 years

NIH grants policies as described in the *NIH Grants Policy Statement* will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as defined in the NIH Grants Policy Statement, **are not** allowed.

An applicant institution must have **a funding 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.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- NATO Commercial and Government Entity (NCAGE) Code – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account and should work with their organizational officials to either create a new account or to affiliate an existing account with the applicant organization's eRA Commons account. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the *NIH Grants Policy Statement*.

3. Additional Information on Eligibility

Number of Applications

Only one application per institution is allowed.

NIH will not accept any application that is essentially the same as one already reviewed within the past thirty-seven months (as described in the *NIH Grants Policy Statement*), except for submission:

- To an RFA of an application that was submitted previously as an investigator-initiated application but not paid;
- Of an investigator-initiated application that was originally submitted to an RFA but not paid; or
- Of an application with a changed grant activity code.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants can access the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at Grants.gov.

Most applicants will use NIH's ASSIST system to prepare and submit applications through Grants.gov to NIH. Applications prepared and submitted using applicant systems capable of submitting electronic multi-project applications to Grants.gov will also be accepted.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

Letter of Intent

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 IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

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

The letter of intent should be sent to:

Director, Office of Cancer Centers
National Cancer Institute (NCI)
Telephone: 240-276-5600
Fax: 240-276-5625
Email: ncicenters-r@mail.nih.gov

Page Limitations

Component Types Available in ASSIST	Research Strategy/Program Plan Page Limits
Overall	30 pages
Admin Core	12 pages
Core (Use for: Planning and Evaluation Developmental Funds Shared Resources Clinical Protocol and Data Management Protocol Review and Monitoring System Early Phase Clinical Research Support Center)	12 pages each
Project (use for Research Programs)	12 pages each

Additional page limits described in the SF424 Application Guide and the Table of Page Limits must be followed.

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in the SF424 (R&R) Application Guide, and should be used for preparing a multi-component application.

The application should consist of the following components:

- Overall (required) to include:
  - Director's Overview
  - Six Essential Characteristics
- Administrative Core (required) to include:
  - Cancer Center Administration
  - Senior Leadership
- Cores
  - Planning and Evaluation (required)
  - Developmental Funds (optional)
  - Shared Resource (at least one is required)
  - Clinical Protocol and Data Management (required for clinical and comprehensive cancer centers) to include: Clinical Protocol and Data Management, Data and Safety Monitoring, Inclusion of Women and Minorities, and Inclusion of Children in Clinical Research
  - Protocol Review and Monitoring System (required for clinical and comprehensive cancer centers)
  - Early Phase Clinical Research Support (optional)
- Research Programs (at least one is required)

Overall Component

When preparing your application in ASSIST, use Component Type ‘Overall’.

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

Note: Human Embryonic Stem Cell lines from other components should be repeated in cell line table in Overall component.

Research & Related Other Project Information

Follow standard instructions.

Project Summary/ Abstract: Briefly describe the problems being addressed by the Cancer Center and how the Cancer Center solves target problems related to health effects.

Project Narrative: Indicate the relevance of the Center's research to public health.

Facilities and Other Resources: Include a description of the following in a single attachment.

Physical Space

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 may be provided.

Institutional Commitment

- A table providing information on funding from the institution and individual consortium partners.
- A chart indicating the organizational status of the Cancer Center within the institution may be provided.
- A table summarizing institutional commitment to research, clinical and administrative space and positions may be provided.

Other Attachments: The following "Other Attachments" should be included with the overall component in order to aid in the review of applications. The filename provided for each attachment will be the name used for the bookmark in the application image.

I. Supportive Data Tables

These data tables (see CCSG Summary 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.

For each Data Table, please use a separate attachment.

- Data Tables 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.

  Please title this attachment "DT1"

- Data Table 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. Please title this attachment "DT2A"
- Data Table 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.

  Please title this attachment "DT2B"

- Data Table 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.)

  Please title this attachment "DT3"

- Data Table 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.)

  Please title this attachment "DT4"

- Data Table 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.

  Please title this attachment "DT5"

II. Information on Consortium

If the application is submitted as a consortium, a table listing locations of all partnering institutions may be provided.

Project/Performance Site Location(s) (Overall)

Enter primary site only.

A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components will be generated upon submission.

Research & Related Senior/Key Person Profile (Overall)

Include only the Project Director/Principal Investigator (PD/PI) (*i.e.* Director of Cancer Center) and any multi-PDs/PIs (if applicable to this FOA) for the entire application.

A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall section of the assembled application image in eRA Commons will be generated upon submission.

Budget (Overall)

The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover.

A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.

PHS 398 Research Plan (Overall)

Introduction to Application: For Resubmission and Revision applications, an Introduction to Application is required in the Overall component

Specific Aims: Describe the mission and specific aims of the Cancer Center.

Research Strategy: This section must contain two parts:

Part I: Director Overview

Provide a short history and overview of the Cancer Center. Briefly describe the most important research accomplishments during the last period of support. If you are presenting a consortium Center, briefly outline the contributions of each institution, and the history, objectives, and benefits of the consortium arrangement. Do not duplicate text in the Six Essential Characteristics below.

Part II: Six Essential Characteristics

Physical Space: 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, briefly describe the physical facilities dedicated to cancer research, Center shared resources, and administration. Indicate how the Center facilitates access to shared resources and other services (i.e., Clinical Protocol and Data Management).

Organizational Capabilities: 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.

While a formal written strategic plan is not required, general processes 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 documented, including those for determining and sustaining individual membership in the Center.

Using the above description, discuss how the organizational structure enhances the capabilities 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.

Transdisciplinary Collaboration and Coordination: An actively functioning Center promotes innovative and interactive research opportunities through the formation of formal scientific 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 NCTN) 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.

Cancer Focus: 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.

Institutional Commitment: 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 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.

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.

Center Director: 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, briefly describe the scientific and administrative qualifications and leadership experience specifically pertinent to the Center Director role. 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.

Letters of Support: As the attachments, include letters of support signed by the Dean and Hospital President and/ or other appropriate institutional officials documenting specifics of institutional commitment both for the long-term future of the Center and for this award period.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Administrative Core

When preparing your application in ASSIST, use Component Type 'Admin Core.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Administrative Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project: Administrative Core
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Administrative Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Administrative Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Summary/ Abstract: Required

Project Narrative: Do not complete

Other Attachments: In a table, provide sources of funding for activities of the administrative office, including the CCSG.

Project /Performance Site Location(s) (Administrative Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Administrative Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.

Budget (Administrative Core)

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).

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, a consolidated budget of person months and justifications for all senior leaders.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Administrative Core)

Introduction to Application: For Resubmission and Revision applications, an Introduction to Application is allowed for each component

Specific Aims: Summarize the broad, long-range objectives and goals of the proposed Core.

Research Strategy: This section must contain two parts:

Part I: Cancer Center Administration:

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

- Roles of administrative staff 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.

Part II: Senior Leadership:

Provide a one paragraph description of the role of each senior leader. 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 problems applicable to the catchment area served by the Center.
- 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.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Administrative Core)

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report (Administrative Core)

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

Planning and Evaluation

When preparing your application in ASSIST, use Component Type 'Core.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Planning and Evaluation)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project: Planning and Evaluation
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Planning and Evaluation)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Planning and Evaluation)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Summary/ Abstract: Required

Project Narrative: Do not complete

Other Attachments: In one document, provide a consolidated list of EAC members with titles and affiliations and attach their biosketches.

Project /Performance Site Location(s) (Planning and Evaluation)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Planning and Evaluation)

- Include only the Project Director/Principal Investigator (PD/PI) (*i.e.* Director of Cancer Center) and any multi-PDs/PIs (if applicable to this FOA) for the entire application.
- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.

Budget (Planning and Evaluation)

Provide an overall description, a consolidated budget, and a narrative justification for each planning and evaluation activity. Budgetary support is allowable for all activities listed in the Research Strategy section, with the exception of development of future scientific programs. 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.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Planning and Evaluation)

Introduction to Application: For Resubmission and Revision applications, an Introduction to Application is allowed for each component

Specific Aims: Summarize the broad, long-range objectives and goals of the proposed Core.

Research Strategy: 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.

Planning and evaluation activities may also include *ad hoc* scientific and technical consultation with experts outside the Center, seminar series (when 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 narrative should describe the vision and general plans for the future scientific development of the Center, including plans for developing new programs. It also should summarize the activities that supported Center development and improvement over the last project period. Discuss recommendations made by the EAC, any actions taken in response to those recommendations, and reasons for not responding. Describe 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.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Planning and Evaluation)

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report (Planning and Evaluation)

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

Developmental Funds

When preparing your application in ASSIST, use Component Type 'Core'.

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Developmental Funds)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)

- Descriptive Title of Applicant's Project: Developmental Funds
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Developmental Funds)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Developmental Funds)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Summary/ Abstract: Required

Project Narrative: Do not complete

Other Attachments: If a budget is requested to support pilot projects, please provide a list of awardees and their projects with the outcome for the preceding project period.

If the budget is requested to support Staff Investigators, please provide a biosketch for each proposed Staff Investigator with a list of her/ his grants or clinical trials that s/he oversees.

Project /Performance Site Location(s) (Developmental Funds)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Developmental Funds)

- Include only the Project Director/Principal Investigator (PD/PI) (*i.e.* Director of Cancer Center) and any multi-PDs/PIs (if applicable to this FOA) for the entire application.
- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.

Budget (Developmental Funds)

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.

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.

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 three 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.

Interim salary and support are 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.

CCSG funds may be used to help Centers develop new shared resources when there is a recognized 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. CCSG funds may not be used for upgrades or routine purchases of equipment when developing a new shared resource.

When purchasing a shared service from other NCI-designated Cancer Centers, 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.

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.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Developmental Funds)

Introduction to Application: For Resubmission and Revision applications, an Introduction to Application is allowed for each component

Specific Aims: Summarize the broad, long-range objectives and goals of the proposed Core.

Research Strategy: 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.

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.

In your application, explain how these developmental funds were used in the previous three to five 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 are 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.

The application should describe the processes for eliciting and reviewing proposals, and list the awardees and their projects for the preceding project period.

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. The NCI OCC staff will act as the liaison between the Centers and the NIH Fogarty International Center, which is responsible for coordinating all clearances.

Pilot projects supported via this application component may be subject to NIH requirements for approval of human subjects, planned enrollment and inclusion reporting for delayed onset awards. Further information is available at: http://grants.nih.gov/grants/guide/notice-files/not-od-12-130.html.

- Development of new Shared Resources: Centers may develop new shared resources when there is a recognized need. 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. 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. 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.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Developmental Funds)

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

Pilot projects supported via this application component may be subject to NIH requirements for approval of human subjects, planned enrollment and inclusion reporting for delayed onset awards. Further information is available at: http://grants.nih.gov/grants/guide/notice-files/not-od-12-130.html

PHS 398 Cumulative Inclusion Enrollment Report (Developmental Funds)

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

Pilot projects supported via this application component may be subject to NIH requirements for approval of human subjects, planned enrollment and inclusion reporting for delayed onset awards. Further information is available at: http://grants.nih.gov/grants/guide/notice-files/not-od-12-130.html

Shared Resources

When preparing your application in ASSIST, use Component Type 'Core.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Shared Resources)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project: Name of a Shared Resource
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Shared Resources)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Shared Resources)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Summary/ Abstract: Required

Project Narrative: Do not complete

Other Attachments: The requested budget for each Shared Resource 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.

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				

Project /Performance Site Location(s) (Shared Resources)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Shared Resources)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.

Budget (Shared Resources)

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.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Shared Resources)

Introduction to Application: For Resubmission and Revision applications, an Introduction to Application is allowed for each component

Specific Aims: Summarize the broad, long-range objectives and goals of the proposed Core.

Research Strategy: In addressing Research Strategy for each Shared Resource, the applicant must adhere to the general guidelines below.

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).

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 this effort would normally be supported by an appropriate time-and-effort allocation as a collaborator on that grant.

In the narrative 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).
- Processes relevant to facility planning and oversight.
- Current and/or anticipated use of services providing 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 provide a list of users. Do not include users from other Centers in your calculations.
- Policies on operation and use of the shared resource, *e.g.*, access, priorities, hours of operation, staffing, etc., and charge back systems. For institutionally managed (as opposed to Cancer Center managed) resources, describe the Center's role in planning and oversight of the shared resource(s).

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

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Shared Resources)

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

For this FOA, planned enrollment report and inclusion data are reported in '*Center Inclusion of Women and Minorities, and Inclusion of Children in Clinical Research'.*

PHS 398 Cumulative Inclusion Enrollment Report (Shared Resources)

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

For this FOA, inclusion data are reported in '*Center Inclusion of Women and Minorities, and Inclusion of Children in Clinical Research'.*

Clinical Protocol and Data Management

When preparing your application in ASSIST, use Component Type 'Core.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Clinical Protocol and Data Management)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project: Clinical Protocol and Data Management
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Clinical Protocol and Data Management)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Clinical Protocol and Data Management)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Summary/ Abstract: Required

Project Narrative: Do not complete

Other Attachments:

I. Provide an overview of accrual to interventional clinical trials over the project period preceding the renewal application. [Note: This is a summary of Data Table 4 interventional trial data and the definitions, reporting years, and accrual sites used in Data Table 4 apply to the data in this table]. A sample template is below:

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)					
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 4 data for observational, ancillary, and correlative studies.

II. For the Inclusion of Women and Minorities, include in tables information on:

Demographics. In three sections, provide summary information showing the demographics of the primary geographic catchment area 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 have the option of also providing data on demographics of cancer patients in the catchment area, if available.

Project /Performance Site Location(s) (Clinical Protocol and Data Management)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Clinical Protocol and Data Management)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Clinical Protocol and Data Management)

Clinical Protocol and Data Management 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, NCTN, 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 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 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.

Data and Safety Monitoring: Funding may be requested for appropriate support staff and supplies. Do not include DSM activities directly supported on other grants and contracts.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Clinical Protocol and Data Management)

Introduction to Application: For Resubmission and Revision applications, an Introduction to Application is allowed for each component

Specific Aims: Summarize the broad, long-range objectives and goals of the proposed Core.

Research Strategy: This section must contain four parts:

Part I: Clinical Protocol and Data Management (formerly a shared resource)

It 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 nurses; 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.

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.

Part II: Data and Safety Monitoring

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.

Provide a very brief summary of the Center's DSM plan. Do *not* include the entire plan within the text but provide a copy as per Section V.2 (Review and Selection Process/ Review Materials to be Available) of this FOA.

If funding is requested, 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.

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.

Part III: Inclusion of Women and Minorities:

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.

When women or minorities are substantially under-represented in relation to catchment area 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 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.

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 if desired.

Plans for Accrual of Women and Minorities: In this section, 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, which demonstrate a clear effort to recruit and retain women and minorities and correct deficiencies that are potentially avoidable.

Part IV: Inclusion of Children in Clinical Research:

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 Guidelines" on the inclusion of children as participants in research involving human subjects (http://grants.nih.gov/grants/funding/children/children.htm).

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Clinical Protocol and Data Management)

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report (Clinical Protocol and Data Management

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

Protocol Review and Monitoring System

When preparing your application in ASSIST, use Component Type 'Core.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Protocol Review and Monitoring System)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project: Protocol Review and Monitoring System
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Protocol Review and Monitoring System)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Protocol Review and Monitoring System)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Summary: Required

Project Narrative: Do not complete

Other Attachments:

1. In Data Table 4 format, provide a list of 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 review as per Section V.2 (Review and Selection Process/ Review Materials to be Available) of this FOA.

2. 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. A sample template is below:

Number of Protocols Reviewed or Prioritized by Source of Support and Year (for most recent three years of activity)

Year (Specify mm/yyyy-mm/yyyy)				Total
National Group				

Externally Peer-Reviewed				
Institutional				
Industry				

Project /Performance Site Location(s) (Protocol Review and Monitoring System)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Protocol Review and Monitoring System)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list all PRMS Committee Members and provide their biosketches.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Protocol Review and Monitoring System)

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

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Protocol Review and Monitoring System)

Introduction to Application: For Resubmission and Revision applications, an Introduction to Application is allowed for each component

Specific Aims: Summarize the broad, long-range objectives and goals of the proposed Core.

Research Strategy: In addressing Research Strategy for Protocol Review and Monitoring System, the applicant must adhere to the general guidelines below.

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.

In the Research Strategy section:

Describe the criteria for selection of the membership of the committee. List the members of the committee and their expertise. 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
- Process for review of all cancer clinical research protocols of the institution
- 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;
- 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.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Protocol Review and Monitoring System)

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report (Protocol Review and Monitoring System)

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

Early Phase Clinical Research Support

When preparing your application in ASSIST, use Component Type 'Core.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Early Phase Clinical Research Support)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project: Early Phase Clinical Research Support
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Early Phase Clinical Research Support)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Early Phase Clinical Research Support)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Summary: Required

Project Narrative: Do not complete

Other Attachments:

1. Provide a listing of all studies supported with Early Phase Clinical Research Support (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).

2. Provide a list of proposed pilot/ Phase I projects.

Project /Performance Site Location(s) (Early Phase Clinical Research Support)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Early Phase Clinical Research Support)

Include only the Project Director/Principal Investigator (PD/PI) (*i.e.* Director of Cancer Center) and any multi-PDs/PIs (if applicable to this FOA) for the entire application.

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.

Budget (Early Phase Clinical Research Support)

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.

Funds in this component may not be used for any supervisory functions.

These funds may be used for global health projects, but must meet all eligibility criteria listed below. 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.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Early Phase Clinical Research Support)

Introduction to Application: For Resubmission and Revision applications, an Introduction to Application is allowed for each component

Specific Aims: Summarize the broad, long-range objectives and goals of the proposed Core.

Research Strategy: 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 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.

In this section, 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.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Early Phase Clinical Research Support)

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

Pilot projects supported via this application component may be subject to NIH requirements for approval of human subjects, planned enrollment and inclusion reporting for delayed onset awards. Further information is available at: http://grants.nih.gov/grants/guide/notice-files/not-od-12-130.html.

PHS 398 Cumulative Inclusion Enrollment Report (Early Phase Clinical Research Support)

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

Pilot projects supported via this application component may be subject to NIH requirements for approval of human subjects, planned enrollment and inclusion reporting for delayed onset awards. Further information is available at: http://grants.nih.gov/grants/guide/notice-files/not-od-12-130.html.

Research Programs

When preparing your application in ASSIST, use Component Type 'Project.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Research Programs)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project: for each Program, please provide the title with the Program code (used in Data Tables 1 and 2 of the Standard Cancer Center Information Summaries)
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Research Programs)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Research Programs)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Summary/ Abstract:

For each Program, please provide the following:

- 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).

Project Narrative: Do not complete

Other Attachments:

For each Program, please provide:

- *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 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 NCTN 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, multi-investigator grants and publications, 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).* 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 for all publications receiving direct cost support through the CCSG Shared Resources and Developmental and Early Phase Clinical Research components. Divide the publications list into two parts, those with a PMC ID (*i.e.,* meeting the criteria above) and those without. Renewal applications should limit this list to significant publications from the last project period.
- *A list of the clinical research of the Program (no page limit)* using the definitions and format specified in the instructions for Data Table 4. NOTE: Centers may present Data Table 4 in individual programs, in one centralized program, or in some combination of these approaches, depending on the organization of their center.

Project /Performance Site Location(s) (Research Programs)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Research Programs)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the Project Director/Principal Investigator section, use Project Role of 'Other' with Category of 'Program Leader' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Program co-Leaders that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.

Budget (Research Programs)

Please provide budget for the person months of the first and future years for the Program leader(s). 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.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Research Programs)

In addressing Research Plan for each Research Program, applicant must adhere to the general guidelines below.

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.

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.

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 PD(s)/PI(s) 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. Each Program leader should have a specific role in facilitating the discovery process and promoting transdisciplinary research important to cancer, and any projected use of funds to support other scientific activities.

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, P01 and 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 activity codes, 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.

Introduction to Application: For Resubmission and Revision applications, an Introduction to Application is allowed for each component

Specific Aims: Summarize the broad, long-range objectives and goals of the proposed Research Program.

Research Strategy: For each Program, 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 and the effect of those accomplishments. Discuss how the Cores (Shared Resources) have supported those accomplishments.
- 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
- For Programs with clinical trials:
  - activated interventional clinical trials that are making a difference, e.g., advancing the field or changing medical practice
  - accrual of patients to interventional clinical trials over the project period preceding the current application, including a brief overview of accrual by types of trials (national, institutional, externally peer-reviewed, and 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 is addressed. This may include, for example, a discussion of research focused on cancer health disparities (*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.

  NOTE: 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.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Research Programs)

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report (Research Programs)

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement*.

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement*.

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.

6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

For information on how your application will be automatically assembled for review and funding consideration after submission go to: http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically.

Important reminders:
All PD(s)/PI(s) and component Project Leads must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH. Applications that are incomplete will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030.

Section V. Application Review Information

NEW Important Update: **See NOT-OD-16-006 for updated review language for applications for due dates on or after January 25, 2016.**

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIH mission, all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Cancer centers may have a number of appropriate missions — research, education, and care. Nevertheless, the CCSG predominantly supports the research mission of the center.

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

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 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.

Overall Impact - Overall

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

Scored Review Criteria - Overall

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. 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.

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?

Investigator(s)

Are the PD(s)/PI(s), 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?

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?

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?

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?

Additional Review Criteria - Overall

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Physical Space: (merit descriptor)

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

Organizational Capability: (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 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: (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: (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: (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 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: (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?

Cancer Center Administration: (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?

Senior Leadership: (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?
  - Establishing a process for integrating the training and education of biomedical scientists and health care professionals into programmatic research efforts?

Planning and Evaluation: (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?

Developmental Funds: (merit descriptor)

- How effective has the Center been in using developmental funds to strengthen cancer related science in the prior project period, if applicable, 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 is the Center 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?

Shared Resources and Services: (merit descriptor)

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

Clinical Protocol and Data Management: (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: (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?

Center Inclusion of Women and Minorities & Inclusion of Children in Clinical Research (approval/disapproval)

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Inclusion of Minorities and Women in Clinical Research: (approval/ disapproval)

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

Inclusion of Children in Clinical Research: (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?

Protocol Review and Monitoring System (PRMS): (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?

Early Phase Clinical Research Support (EPCRS): (merit descriptor)

- How well do the proposed studies comply with criteria for support outlined in this FOA?
- 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 are the prioritization and selection process for use of funds in this component?

Scientific Quality of Each Program: (merit descriptor for each Program)

- 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 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?
- For Programs with clinical trials:
    - 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 coordination across clinical funding mechanisms of the NCI or collaborations with industry or other partners?
    - How successfully do feasibility and other early phase trials capitalize on the scientific strengths of the Program?
    - 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 represented?
- How appropriate and effective are the Program Leaders in relation to expertise, program management, and time commitment?

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: 1) defined the cancer problems relevant to its catchment area and 2) served its catchment area (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?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations - Overall

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Not Applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the NCI, in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Cancer Advisory Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons.

Information regarding the disposition of applications is available in the *NIH Grants Policy Statement*.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the *NIH Grants Policy Statement*.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements as noted on the Award Conditions and Information for NIH Grants website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities. More information is provided at Award Conditions and Information for NIH Grants.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590 or RPPR) annually and financial statements as required in the *NIH Grants Policy Statement*.

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the *NIH Grants Policy Statement*.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the *NIH Grants Policy Statement* for additional information on this reporting requirement.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Web ticketing system: https://public.era.nih.gov/commonshelp
TTY: 301-451-5939
Email: commons@od.nih.gov

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact Center Telephone: 800-518-4726

Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx
Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Telephone 301-435-0714
TTY 301-451-5936
Email: GrantsInfo@nih.gov

Scientific/Research Contact(s)

Office of Cancer Centers
National Cancer Institute (NCI)
Telephone: 240-276-5600
Email: ncicenters-r@mail.nih.gov

Peer Review Contact(s)

Referral Officer
National Cancer Institute (NCI)
Telephone: 240-276-6390
Email: ncirefof@dea.nci.nih.gov

Financial/Grants Management Contact(s)

Office of Grants Administration
National Cancer Institute (NCI)
Telephone: 240-276-6277

Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts*. All awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement*.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.