December, 2007

Guidelines

Specialized Program of Research Excellence (SPORE)

Organ Systems Branch
Office of Centers, Training, and Resources
Office of the Director
National Cancer Institute

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Section I. Overview of Specialized Program of Research Excellence (SPORE)

A. Introduction

Specialized Program of Research Excellence (SPORE) were conceived and implemented by the National Cancer Institute (NCI) through a special $20 million appropriation from Congress in Fiscal Year 1992. This program was initiated by the NCI to promote interactions between basic and applied scientists for the development of new approaches to the prevention, early detection, diagnosis, and treatment of human cancer. Since the objective of this program is to encourage a diversity of approaches to translational research, the P50 mechanism was chosen to support these grants. This mechanism has all of the features necessary to enable SPORE to achieve translational goals, including the support of the following features: multiple translational research projects; co-leadership on all projects; specialized cores; flexibility to terminate and initiate new research projects without additional peer review; research engines to develop pilot projects as well as to foster the development of translational scientists; and encouragement to combine resources and expertise between SPOREs to test new technologies and human applications.

B. SPORE Definition of Translational Research

There is currently no consensus definition of translational research. For the SPORE, the NCI defines translational research as follows: **translational research uses knowledge of human biology to develop and test the feasibility of cancer-relevant interventions in humans and/or determines the biological basis for observations made in individuals with cancer or in populations at risk for cancer**. The term "Interventions" is used in its broadest sense to include molecular assays, imaging techniques, drugs, biological agents, and/or other methodologies applicable to the prevention, early detection, diagnosis, prognosis, and/or treatment of cancer. Translational research in SPORE is always based upon knowledge of human biology stemming from research involving the use of any cellular, molecular, structural, biochemical, genetic, and/or other appropriate experimental approaches.

SPOREs conduct early-stage interventions to establish the feasibility or proof-of-principle of specific approaches in cancer. All of these research projects, whose goals are the development and testing of interventions, are expected to reach the feasibility testing stage in humans within the anticipated 5-year periods of grant support. Similarly, studies that seek to determine the biological bases for observations in human cancer should do so within 5 years. Some, but not all, types of behavioral research are appropriate for SPOREs. Bio-behavioral research projects that are clearly focused on links between biological variables, processes, and mechanisms pertaining to behavior and/or psychosocial variables are appropriate. Psychosocial variables might include cognition, affect, personality, and/or interpersonal context(s) or process(es) (e.g., social support, familial interactions, physician-patient communication). Behavioral research projects that are focused on psychosocial processes or behavior changes without clear, specific linkages to biological processes (e.g., disease susceptibility, etiology, or progression) are not appropriate. SPOREs are also not the mechanism for definitive validations of new interventions, which are supported by other programs within other extramural program (funding) components of the NCI.

Within the limits of the definitions and time frames outlined above, SPOREs have considerable flexibility in selecting and developing areas of research with the greatest anticipated potential for improving cancer outcomes. Investigators who question whether their research goals adhere to the above definition of translational research and/or the expectations of this program are advised to consult with NCI program staff in the Organ Systems Branch (OSB). A current listing of OSB program staff can be found at http://spores.nci.nih.gov.

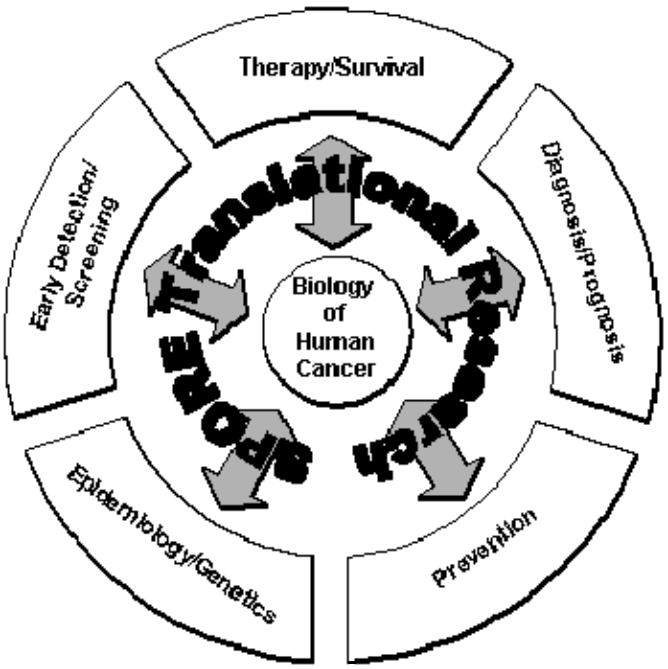

Figure 1. Translational research focus of SPOREs. Research projects should be designed to: (a) test the relevance of a biological discovery in human cancer risk, epidemiology/genetics, prevention, early detection/screening, diagnosis, prognosis, and/or treatment; and/or (b) determine the biological basis of an observation made in the clinic or population within the 5-year term of the grant.

C. General Description of the SPORE Program

For the SPOREs, the NCI utilizes the NIH P50 grant mechanism to support interdisciplinary teams of investigators who are dedicated to translational research focused on an organ-specific human cancer (e.g., breast cancer) or a highly related group of human cancer types (e.g., gastrointestinal cancers). SPOREs are open to any scientific approaches that can have impact(s) on the disease and that are dependent upon team approaches in the design and implementation of the research. SPOREs differ from NIH/NCI program project (P01) grants by focusing exclusively on translational research and human disease, having a flexible approach to initiating and terminating research projects, supporting the critical acquisition and banking of human specimens, and encouraging the development of new translational opportunities through developmental programs. In addition to their organ-site orientations, all SPOREs include the following common features.

1. Translational Research Focus

All SPOREs must be focused on translational research that meets the definition provided in Section I.B. above. SPOREs are dedicated to capitalizing on research opportunities that have the potential to impact upon the prevention, detection, diagnosis, and/or treatment of human cancer. SPORE projects can include some basic science objectives if they are relevant to human cancer and will lead to a human application during the 5-year term of the grant. If a project has lost its translational focus or the likelihood of having an impact on human cancer, it should be discontinued as a SPORE project and another funding source should be sought.

2. Collaborative Design and Implementation of Research Projects

Every project in a SPORE is inherently translational because, in general, it is collaboratively designed and executed by basic scientists working at the cellular and molecular levels, physicians experienced in patient-oriented research, and population scientists experienced in studying the patterns of disease.

3. Flexibility to Change Research Direction/Team Approach

SPOREs continually select the most promising research approaches likely to have immediate impacts on improving cancer prevention, detection, diagnosis, prognosis, and/or treatment. The flexibility of the SPORE program promotes the termination of research projects that demonstrate little or no translational progress and enables new projects with greater potential to be initiated. While the team of scientists that participates in the SPORE remains largely the same, the roles of co-leaders on projects may change through the course of the research.

The principal investigator (PI) of the SPORE is expected to make decisions about the continuation or discontinuation of projects in consultation with his/her internal and external advisors, as well as with other lead investigators on the SPORE. The flexibility option is evoked only after the SPORE application has been awarded; a new project cannot be proposed for one that has overlap with an awarded or soon-to-be awarded U.S. Public Health Service (PHS) grant. Although it is acceptable for investigators to concurrently submit essentially the same research proposal as a SPORE project and as an independent R01, R21, etc., application to the NIH, they

must be prepared to relinquish the R01 (or other single project) application if both are determined to be meritorious and eligible for funding. It is against NIH policy to concurrently submit both a P01 and a P50 application requesting support for the same projects/activities as well as for an investigator(s) to submit a project proposal(s) that has significant overlap with an already funded activity. These latter types of potential overlaps will be screened and evaluated by NCI staff prior to review; submitted applications will be returned without review if they do not conform to these policies or fail to meet the minimal requirements of the SPORE Program. For additional information, please see PHS 398 Instructions (Rev. 09/2004; Part I, page 38) and Section E.4.f. below.

4. Specialized Research Infrastructure

SPOREs are expected to develop the critical research infrastructure needed to sustain translational research objectives for projects within the SPORE, as well as for potential collaborative research with other SPOREs and other research groups within the biomedical research community. SPOREs are expected to be in a position to facilitate the complex research objectives inherent in studying human cancer.

5. Fostering Translational Research Careers

SPOREs provide a unique environment for translational research that can be used to prepare new scientists for careers in this evolving field or provide the opportunity for established scientists to re-orient their research careers toward translational research.

6. Research Collaborations, Networks, and Consortia

SPOREs are expected to identify the kinds of research questions that can only be accomplished through collaborations, networks, and consortia. SPOREs collaborate with other scientists in cancer research field to answer research questions that take full advantage of SPORE scientific expertise and infrastructure. Through the promotion of inter-SPORE research, SPOREs also conceive and initiate research that is linked to other key programs of the NCI and NIH.

7. Sharing Information, Data, and Resources

SPOREs readily share information, data, and resources within their organ site network, as well as

with other SPOREs, to take advantage of research results that are applicable to various cancer sites. Applications for SPORE grants are required to include a data and research resources sharing plan. The plan should outline how final research data will be shared among the SPOREs, as well as with the research community at large, or state why this is not possible. For additional information on the NIH Data Sharing Policy, see http://grants.nih.gov/grants/policy/data_sharing/. The NIH also requires the timely sharing of biomedical resources by grant recipients. Therefore, the plan should also describe how unique research resources will be distributed, e.g., through the institution, a repository, or national coordinating center. For information regarding research resources sharing, see http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc546000132 information regarding the sharing of model organisms can be found at http://grants.nih.gov/grants/policy/model_organism/index.htm.

D. Eligibility Requirements for Submission of a SPORE Application

P50 SPORE Applications must meet all of the following eligibility criteria as well as contain the required components of a SPORE. Applications that are not responsive to these requirements will be returned to the applicant by NCI program staff and will not undergo scientific peer review.

1. **Eligibility**

   (a) Institutional and individual

   Applications may be submitted by domestic for-profit and non-profit organizations, either public or private, including universities, colleges, hospitals, and laboratories, units of State and local governments, units of State and local Tribal governments, eligible agencies of the Federal government, and faith-based or community-based organizations. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators (PIs).

   Because SPOREs are supported by P50 mechanism, foreign institutions cannot apply as a primary site. These grants can only be awarded to institutions located within the United States. Consortium agreements with foreign institutions, however, can be proposed as

long as the appropriate federal-wide assurances for the protection of human subjects are in place (see http://www.hhs.gov/ohrp/) and the activities at the foreign site(s) do not exceed 49 percent of the direct costs of the overall budget. NIH provides limited facilities & administrative (F&A) costs (8 percent of total direct costs less equipment) to foreign institutions and international organizations to support the costs of compliance with NIH requirements, including, but not limited to, protection of human subjects, animal welfare, and research misconduct. See the NIH Grants Policy Statement (Revised December 2003) at http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm.

(b) Statement of Institutional Commitment

An institution applying for a SPORE grant should demonstrate a commitment to the proposed SPORE's stability and success by promising to incorporate the SPORE, if awarded, high within its institutional priorities. The application must provide a statement of commitment that includes a plan addressing how the institutional commitment will be established and sustained, how the institution will maintain accountability for promoting scientific excellence, and how the SPORE research effort will be given a high priority within the institution (relative to other research efforts). The institutional commitment may be in the form of support for recruitment of scientific talent, provision of discretionary resources to the SPORE Director, assignment of specialized research space, cost sharing of resources, and/or other ways proposed by the applicant institution. *Letters from a high-level institution official(s) (e.g., Dean of the School of Medicine, President, and Vice President for Research) and the Cancer Center Director should be attached confirming this commitment*. In the case of a SPORE that involves a consortium arrangement between two or more institutions, the institution that submits the P50 application must receive a formal written agreement(s) from the other participant organization(s). This agreement should clearly delineate the institutional commitment of the participating organization(s) (in the ways outlined above) to the Program.

The primary institution is strongly encouraged to demonstrate this commitment by providing financial support to the Developmental Research and Career Development Programs on an awarded SPORE, as well as other programmatic needs identified as high priority on the original

application. Up to $50,000 of the SPORE direct costs budget per year may also be requested for use as discretionary funds by the PI. The institution(s) is encouraged to match this request. These funds can be used to support anticipated, as well as unanticipated, activities, such as a clinical trial in year 2, pre-clinical testing of an agent in year 3, etc. Discretionary funds should be justified in detail and requested within the Administrative Core. All financial commitments made by the institution to the SPORE will be monitored and are expected to be maintained during the entire term of the award.

(c) Cancer Patient Population

Each SPORE must document access to a substantial patient population in the cancer-site focus of the application and provide reasonable assurance that the patients and human specimens needed for translational research are readily available. If the appropriate patient population is not available at the applicant institution, a consortium agreement may be established with a different institution to provide adequate access to clinical specimens (e.g., tissues, blood, and urine) and/or patients at another site.

(d) Minimum Research Base

In order for a SPORE application to be accepted by NCI, the application must include four or more independent investigators who currently serve as PIs (or project leaders) on *peer-reviewed* research grants (e.g., R01, R21, P01, U01, U10, American Cancer Society [ACS], U.S. Department of Defense [DOD], or equivalent) or are overall chairpersons or site chairpersons on active NCI cooperative group clinical trial(s) or committees directly related to the cancer(s) being investigated. PIs supported by the NCI through K05, K22, K24, or K25 career development grants can also be included in the research base requirement if the career award is directly relevant to the cancer being investigated on the SPORE. Please note that an investigator who is a PI on multiple qualified grants or clinical trials only counts once towards the research base and, in order to qualify, the investigator must be the PI (*not* co-investigator) on the highlighted activity. The qualifying investigators also must have a significant role on the SPORE (i.e., greater than or equal to a 5 percent contributed effort as a project co-leader, co-investigator, or core director); they cannot just serve as mentors within the proposed Career Development

Program or be the project leader of a proposed Developmental Research project. The funded activities of the investigators who fulfill the requirements of a minimal research base should be included in the Program Description part of the SPORE application as discussed in Section II below.

(e) Budget Limitation

By NCI policy, all competing SPOREs are subject to a *total cost budget cap of $2.5 million.* The PHS 398 (Rev. 09/2004) budget forms allow for a clear distinction between direct costs (including all direct costs from consortia) and total costs (including all direct and indirect costs from all participating organizations). Consortium indirect costs must be included in the total costs, which, overall, may not exceed the $2.5 million cap. Applications with requests exceeding these financial limits will be returned to the applicant without peer review. In non-competing years, applications can exceed these caps as a result of annual cost-of-living increases (less than or equal to 3 percent of direct costs) or as a result of special supplements approved by the NCI. An applicant should not submit an application anticipating the support of a critical or required activity by an administrative supplement. For more information about the budget cap in any given year, applicants must contact the Organ Systems Branch using the telephone number, fax number, and/or e-mail address listed under INQUIRIES below.

Section II. Important Considerations for Competing SPORE Grant Applications

A. General Information for Application Preparation and Submission

These instructions provide information needed for the preparation of either a new or competing continuation grant application for a Specialized Program of Research Excellence (SPORE).

General instructions for the preparation of an NIH grant application (PHS 398, Rev. 09/2004, Interim Rev. 04/2006) are available at http://grants1.nih.gov/grants/funding/phs398/phs398.html. Although the PHS 398 application is intended primarily for a single research project (i.e., R01)

grant, many of the general instructions and forms also apply to SPORE grant applications. However, as outlined in Section I, SPORE grants have unique requirements and review criteria. Accordingly, the special instructions in this document were prepared for use along with the PHS 398 forms.

Please note that the NIH will eventually transition the P50 mechanism to electronic submission through Grants.gov and the use of the SF 424 Research and Related (R&R) forms (http://grants.nih.gov/grants/forms.htm. For general information on this transition, please see the electronic submission website at http://era.nih.gov/ElectronicReceipt/ and the transition timeline at http://era.nih.gov/ElectronicReceipt/files/Electronic_Receipt_Timeline_Ext.pdf. NIH will announce each grant mechanism change in the NIH Guide to Grants and Contracts (http://grants.nih.gov/grants/guide/index.html).

B. Application Receipt Dates

Receipt dates for SPORE grant application submission will be announced in a formal program announcement in the NIH Guide. See the Program Announcement (PA) for Specialized Program of Research Excellence for Year 2008 and 2009 (http://grants.nih.gov/grants/guide/pa-files/PAR-08-020.html). Any subsequent reissuance of the SPORE PAs will be available in the NIH Guide at http://grants1.nih.gov/grants/guide/index.html#search and posted at http://spores.nci.nih.gov.

The SPORE program adheres to the same general policy for resubmitted (i.e., revised/amended) applications as issued by the NIH (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-041.html) with the following points of clarification:

Resubmitted (i.e., revised/amended) applications will be reviewed as amended applications (as opposed to new applications) unless greater than 50 percent of the research projects have changed significantly in direction. The peer reviewers will be provided with a copy of the previous Summary Statement for all amended applications. Significant changes include the deletion of a previous project and addition of a new project with completely different aims and, potentially, led by different investigators. If less than 50 percent of the research projects have changed, then the application will be considered an amended (revised) application. Changes in

direction that are the result of the normal progression of a project over time would not be considered as significant changes in direction. Projects that have received funding under another award mechanism (e.g., R01 or P01) during the interim are not eligible for inclusion. Up to two resubmission applications can be submitted.

C. Planning for Application Preparation and Submission

1. Pre-application Consultation (Strongly Recommended)

NCI program staff strongly encourages each prospective applicant to schedule a pre-application consultation. The consultation should be scheduled 4 to 6 months in advance of the due date for submission and is intended to help the applicant (along with one or more of his/her intended co-investigators) understand the Program and discuss strategies for preparing a competitive application. NCI staff will clarify the intent of the guidelines, discuss funding trends, and describe the peer-review process. The applicant can define which issues would be most helpful to discuss and then work with NCI program staff to decide what information should be provided. The following are examples of items that help NCI program staff understand the plans of applicants:

(a) A brief description of the background and proposed responsibilities of the SPORE Director and key senior leaders of the SPORE;
(b) A diagram showing the proposed reporting, programmatic, and advisory structure of the SPORE and how it relates to the structure of the institution as a whole;
(c) A brief description (1-2 pages) of the proposed translational research projects, along with their specific aims and the names of project co-leaders;
(d) Estimated budgets for each component (i.e., full projects, resources, developmental/career programs) of the anticipated SPORE application; and
(e) A list of active peer-reviewed research grants, cooperative agreements, and contracts that form the research base of the scientific leaders of the SPORE.

2. Letter of Intent

Although it is not required and does not enter into the review of an application, all prospective applicants are requested to submit a letter of intent at least 30 days prior to the receipt date for

the application. The letter of intent should include: an overall title of the proposed application; the name, address, and telephone number of the PI; the identities of other key personnel and all participating institutions; and the number and title of the PA in response to which the application will be submitted. This information allows NCI staff to estimate the potential review workload, begin to identify potential reviewers, and avoid conflicts of interest in the review. Furthermore, NCI staff can make sure that applicants are fully aware of all applicable NIH and NCI policies, that they meet eligibility requirements, and that they understand the peer review process before this applications are submitted. The letter of intent should be sent to the NCI program director assigned to the organ site of interest (see http://spores.nci.nih.gov for current program director assignments) at the following address:

Organ Systems Branch
OCTR, OD, NCI
6116 Executive Boulevard, Suite 7013, MSC 8347
Bethesda, MD 20892-8347 (for regular mail delivery)
Rockville, MD 20852 (for courier/express delivery)

Alternatively, the letter of intent can be sent as an e-mail attachment directly to the appropriate program director within the Organ Systems Branch.

SPORE applicants are exempt from the requirement to seek approval 6 weeks prior to submitting an application requesting $500,000 or more in direct costs (see http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html and http://grants.nih.gov/grants/guide/notice-files/NOT-CA-02-029.html). This requirement is only for the submission of *unsolicited* grant applications (i.e., not submitted in response to an NIH funding opportunity announcement). Applicants, however, must adhere to the budgetary cap restrictions of the SPORE program as outlined in Section I.E.1.(d) to avoid return of their application without review.

D. Major Components of SPORE Applications

1. Research Projects

Research projects may be conducted solely through the parent institution, or through collaborative associations that have been developed and/or are planned with other SPOREs and/or with other investigators in the biomedical research community. However, all SPOREs must meet the following requirements:

(a) Each proposed research project must meet the definition of translational research as described in Section I.B above. Investigators who are not certain about whether their project fits this definition are advised to consult with NCI program staff.

(b) Each proposed research project must be designed to test the relevance and/or potential importance of the research to human cancer within the 5-year term of the grant (e.g., validation of a new screening mechanism or diagnostic test, early phase therapeutic trial, analysis of human tissues such as tumor or blood samples). Basic research projects, such as those employing animal models or cell lines, qualify as translational only if a human application is included in the specific aims of the research. A project(s) proposed in a competitive renewal application may focus solely upon the human application or laboratory effort if it marks the final stage of an ongoing translational SPORE study. *Applicants are encouraged to contact the Organ Systems Branch (see INQUIRIES above) if they have any questions concerning this essential requirement.*

(c) Each proposed research project must be led by project co-leaders, one in basic biological sciences and one in applied sciences, who commit adequate percent efforts and who use their combined conceptual and experimental skills in designing and implementing the project. It should be evident from this collaboration that translational research objectives will be accelerated such that it will be possible to test the relevance of the underlying hypotheses or to generate new hypotheses relevant to human disease. It is not necessary that the co-leaders commit equal effort to the project. There are **NO** exceptions to this requirement.

(d) For most organ sites, at least **ONE** research project must focus on early detection, screening, prevention (primary or secondary), and/or population science research. See Table 1 below for a list of the organ sites supported by the SPORE program and which of these sites require a project focused on early detection, screening, prevention, or population science. If such a project is required, then at least one scored project in this category will be required for award (see REVIEW CONSIDERATIONS, Section II.G.1.) and must be maintained throughout the entire term of the award.

Cancer sites (e.g., brain, endometrium, genitourinary, leukemia, lymphoma, myeloma, and pancreas) for which a project on early detection, screening, prevention, or population science is not a formal requirement are still *strongly encouraged* to include a project focused on one of these four underutilized areas of science. The leader(s) of a SPORE may reach out to another institution to include them as a consortium to fulfill this requirement either because of the relevant expertise of an investigator(s) or patient base/population present at the additional site. The leader(s) of a SPORE may also propose a prevention, screening, early detection, or population science project that capitalizes upon an existing or evolving inter-SPORE collaboration or related research activity supported by another NCI/NIH Networks.

Table 1. SPORE Organ Sites

Organ Site(s)	Includes the following cancers*	Required Project**
1. Brain	Brain, but *not* peripheral nervous system (PNS) tumors	No
2. Breast	Breast	Yes
3. Gastrointestinal (GI)	Esophageal, Stomach, Intestinal, Colon Liver, Pancreatic	Yes
4. Genitourinary (GU)	Bladder, Kidney, Testicular, but *not* Prostate	No
5. Gynecological (GYN)	Cervical, Endometrial, but *not* Ovarian	Yes (cervical); No (endometrial)
6. Head and Neck	Salivary, Larynx, Nasopharyngeal, Oral, Thyroid	Yes
7. Leukemia	Leukemia, myelodysplastic syndrome (MDS)	No
8. Lung	Lung	Yes
9. Lymphoma	Lymphoma (Hodgkin's, Non-Hodgkin's, chronic lymphocytic leukemia [CLL])	No
10. Myeloma	Myeloma, monoclonal gammopathies of undetermined significance (MGUS)	No
11. Ovary	Ovarian	Yes
12. Pancreas	Pancreatic	No
13. Prostate	Prostate	Yes
14. Skin	Skin	Yes
15. Other Cancer Sites	Contact Program Director/Official	

* Not all inclusive; if proposing projects on other cancers, contact appropriate OSB program staff.

** Applications requiring a project focused on early detection, screening, prevention, or population science.

(e) A minimum of **four** research projects, representing a balance and diversity of translational research objectives (e.g., screening, prevention, diagnosis, treatment), are required. Applications with a specific theme (e.g., gene therapy in prostate cancer) are discouraged. (Note that four projects scored by the peer review group will be required for award, see REVIEW CONSIDERATIONS, Sections II.G.1. and II.G.5. below.)

(f) Research projects involving **HUMAN SUBJECTS** must include women, children, and members of minority groups and their subpopulations unless a clear and compelling rationale establishes inclusion is inappropriate with respect to the health of the subjects, the purpose of the research, or another extenuating circumstance. Instructions are provided at http://grants1.nih.gov/grants/funding/phs398/HumanSubjects.pdf or can be downloaded in MS Word format from http://grants1.nih.gov/grants/funding/phs398/phs398.html.

Each project or core that involves human subjects must also adequately address the protection of human subjects from risks, the overall benefit of the study to participants, the inclusion (or exclusion) of women, minorities, and children as instructed in the PHS 398 Instructions (Rev. 09/2004, Part II; Interim Rev. 04/2006). A project proposing the involvement of human subjects in clinical research must also include a Targeted/Planned Enrollment Table. The table is available at http://grants.nih.gov/grants/funding/phs398/enrollment.pdf. If applicable, competing renewal applications that include ongoing projects from the previous funding period must also provide Inclusion Enrollment Reports on any clinical research activity performed during the past 12 months. Any past difficulties encountered in the recruitment of women, minorities, and/or children should be discussed, along with any new plans to enhance recruitment.

Only early (Phase I and Phase II) clinical trials may be supported by the SPORE mechanism. A plan for a clinical trial must include provisions for rigorous data management, quality assurance, and safety monitoring. These monitoring activities are distinct from the requirement for study review and approval by an Institutional Review Board (IRB). For details about the Policy of the NCI for Data Safety Monitoring of Clinical Trials, see http://deainfo.nci.nih.gov/grantspolicies/datasafety.htm and the PHS 398 Instructions (Rev. 09/2004; Part II, page 34). A general description of the data and safety monitoring plans should be included in the application (see

http://grants.nih.gov/grants/guide/notice-files/not98-084.html). This description should explain the rules and procedures for detecting, monitoring, and reporting any adverse drug reaction or event during a clinical trial. A copy of a draft or IRB-approved clinical trial protocol, along with informed consent forms and a specific data and safety monitoring (DSM) plan, are also required and should be included in an Appendix if the trial is already underway or is anticipated to begin within the first 2 years of an award. If the trial will be performed during the latter part of the grant term, submission of these items to NCI program staff is required prior to the initiation of the trial. Please note that a data safety and monitoring board (DSMB) is required for a multicenter clinical trial.

The NIH also requires that all investigators proposing research involving human subjects are educated on the protection of human research participants. For information relating to this requirement, see the NIH Guide Notices at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html, and also the answers to Frequently Asked Questions found at http://grants.nih.gov/grants/policy/hs_educ_faq.htm.

2. Shared Cores

(a) Specimen Core (*Required*)

Each SPORE must have a dedicated core for collecting and distributing human cancer site-specific and/or related specimens. Specimens include fixed tissue, frozen tissue, paraffin blocks, slides, preserved cells, serum, plasma, urine, sputum samples, and other body fluids. This core should be a specialized specimen resource that can be used for novel and robust biomarker development and accurate testing of translational hypotheses with minimal preanalytical concerns. Each specimen should have detailed annotation of parameters of collection and preservation that are pertinent to the preanalytic and analytic considerations of potential studies. The specimen core should also include the essential pathological, clinical, and family history information needed for conducting a wide range of translational research activities. Appropriate informatics capability for tracking, as well as linkage to clinical and follow-up data sets, should be demonstrated. Networking with informatic systems at other SPORE sites is encouraged, but

is not required. The development, acquisition, storage, and usage of standardized reference specimens and materials are also strongly encouraged. This core may also provide services related to the analysis of specimens (e.g., tissue microdissection, immunohistochemistry). Other research activities may also be included if they are designed to improve core services that are of obvious benefit to the SPORE.

Specimen core should be essential to the research activities of the SPORE as well as to those of other scientists within and outside the parent institution who are invested in translational research. A plan must be proposed for prioritizing distribution of biospecimens to SPORE scientists and others, both inside and outside the parent/consortium institution(s), based on the merit of the proposed translational cancer research projects. Competing renewal (type 2) applications should also include a list of the studies and/or collaborations that benefited from this core, as well as a summary listing the numbers and types of specimens accrued and distributed during the previous funding period.

(b) Other Cores (*Optional*)
Additional shared cores (e.g., administrative, clinical, biostatistical, animal, etc.) may also be proposed that are supportive of one or more of the research projects of the SPORE. These cores should provide essential services to *at least one* SPORE project and may also include other analytical or non-hypothesis driven research activities designed to enhance a service. Administrative, clinical, and biostatistical cores are strongly encouraged.

For all non-administrative cores, the application must document that the proposed cores will not duplicate pre-existing resources at the institution. A proposed SPORE core must include a budgetary request. If the SPORE is benefiting from a *funded* institutional, local, State, or national resource/consortium, the benefit to the SPORE should be described in the overall Program Description (see Section II). The utilization of this pre-existing resource will factor into the merit of the institutional commitment or the collaborative interactions component of the application.

For competing renewal applications, utilization of an ongoing core that was previously supported

by the SPORE should also be clearly documented. Details should be provided on the services the core provided to projects supported in the previous funding period, including those supported by the developmental research program (DRP) and career development program (CDP). A list of joint publications, including investigators from both the projects and the cores, should also be included in the preliminary studies/progress report for the core.

If an Administrative Core is proposed, costs to cover the travel of (up to) 10 investigators per SPORE to the annual SPORE Workshop (see below) and some additional support for inter-SPORE meetings can be requested within this core. In addition, any requests for discretionary funds (up to $50,000 direct costs per year) should also be discussed within the administrative core; institutions are encouraged to match this request. See Section II for additional guidance.

If a Clinical Core is proposed, the Director of this core should discuss its integration with Cancer Center resources and discuss how duplication in the reporting of clinical trial data to the NCI will be avoided.

A brief description of any related Cancer Center Support Grant (CCSG) core must be provided in the SPORE core description, along with its staffing commitments and capabilities, as well as any fees charged to investigators for its use. At a Cancer Center with two or more pre-existing SPORE awards, an additional section must address how related (e.g., specimen banking) activities are coordinated across all SPOREs, as well as within the Cancer Center. It is anticipated that a request to support a Specimen Core at an institution with a CCSG and substantial pre-existing SPORE support should be smaller based on the infrastructure already in existence at the institution. Prior to an award, NCI will carefully review proposed SPORE core activities and budgets for overlaps with pre-existing CCSG and SPORE cores. It should be the objective of all involved core directors to make sure that specimen-related, biostatistical, bioinformatic, and clinical activities are performed in a cost effective and coordinated manner.

In summary, all non-administrative core directors are expected to provide brief descriptions of all cores dedicated to similar activities at their Cancer Center or institution, including cores or resources supported by P01, P20, other P50 grants, and Cancer Center cores. If there are no

related cores at the Cancer Center or institution, this fact should be stated. Descriptions should briefly outline the activities of the already funded core(s) or resource(s), the staff available to support these activities, and any "charge-backs" to investigators who utilize the core/resource(s).

3. Developmental Research Program (DRP)

Every SPORE must allocate a significant effort to support pilot projects that take maximum advantage of new research opportunities. Such projects may be collaborative among scientists within one or more SPOREs, or with scientists outside the SPORE environment. In the application, the applicant SPORE application should propose an institutional review process for funding pilot projects that generate feasibility data and have the most promising translational research potential. These funds are intended to remain flexible and to support studies of a limited duration, of 2 years or less. The expectation is that successful feasibility studies will replace full projects that are not progressing satisfactorily with regard to translational research objectives within the SPORE (see above). New applicants may supply a short description of eligible projects as examples. Competing renewal applicants should supply their track records of funding pilot projects, ongoing pilot projects, and short descriptions of other potentially eligible projects.

A DRP, as a required component of a SPORE, must be maintained throughout the entire term of the grant. A minimum commitment of $50,000 direct costs per year from SPORE funds must be proposed for a DRP. Matching funds of $50,000 or more are also, generally, promised by the parent institution. Most DRPs have commitments of between $100,000 to $300,000 direct costs per year, including the contribution(s) made by the parent and/or consortium institutions. The NCI will monitor the activities of both SPORE and institutionally sponsored DRP projects during non-competitive years to assure that the institutional commitment is being maintained and that there is adherence to the translational intention of the SPORE program during the term of the award. DRP funds should be utilized for research activities and cannot be used for the purchase of any large equipment.

4. Career Development Program (CDP)

The SPORE must demonstrate a consistent and significant commitment to a career development

program (CDP) in translational cancer research. Funds from this program may be used to support advanced post-doctoral or clinical fellows (who will be independent investigators within the next year), junior faculty, or established investigators who wish to develop or refocus their careers on translational research. SPORE career development programs are not intended for predoctoral candidates or junior level post-doctoral and clinical fellows. Investigators supported by NCI career development awards (K series) may also be eligible for support through this program.

A minimum of $50,000 direct costs per year from the SPORE budget must be dedicated to this program and be utilized to support the salary and research costs of candidates with outstanding potentials. Each junior level candidate (senior post-doctoral fellows, clinical fellows, and assistant professors) should have a mentor(s) and devote a significant percentage of his/her effort to translational research. The description of this program should include the policies, criteria, and processes for selecting candidates, including special efforts to recruit qualified women and minorities. The plan should include the number and types of positions (e.g., advanced post-doctoral fellows, junior faculty, and established investigators) that will be made available, the criteria for eligibility and selection of candidates, and a description of the selection process. New applicants should provide a list and short descriptions of potential candidates, as well as the names and research activities of mentors. Renewal applicants should provide this information in addition to their past performance on recruiting women and minorities and the track records of awardees supported on the SPORE. Similar to the DRP, support of a CDP awardee should not exceed 2 years.

A CDP, as a required element of a SPORE, must be maintained throughout the entire term of the grant. A financial commitment of $50,000 or more direct costs per year from the parent and/or consortium institutions is also encouraged. Funds from the CDP should be utilized to support research activities, including partial salary support for the candidate, research personnel, supplies, travel, and/or other expenses. CDP funds should not be used for the purchase of any large equipment.

5. Intellectual Property Rights

An intellectual property management plan (IPMP) must be included in the application which discusses the plans for evaluation, protection, and commercialization of solely or jointly owned SPORE inventions, including any patenting and licensing strategies. This plan should be comprehensive for all proposed SPORE projects and be included in the Program Description as specified in Section II. The IPMP will not be evaluated during the peer review of applications, but it is an administrative requirement that will be evaluated carefully by NCI program staff.

The institution should provide a written assurance that it will protect the intellectual property rights arising from inventions of the SPORE investigators and their collaborators; under no circumstances should the institution enter into agreements with commercial entities (e.g., pharmaceutical or biotechnology companies) that would compromise the ability of SPORE investigators to have unhindered access to institutional resources developed in SPORE-related research or participate fully in collaborations with any other researchers. The statement of commitment should also include a written assurance that in its interactions with commercial entities under sponsored research agreements, the SPORE institution(s) will comply with the requirements of the Bayh-Dole Act (37 CFR 401; https://s-edison.info.nih.gov/iEdison/37CFR401.jsp), the NIH Grants Policy Statement, and any relevant NIH funding agreements while upholding basic principles of academic freedom. Sponsored research agreements with commercial entities should be entered into by the SPORE institution(s) only upon due consideration of the points outlined in "Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts" (Federal Register, Vol. 59, No. 215; Tuesday, November 8, 1994; pp. 55674-5567).

The statement of commitment should also include a written assurance that the SPORE institution(s) will manage its interactions with third parties so that they do not restrict the SPORE's ability to receive and disseminate biomedical research materials developed with NIH funding from and to the scientific community. *Likewise, letters should be supplied by any relevant third parties (including any external co-investigators, collaborators, or consultants) confirming their adherence to these policies.* These letters should outline in detail the agreement made between the commercial entity and the SPORE institution.

Costs related to the patenting and/or licensing of intellectual property may be allowable as F&A costs (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-045.html).

Applicants should, in developing their Intellectual Property Management Plans (IPMPs), confer with their institutions' offices that are responsible for handling technology transfer-related matters and/or sponsored research. Applicants may also wish to independently research and review examples of approaches considered by other institutions, such as those described on the NCI Technology Transfer Branch web site at http://ttb.nci.nih.gov/ipplans.html. Furthermore, applicants are welcome to address inquiries regarding the development of IPMPs directly to the NCI program staff persons in the Organ Systems Branch of the NCI.

6. SPORE Workshop and Meetings

(a) Annual SPORE Workshop

SPORE investigators will be expected to participate in an annual workshop organized by the Organ Systems Branch of the NCI to share research results (both positive and negative) with other SPOREs, share materials, assess progress, identify new research opportunities, as well as establish interactions, research priorities, and collaborations that will maximize the impact of the research on reducing incidence and mortality, and improving survival. A statement of commitment to attend this workshop should be included in the Program Description. Travel funds for the PI and (up to) nine selected SPORE investigators and collaborators should be budgeted for this purpose. Support for attendance at the SPORE Workshop can be requested in either the Administrative Core or in the projects of the SPORE (but not in both).

(b) Additional Inter-SPORE and NCI/NIH Network Meetings

SPORE investigators are also expected to attend additional meetings during each year that are and will be designed to foster and/or support collaborative activities across SPOREs and/or NCI/NIH Networks. SPORE PIs may also be requested to attend and/or participate in planning and/or review activities by the NCI leadership. A small amount of funds (less than or equal to $5,000 in direct costs) can be requested within the Administrative Core and/or projects to support attendance at these meetings.

Because of the collaborative nature of this program, an unwillingness or routine inability of a PI or SPORE group to attend these required meetings may be basis for termination of the grant. As stated within Section I.C.4., SPOREs are expected to develop the infrastructure necessary to quickly address translational needs and should be able to, as a group, rapidly test new biomarkers or agents for the advancement of clinical applications.

7. Other Provisions

If a SPORE application originates from an institution that is supported by an NCI Cancer Center Support Grant (CCSG; P30), the following items should also be addressed (within the Program Description).

(a) Once a SPORE is funded, the PI of the SPORE should become a senior leader in the Cancer Center. The PI of the SPORE may or may not be the Cancer Center Director.

(b) Lines of authority should be clearly indicated such that the SPORE is an integral part of the Cancer Center, but they should not interfere with the P30 chain of authority. A letter of commitment which delineates these organizational relationships is required. This letter must be signed by the proposed PI of the SPORE as well as by the Cancer Center Director.

(c) The applicant should discuss how the SPORE will interact synergistically with existing P30 programs in order to maximize both SPORE and Cancer Center research objectives. While the SPORE is expected to become an integral element within the NCI-designated Cancer Center, a distinct institutional commitment to the SPORE must still be maintained throughout the term of the SPORE grant (see Section E.2. above).

(d) The proposed cores within the SPORE should not duplicate any available facility already in place and supported by another granting mechanism (e.g., P30, P01, U01, U10, DOD, etc.). Applicants can, however, use SPORE funds to augment pre-existing Cancer Center resources in order to direct these activities toward more effective fulfillments of the requirements of the SPORE. The SPORE should also utilize the IRB(s) and DSMB(s) as well as clinical resources

available throughout the Cancer Center, whenever applicable.

8. Required Federal Citations

Required Federal Citations include the following topics: Use of Animals in Research; Human Subjects Protection; Data and Safety Monitoring Plan; Sharing Research Plan; Access to Research Data through the Freedom of Information Act; Sharing of Model Organisms; Inclusion of Women and Minorities in Clinical Research; Inclusion of Children as Participants in Research; Required Education on the Protection of Human Subject Participants; Human Embryonic Stem Cells; NIH Public Access Policy; Standards of Privacy of Individually Identifiable Health Information; URLs in NIH Grant Application or Appendices; Authority and Regulations; and Loan Repayment Plans. Each of these topics must be satisfactorily addressed in the application.

For the latest Required Federal Citations, see Section VIII. Other Information – Required Federal Citations in the Program Announcement (PA) for Specialized Programs of Research Excellence for Year 2007 (PAR-06-505; http://grants.nih.gov/grants/guide/pa-files/PAR-06-505.html). Any subsequent reissuances of the SPORE PAs will be available in the NIH Guide at http://grants1.nih.gov/grants/guide/index.html#search, and will contain these (and possibly additional) requirements.

E. Preparation of a P50 SPORE Application with Use of the PHS 398

1. Outline -- It is recommended that all applicants follow a format similar to that outlined below:

I. Face Page (PHS 398 Form, page 1)
II. Description, Performance Sites, Key Personnel (PHS 398 Form, page 2)
III. Table of Contents (PHS 398 Form, page 3)
IV. Initial Budget (PHS 398 Form, page 4; see item 4 below)
V. Summary Budget (PHS 398 Form, page 5; see item 5 below)
VI. Biographical Sketches
VII. Resources
VIII. Eligibility Statement
IX. Program Description

A. Introduction
B. Scientific and Administrative Leadership
C. Institutional Commitment
D. Relationship to NCI-Designated Cancer Center
E. Cancer Patient Population
F. Scientific Integration -- Interactions and Collaborations
G. Translational Research Objectives
H. Planning and Evaluation Activities
I. Collaboration
J. Intellectual Property Management Plan
K. Data Management
L. Data and Research Resources Sharing Plan

X. Research Projects (Minimum of four projects required)

Research projects should be numbered consecutively with use of only integers (e.g., Project 1, Project 2, Project 3, Project 4, etc.); projects numbers should not have suffixes (e.g., Project 1A or 1a, Project 1B or 1b, etc.). Cores should be "numbered" consecutively with capital letters only (e.g., Core A, Core B, etc.). For competing continuation applications, applicants should outline the scientific accomplishments and discuss the potential impact on the disease for each project completed in the last grant period. Publications should be restricted to those that cite support from the SPORE grant. With the exception of the publication list, this information should be incorporated into the Preliminary Studies/Progress Report of each project and count towards the 25-page limit according to the PHS 398 instructions (Rev. 09/2004; Part I, page 31).

A. Project (e.g., Project 1; Project 2; Project 3; Project 4; etc.)
    1. Title Page with Project Co-Leaders
    2. Abstract Page
    3. Budget/Budget Justification Pages
    4. Research Proposal (If an ongoing project, discuss scientific progress within the original 5-year time frame)
    5. Human Subjects Research

a. Data Safety and Monitoring Plan

6. Women and Minority Inclusion
    a. Targeted/Planned Enrollment Table
    b. Inclusion Enrollment Report Table (competing continuation)
7. Inclusion/Exclusion of Children
8. Vertebrate Animals
9. Literature Cited
10. Consortium/Contractual Arrangements
11. Resource Sharing
12. Consultants/Commercial Agreements

XI. Cores (Specimen Core is required)

A. Core (e.g., Core A; Core B; etc.)

1. Title Page with Director(s)
2. Abstract Page
3. Budget/Budget Justifications
4. Plan/Interactions/Progress (for competing renewals)
5. Human Subjects and Vertebrate Animals

XII. Development Research Program (DRP)

1. Title Page with Director(s)
2. Budget/Budget Justification Pages
3. Plan/Examples
4. For competing renewals, describe each project funded during the last grant period and the outcome of each project relative to the SPORE objectives.

XIII. Career Development Program (CDP)

1. Title Page with Director(s)
2. Budget/Budget Justification Pages
3. Plan/Examples

4. For competing renewals, denote individuals supported during the last grant period, their scientific accomplishments while supported by the SPORE, and how SPORE support has advanced their translational research careers.

XIV. Checklist

XV. Appendix Material(s)

2. Amended Applications

Amended (revised) applications should include additional sections prior to the Program Description, as well as each revised research project, core, and development program that address the critiques from the previous review. These sections should be limited to three pages or less and be entitled as "Introduction to Amended/Revised Application," "Introduction to Amended/Revised Project," etc.

3. Current Funding Opportunity Announcements in the NIH Guide

For additional details and definitive guidance, see Section I above and the Program Announcement (PA) for Specialized Program of Research Excellence for Year 2008 and 2009 (http://grants.nih.gov/grants/guide/pa-files/PAR-08-020.html). Any subsequent reissuance of the SPORE PAs will be available in the NIH Guide at http://grants1.nih.gov/grants/guide/index.html#search.

F. Receipt of P50 SPORE Grant Applications at the NIH

SPORE applications, like all other PHS applications, are received and initially processed by the NIH Center for Scientific Review (CSR). Following the current NCI referral guidelines, the application is assigned to NCI and subsequently to the Organ Systems Branch and SPORE program area. A scientific review officer (SRO), [previously referred to as scientific review administrator (SRA)], in the Research Programs Review Branch in the NCI Division of Extramural Activities will be assigned to manage the review.

Applicants are expected to submit complete application (a signed, original of the application, including the checklist, and three signed photocopies in one package) by the specified receipt dates to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (for U.S. Postal Service express or regular mail)
Bethesda, MD 20817 (for express/courier delivery; non-USPS service)

At the time of submission, two additional paper copies of the application and the **appendix materials in pdf format on one CD** must be sent to:

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

Appendices: Applicants must follow the instructions in recent NIH guide notices about what is allowable in appendix material: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-051.html and http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-018.html. NOTE: Original color or gray scale photographs or images that do not reproduce in the black and white copies that will be made by the central NIH print shop may be submitted on the CD with your appendices.

Format of the Appendices:

- Send one CD containing all appendices in PDF format
- Use no more than one PDF file for each project, core, or developmental program
- Bookmark the PDF files so that reviewers can navigate through the CD and find appendix materials for individual components (project/core) and individual items within each PDF file easily
- Do not include documents in MSWord, WordPerfect or Excel format or make subdirectories or subfiles on the CD
- Do not create read only, password protected, write protected or encrypted PDF files or lock the files containing your appendix material in any way since that will prevent NCI staff from making the required copies
- Send one complete CD. NCI review staff will make the necessary copies to send to the reviewers

After application submission, all correspondence should be directed to the SRO.

G. Peer Review of P50 SPORE Applications

1. Review Policies and Procedures

Upon receipt of an application, the SRO reviews it for completeness and conformance to NIH policies. The application is concurrently evaluated for responsiveness to all required components in the PA by OSB program staff. Applications that are incomplete or are non-responsive to the NCI SPORE Guidelines will be returned to the applicant without further consideration (see Section I.E. above).

Applications that are complete and responsive will be evaluated for scientific and technical merit by a peer review group convened by the National Cancer Institute. The peer reviewers should be thoroughly cognizant of the review criteria provided below. While all eligible applications will receive a written critique, some may be removed from further consideration (i.e., "streamlined") by the peer review group in the initial stages of the merit review process and will be unscored. In these instances, only applications deemed to have the highest scientific merit will be fully discussed by the review panel. In addition, if a required component(s) of an otherwise meritorious SPORE application is of such low merit that it is not recommended for further consideration (NRFC) by the peer review committee, the entire application will be "NOT RECOMMENDED FOR FURTHER CONSIDERATION (NRFC)." See Section I.D. of this document for a description of the required components of a SPORE application. Applications that receive a full discussion are assigned a priority score and undergo a second level of review by the National Cancer Advisory Board (NCAB).

For the latest and most definitive review considerations, see Section V, Application Review Information, in the Program Announcement (PA) for Specialized Program of Research Excellence for Year 2008 and 2009 (http://grants.nih.gov/grants/guide/pa-files/PAR-08-020.html). Any subsequent reissuance of the SPORE PAs will be available in the NIH Guide at http://grants1.nih.gov/grants/guide/index.html#search and on the SPORE web site at http://spores.nci.nih.gov, and will contain these (and possibly additional newer) requirements. Current review considerations are summarized below.

As the manager of the review process, the SRO serves as the resource for both applicants and reviewers with respect to NIH review policies, guidelines, rules, regulations, options available, procedures, etc. He/She ensures that the review is conducted in accordance with NIH and NCI policies. The NCI program director serves as a resource, as needed, concerning the history, intent, and development of the program, changes in program direction, objectives, and any other relevant programmatic matters.

The scientific merit of a SPORE application is initially assessed by a peer review committee. This committee includes primarily senior scientists with extensive review experience, a broad perspective on cancer research, and a wide variety of expertise. Because of the multi-disciplinary nature of SPORE applications, breadth is a necessary component of the review committee. Patient/consumer advocates also serve as members on these committees since they provide unique and important perspectives on translational research conducted by SPOREs. Beginning in 2005, review of SPORE applications will be performed by a standing Special Emphasis Panel (SEP) that will include experienced SPORE reviewers committed to continuous participation in SPORE reviews for a term of up to 4 years. These standing members will assist in ensuring consistency in the review process across all organ sites.

Applicants should take into account the fact that their application is reviewed by multiple individuals. Any piece of information that is critical to a particular project, resource, and/or program should be presented within the section(s) designated for that activity (and not just within the overall "Program Description," for example).

Following assignment of a priority score by the review committee, a second level of review by the NCAB completes the peer review process.

2. Review Criteria

The evaluation of applications is based on the following:

(a) Research Projects

Within the SPORE concept of translational research (see definition in Section I.B.

above), reviewers will evaluate each research project using the recently updated five review criteria (see http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-002.html) and additional factors noted below. Each criterion will be considered by the reviewers in assigning the overall merit score of the project, although a project does not need to be strong in **all** criteria in order to be viewed as being meritorious.

(a.1) Significance

Does this study address an important translational research goal or barrier? Is it likely the study will be completed within the project period? If the aims of the application are achieved, how will scientific knowledge or clinical practice are advanced? What will be the **impact** of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? If a project is ongoing, did it achieve its goals within the previous funding period; is scientific progress adequate?

(a.2) Approach

Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Is there clear **evidence of co-leadership** between a basic biological scientist and an applied or clinical scientist in the conception, design, and proposed implementation of the project? Do the project co-leaders acknowledge potential problem areas and consider alternative tactics? If the project is ongoing and has changed research direction, is there appropriate rationale for the new approach?

(a.3) Innovation

Is the project original and innovative in the context of translational research? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop and/or employ novel concepts, approaches, methodologies, tools, and/or technologies for this organ site?

(a.4) Investigators

Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level and time commitments of the co-leaders and co-investigators on the project? Does the investigative team bring complementary and integrated expertise to the project?

(a.5) Environment

Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, and/or employ useful collaborative arrangements? If applicable, is there evidence of effective use of SPORE cores?

For competing renewal (type 2) grant applications: Has adequate progress been demonstrated on projects that are ongoing? Are there any difficulties in achieving the previously proposed specific aims addressed? Do the new research goals constitute logical extensions of the project? Is there clear evidence that such a project reached its anticipated human application(s) during the previous funding period? Is there clear evidence that the continuation of the project will lead to new translational findings? Is it evident that the investigative team, especially the project co-leaders, established a productive working relationship during the past performance period? Have they published or submitted for publication manuscripts describing their previous findings? For research projects that will not be continuing in the renewal: Has a progress report been provided that includes the reasons why the project was discontinued in the SPORE?

(b) Cores

(b.1) Specimen Core

- Does the proposed plan for this core adequately address the development, annotation, and maintenance of a human cancer site-specific specimen resource, including linkage of specimens with pre-analytical parameters and pathological, clinical, and family history data that maximize their potential use in translational research?
- Does the proposed plan adequately address and prioritize the distribution of specimens within and outside the SPORE? (For competing renewal applications, there should be

clear documentation of the use of specimens by SPORE investigators within full and developmental projects, as well as details, if applicable, about the distribution and use of SPORE collected specimens outside of the SPORE and/or institution.)

- If applicable, does the proposed plan adequately address the performance of analyses on specimens (e.g., tissue microdissection, immunochemistry) and/or develop new technologies and methodologies that enhance or benefit activities of the SPORE? (For competing renewal applications, there should be clear documentation that demonstrates these analyses were critical to the success of certain projects and are worthy of continued support, if requested.)

- Is sufficient evidence of experienced personnel dedicated to the activities of specimen collection, annotation, quality control, storage, distribution, and analysis; as well as overseeing the collection of initial and follow-up clinical information, data entry, and maintenance of database and computer networks presented? (For competing renewal applications, the performance and relative time commitments of these individuals should also be evaluated based on the past accomplishments of the core).

- Does the proposed plan give sufficient evidence that the activities of the core are well integrated with those of the projects and the investigators within the projects are working closely with those of the core to meet project objectives?

- Does the proposed plan adequately augment and/or complement any existing specimen resource supported by a Cancer Center Support Grant (CCSG; P30 grant mechanism) or other funding mechanism(s) to avoid duplication and maximize productivity? Do investigators applying from institutions with a CCSG and multiple SPORE grants address how their core will benefit from already established infrastructure, databases, etc., that will enable this proposed specimen core to be more cost effective and efficient?

- Does the proposed plan adequately address if and how the investigators will obtain written informed consent for all prospectively collected tissues/specimens in a manner that will protect patient confidentiality?

(b.2) Other Cores

- Does the proposed plan for each other core adequately indicate that it (will) effectively and efficiently support the research of the SPORE in a manner that can not be supported through other available (institutional or outside) resources?

- Does the proposed plan demonstrate that the activities of the core are essential to one or more SPORE projects? (For competing renewal applications, demonstrated use of each core by SPORE projects during the previous funding period is critical and should be evaluated.)

- Does the proposed plan demonstrate that the activities of the core are well integrated with those of the projects and the investigators within the projects are working closely with those of the core to meet project objectives?

- If applicable, does the proposed plan demonstrate the activities of the core related to the performance of specialized analyses or development of technologies or methodologies that enhance and benefit the projects?
- When appropriate, does the proposed plan address how the investigators will augment any existing shared resource supported by an NCI Cancer Center Support Grant (P30 grant mechanism) of other funding mechanism? (There should be adequate details within the core description to assure there is no duplication of services with pre-existing cores at the Cancer Center or institution.)
- Does the proposed plan address the qualifications, past performance (if applicable), and time commitments of the Core Director(s)?

(c) Developmental Research Program

(c.1) Does the proposed plan for the DRP address attracting new ideas and pilot studies within and outside of the SPORE institution? The outreach capabilities of a SPORE are often demonstrated within this program.

(c.2) Does the proposed plan address continuously reviewing and funding a spectrum of pilot projects with translational research potential? (For competing renewal applications, this program should also be evaluated by the SPORE's ability to promote outstanding translational pilot projects to full projects and/or demonstrate the successful competition of these projects for outside funds.)

(d) Career Development Program

(d.1) Does the proposed plan for the CDP describe how promising candidates for independent careers (academic, industrial, governmental) in translational cancer research will be selected? (For competing renewal applications, current status and research activities of individuals who have been supported by the career development program. This may include the promotion of outstanding career development projects to full projects within the SPOREs and involve the continuing support and integration of successful career development awardees as project co-leaders or co-investigators.)

(d.2) Does the proposed plan address how the investigators will seek out and include

qualified women and minorities for participation in the proposed program?

(e) Overall Program Organization and Capability

All of these items should be addressed within the Program Description part of the application.

(e.1) Leadership

Are the scientific qualifications and involvement of the principal investigator as well as his/her scientific and administrative leadership capabilities and time commitment presented and sufficient for the requirements of the proposed SPORE?

(e.2) Institutional Commitment

Is the institutional commitment for facilitating the research objectives of the SPORE (e.g., special facilities, recruitments, discretionary resources, such as dollars and space) documented and sufficient?

(e.3) Integration within the SPORE and the Institution

Do the plans for integrating the activities of SPORE projects with proposed cores, as well as integrating SPORE research and cores with existing Cancer Center/institutional resources (e.g., use of clinical data and safety management systems, biostatistical cores, etc.), give confidence and sufficient evidence that such efforts are likely to be effective? (Note that SPORE projects are not required to interact with each other.)

(e.4) Cancer Patient Population

Is the access to patients and populations for conducting current and projected therapeutic, prevention, detection, and control research adequate to ensure likely success of the goals of the program? (For competing renewal applications, documentation of accomplished translational goals, including evidence of human subjects enrollment on clinical/population research studies during the past funding period should be provided.)

(e.5) Planning and Evaluation of Activities

Are the plan(s) and/or track record(s) to evaluate the translational research productivity of existing projects and cores; discontinue activities of low productivity; initiate new activities in response to important translational research opportunities; establish collaborations; and utilize the advice of internal and external advisors presented and sufficient for the requirements of the proposed SPORE?

(e.6) Collaborations

Is there evidence of tangible interactions with other SPOREs and/or NIH/NCI Networks? Are the abilities and availabilities of the investigators to interact with other SPOREs and with the NIH/NCI in sharing information, participating in committees, and collaborating on activities of mutual interest evident and sufficient? (For competing renewal applications, contributions and outcomes from annual SPORE Workshop and other related SPORE or NIH/NCI meetings during the term of the award.)

(e.7) Data Management

Are the track records for the overall data management and/or bioinformatics capabilities of the SPORE as they related to the Cancer Center, institution, or activities of other NIH/NCI initiatives presented and sufficient for the requirements of the proposed SPORE?

(e.8) Progress (for Competitive Renewal Applications)

Are the progress and achievements specific to the application and relevant to translational research since the previous competitive review? Are the justifications for adding new projects or cores or deleting previous components appropriate and acceptable?

(f) ***Additional Review Criteria and Considerations***

In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score.

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed.

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed activity. The priority score should not be affected by the evaluation of the budget.

4. Overall Evaluation and Scoring of Applications

A single numerical priority score will be assigned to the SPORE application as a whole after discussing all of the review elements listed above. The score will be based on the overall quality of the research projects (using the SPORE definition of translational research in Section I.B.) and career development and developmental research programs, the overall effectiveness and adequacy of shared cores, and the overall program organization and capability, including plans for and/or productivity of interactions with other SPOREs and/or NIH/NCI Networks.

The final overall priority score for the application will be weighted as follows:

70% Scientific merit of the projects and shared cores, including the likelihood of achieving the proposed translational research objectives; and

30% Overall programmatic organization and capabilities, including developmental programs (Career Development and Developmental Research).

If a required component(s) of an otherwise meritorious SPORE application (i.e., list them here) is of such low merit that it is not recommended for further consideration (NRFC) by the peer review committee, the entire application will also receive a NRFC.

5. Summary Statements

The findings and recommendations of the reviewers are summarized in a written report (i.e., the summary statement) which conveys the evaluation of the P50 application. The summary statement is transmitted to the NCAB for second level review, to the NCI official file, and to the appropriate NCI staff members. NCI program staff will automatically send a copy to the PI as soon as the final document is available.

H. Award Administration Information

1. Grant Mechanism

This program is supported through the NIH specialized center grant (P50) mechanism. Applicants are responsible for the planning, direction, and execution of the proposed SPORE program. Awards can be made for up to 5 years and will be administered under NIH grants policy as stated in the NIH Grants Policy Statement (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-009.html).

2. Awards

Applications will be awarded on a competitive basis. Final funding decisions are made by NCI based on overall priority scores of the applications as determined by peer review, recommendations by the NCAB, the availability of funds, and NCI research priorities during each fiscal year.

3. Conversion to Planning Grants

Under special circumstances, the NCI may consider funding a P50 SPORE application at a reduced level for up to 5 years using the P20 planning grant mechanism. Circumstances leading to the funding of a P20 rather than a P50 include: (1) the research projects in the SPORE application have high scientific merit, but other essential components of the application require further development; (2) the peer review criticisms can be readily addressed within the initial term of the award; and/or (3) the application meets important NCI program objectives (e.g., the organ site to be studied is under-represented in terms of amount of research supported and/or conducted). Applicants cannot apply for a P20 grant directly.

The award and administration of the P50 and P20 grants are subject to the same policies and procedures as other research grants. These policies and cost principles are set forth in the current NIH Grants Policy Statement, other NIH and NCI issuances, and Federal legislation and regulations.

4. Expanded Authorities

In accordance with NIH Grants Policy, NCI P50 and P20 grants may be administered by the awardee under Expanded Authorities, which can be viewed at http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600128. The expanded authorities allow additional flexibility to take advantage of research opportunities as they arise throughout the term of the grant. Under the expanded authorities, NIH has waived the requirement for its approval of specified actions and has provided the authorities to grantees to take such actions without NIH prior approval. In addition to the expanded authorities, the Organ Systems Branch has granted automatic carryover authority (up to 25 percent of total cost) to these P50 and P20 grants.

I. Inquiries

For further clarification of the different topics contained in the present guidelines, individuals may contact the Organ Systems Branch by e-mail (nciosb-r@mail.nih.gov), telephone (301-496-8528), and/or fax (301-402-5319). Direct e-mail addresses are also listed for current OSB program staff on the SPORE web site at http://spores.nci.nih.gov.

Section III. Important Considerations for Non-Competing Continuation SPORE Grant Applications

A. Introduction

These instructions are supplemental to those provided with the Form PHS 2590 (rev. 9/04), "Application for Continuation of a Grant," which is required each year in order to receive continuing support. In general, you should follow the "Information and Instructions for Using Form PHS 2590 to Apply for Continuation of a Grant Award" (http://grants.nih.gov/grants/funding/2590/2590.htm). Please note that *non-competing SPORE applications are not eligible for the streamlined non-competing award process (SNAP).* In order to avoid a gap in funding, non-competing continuation applications should be received 60 days prior to the anniversary date of the award.

Additional guidance important for the preparation of a SPORE non-competing continuation application (Type 5) is provided to you in this section.

*****IMPORTANT CHANGES TO THE PHS 2590*****

- The submission requirement has been changed – grantees need only submit a signed original and one signed copy to the centralized mailing address:

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

- For additional information, visit http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-007.html and http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-007.html.

- Throughout the instruction, the refined definition of Key Personnel has been incorporated: Individuals who contribute no measurable effort on the project/core should be designated as a "Significant Contributor."
- On the Key Personnel Report, the request for a Social Security Number is now limited to the last four digits.

B. Overall Organization of Progress Report

The NCI advocates flexibility and innovation in the use of SPORE funds to achieve translational research objectives and will administer these grants accordingly. Nevertheless, it is important to highlight and explain changes in the component budgets that differ significantly from the approved peer-reviewed budget levels of the original competing application. Areas requiring explanation and justification are as follows:

- Any proposed increase or decrease in the level of effort of key personnel by greater than 5 percent of total effort;
- Substitution, addition, or deletion of key personnel (e.g., Project Co-Leader, Core Director);
- Redistribution of dollars among budget components (NOTE: this is encouraged in a SPORE when it is done to place greater emphasis on more promising *translational* research activities); and
- New research activities not included in the competing application and not peer reviewed (NOTE: this is encouraged, especially in the use of developmental funds, to pursue the feasibility of new hypotheses of potential importance to translational research).

The following organizational format is required for all non-competing continuation grants:

- Face page;
- Table of Contents;
- Composite Budget;
- Director's Overview;
- Research Projects;

- Cores;
- Developmental Research Projects;
- Career Development Projects;
- Supplemental Research Projects;
- Checklists; and
- Personnel Report.

For forms and detailed instructions on the preparation of Budgets, Biographical Sketches, Progress Report Summaries, Checklists, and Personnel Report, please see http://grants.nih.gov/grants/funding/2590/2590.htm.

C. Director's Overview

The intent is to explain how the team of SPORE scientists at the basic and applied levels is pursuing research objectives using integrated, innovative, and flexible strategies thereby maximizing the unique capabilities of the SPORE to achieve translational research objectives.

1. **Scientific Achievement of the SPORE Program**

   Describe the single most significant translational research achievement in the last year of support. Indicate the project, the achievement, and its potential impact on human cancer in one or two paragraphs.

2. **Integration within the SPORE**

   The levels at which applied researchers (e.g., clinical researchers, epidemiologists) interact with basic investigators in the design and implementation of research that is most likely to have an impact on human cancer (i.e., reducing mortality, improving quality of life).

3. **Translational Research Objectives**

   Discuss the specific research activities that appear the most, or least, promising in achieving translational research objectives. Also report on any new ideas, technical breakthroughs, etc., that have occurred to advance a translational goal.

4. **Advisory Committee Activities**

   Discuss how recommendations of the External Advisory Committee, Internal

Advisory Committee, and SPORE leadership have impacted upon the modification, discontinuation, or initiation of any projects or cores.

5. **Collaborations**

Important collaborative efforts including formal Inter-SPORE activities established within and outside the SPORE institution. Please indicate if these activities use developmental or supplemental funds and address interactions with other NCI or NIH networks.

(a) Outreach Activities - Special efforts to recognize unique research opportunities of the SPORE and/or to enhance the research capability of the SPORE through interactions with outside individuals, organizations, and institutions (local, State, national, or international).

6. **Emerging and Derivative Projects**

Discuss research opportunities or studies that have emerged from SPORE scientists, the SPORE environment and/or SPORE collaborative efforts resulting in the submission of grant applications (e.g., R01s) and/or attracting additional support from other sources (e.g., foundations, industry) which are likely to advance fundamental studies in this cancer site. Please list in tabular form grant applications that have been submitted, where and when submitted, and whether pending, funded, or not funded.

7. **Intellectual Property Management and Industrial Relations**

Discuss any opportunities or problems that arose in moving a discovery forward for commercialization during the past year. Report on any patent or licensing activities related to the translational research supported by the SPORE.

D. Research Projects

This section includes materials pertaining to each individual (full) project on the SPORE, including a title page, proposed budget for the upcoming year, budget justification, any biosketches on new personnel, other support and a progress report for the past year. The Progress Report Summary Form Page 5 from the PHS 2590 application and instructions (pages 10-14) should be followed. The "*Studies and Results*" and "*Plans*" sections of the progress report should be relevant to accomplishments of the past year and not the same

at those reported in previous years. Please use the following format when reporting on each full project on the SPORE:

1. Title page
2. Detailed Budget
3. Budget Justification (add Biosketches for new personnel)
4. Other Support (for Key Personnel)
5. Progress Report Summary

(a) Specific Aims (no more that 500 words)

Briefly describe the specific aims of the project as originally funded and how basic/clinical interactions have been employed in the design, implementation, and interpretation of experiments. Provide a short rationale for any changes in specific aims that have occurred over the past year.

(b) Studies and Results (no more than 750 words)

For the past year, describe important positive and/or negative results associated with each specific aim. Describe any changes in approach that may have resulted from technical barriers or discoveries in the field. For those projects that involve clinical research, briefly describe the status of each study. NIH defines clinical research as *"Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease; (b) therapeutic interventions; (c) clinical trials; and/or (d) development of new technologies."*

(c) Significance

Explain in lay terms the importance and intent of the research in terms of translational research objectives that may impact on the disease in a reasonable time span.

(d) Plans

Summarize plans for the next year to pursue existing specific aims and/or new or modified aims that may have a greater impact on the translational research objectives of the SPORE.

(e) Human Subjects

(http://grants1.nih.gov/grants/funding/phs398/HumanSubjects.pdf)

i. For all projects involving human subjects and/or tissue resources please include status of patient/specimen accrual and recruitment of gender and minorities where applicable. *A clinical protocol, consent forms, DSM plan, and IRB approval must be on file with the NCI prior to the initiation of any new clinical trial.* Please submit the clinical trials protocol(s) to the SPORE web site at http://sporesprotocols.nci.nih.gov/spores/index.jsp.

ii. An updated Gender and Minority Inclusion Enrollment Report Table is required each year for each individual project. This table is provided at http://grants.nih.gov/grants/funding/2590/enrollmentreport.pdf. Final assessment of closed or completed studies and pertinent publications and reports should also be included. The format of these forms should not be **altered** or **modified**. Review all enrollment information so that the totals in different sections are internally consistent and accurate. All updates or changes to clinical trial protocols, consent forms, and DSM plans should also be attached.

(f) Vertebrate Animal Studies

If there has been no change, check "No Change" on the Progress Report page. If vertebrate animals were not involved in the last application but are now to be included, or if significant changes regarding the use of animals are now proposed, provide a description of the intended involvement of animals in accord with the PHS policy for use of vertebrate animals in research and

check "Change" on the Progress Report page. Examples of significant changes might include substituting one animal model for another or changing from noninvasive to invasive procedures. If studies involving Vertebrate Animals are planned, and they were not part of the originally proposed research design, then you must comply with the requirements of Section F, "Vertebrate Animals," described in the PHS 398 instructions (Rev. 09/2004) and provide the required information to NIH.

(g) Publications

Provide **one copy** of each and every publication, including those published as well as all manuscripts submitted or "in press," that has not previously been cited and submitted in conjunction with the grant. List the complete citation (author[s], title, journal or book, volume, page number, year) of all publications not previously reported. Report only those publications resulting directly from this grant. State if there have been no publications.

(h) Project-Generated Resources

Please list resources developed from this project, such as patents, data, research materials (e.g., cell lines, microarrays, DNA probes, animal models), protocols, software, and/or other unique information available to be shared with other investigators. Describe the resource(s) and how it may be accessed. Provide updates to and any explanations for changes made to the original Data and Resources Sharing Plan for the project.

E. Cores

Core Director(s) should describe progress in establishing and maintaining the high-quality operation of each core outlined in the original competitive application.

1. Discuss any structural, organizational, logistical, or administrative changes; or problems that have developed in the operation of the core.
2. Discuss the usage of the core by SPORE investigators and outside investigators.
3. Describe how the core supports individual research projects, developmental projects, and career development projects – provide details on usage.
4. For Biospecimen Core, include Gender and Minority Inclusion Enrollment Report

F. Developmental Research Program (DRP)

The director(s) of the DRP should first give an overview describing the overall process of selection of meritorious projects during the past year. Give the breakdown of funds (SPORE and institutional matching funds) devoted to each project. The information requested below should be provided for projects supported by SPORE funds, as well as those supported by matching funds committed to the SPORE by the institution(s).

1. Give a brief description of new projects, including a title, project leader(s), and specific aims. Include Gender and Minority Inclusion Enrollment Report Tables and/or clinical protocols, consent forms, and DSM plans on relevant projects as discussed under III.D.5.(e)i. above.
2. Use the PHS 2590 report summary form for reporting progress on: (1) ongoing projects; and (2) completed/finished projects. Summaries on developmental projects do not need to be as explicit or in-depth as those required for full research projects. Provide appropriate information on clinical interventions, including completed Gender and Minority Inclusion Enrollment Report Tables.
3. Discuss developmental projects that have been converted to full translational research projects in the past year or that have resulted in research grant (e.g., R01) applications.

G. Career Development Program (CDP)

The director(s) of the CDP should first give an overview describing the overall process for selection of meritorious candidates in the past year. Give the breakdown of funds (SPORE and institutional matching funds) supporting these candidates. The information requested below should be provided for candidates supported by SPORE funds, as well as those supported by matching funds committed to the SPORE by the institution(s).

1. Provide brief background information on each newly supported candidate. Describe how each individual is being prepared to pursue a career in translational research. Include a title, specific aims, and a brief description of their translational research project, along with a biosketch.

2. Use the PHS 2590 report summary form for reporting progress on: (1) ongoing career development projects; and (2) completed/finished projects. Summaries on developmental projects do not need to be as explicit or in-depth as those required for full research projects. Provide appropriate information on clinical interventions, along with completed Gender and Minority Inclusion Enrollment Report Tables.
3. Highlight any changes or significant advancements in the careers of individuals who previously received support from this SPORE program in the past.

H. Supplemental Activities

A progress report is also required on all activities that were supported during the last year by administrative supplement funds provided through the SPORE program. Please list all supplements (e.g., Minority supplement, Early-Phase Clinical Intervention, Inter-SPORE, and/or AVON-NCI Progress for Patients) and utilize the "Progress Report Summary" form and instructions (pages 10-14) provided for a PHS 2590 application.

1. For all projects involving human subjects or tissue resources please include status of patient/specimen accrual and recruitment of gender and minorities where applicable. *A clinical protocol, consent forms, DSM plan, and IRB approval must be on file with the NCI prior to the initiation of any new clinical trials. This documentation should be sent to your program director and grants management specialist at the NCI.* An updated Gender and Minority Inclusion Enrollment Report Table is required each year on each clinical trial or intervention. This table is provided at http://grants1.nih.gov/grants/funding/2590/enrollmentreport.pdf.

2. A Progress Report Summary should also be provided on any supplemental study that was closed or completed during the previous year. Pertinent publications and/or summary reports should also be included.