GUIDELINES

FOR

Specialized Program of Research Excellence (SPORE)

January 2010*

Translational Research Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute

FOREWORD

Specialized Programs of Research Excellence (SPOREs) are specialized center grants to support multi-project, interdisciplinary, and in some cases, multi-institutional, translational research involving both basic and applied scientists that will result in diverse new approaches to the prevention, early detection, diagnosis and treatment of human cancers. Each SPORE is focused on a specific organ site, such as breast or lung cancer, or a group of highly related cancers, such as gastrointestinal cancers. The seven required elements of all SPORE grants are a minimum of four translational research projects that must reach a human endpoint within five years, a developmental research program, a career development program, and a biospecimen/pathology CORE. Other key features of SPOREs include: co-leadership by a basic and applied/clinical scientist of all projects; specialized COREs that interact with the research projects; a required research project in early detection, prevention, or population science studies for some organ sites; flexibility to terminate projects that are not meeting translational goals and to replace them with new promising projects during the funding period; the requirement for interSPORE collaboration or collaboration with other research groups; and the requirement for substantial access to cancer patient populations. In addition, for a SPORE application to be eligible for submission, the investigators must have a strong, demonstrable research base in the cancer type to be studied. These Guidelines for NCI SPORE grants are intended as a resource on NCI policies and review procedures for prospective SPORE applicants and for reviewers of NCI SPORE applications. These Guidelines also contain instructions for preparing and submitting a SPORE application to the NCI which supplement the instructions in the PHS 398 form for applications for a Public Health Service Grant (see **http://grants1.nih.gov/grants/funding/phs398/phs398.html**), since the instructions in the PHS 398 form relate primarily to preparing single project R01 applications.

ALL NCI SPORE APPLICATIONS MUST BE SUBMITTED UNDER NIH FUNDING OPPORTUNITY ANNOUNCEMENT PAR-10-003, Specialized Programs of Research Excellence (SPOREs) in Human Cancer for Years 2010, 2011 and 2012 (P50) (http://grants.nih.gov/grants/guide/PA-files/PAR-10-003.html**). Applications not prepared using the current version of the PHS 398 application forms or not adhering to the format and preparation instructions contained in these Guidelines and the NCI SPORE Funding Opportunity Announcements may be deferred or returned without review.**

Submitting and reviewing a SPORE application requires a substantial investment of effort by applicants, applicant organizations, NCI staff, and peer reviewers. To maximize the potential of this effort, prospective applicants are strongly advised to discuss their ideas with relevant NCI program staff in the NCI Translational Research Program (TRP, http://trp.cancer.gov) at least four to six months prior to the submission of an application. In addition, since SPOREs have a fixed total budget cap for all new, resubmitted (amended), and renewal (competing continuation) applications, all applicants should confirm with TRP staff that their proposed SPORE will adhere to current NCI budget policies.

Applicants are asked to submit a letter of intent as outlined in detail in the Funding Opportunity Announcement (http://grants.nih.gov/grants/guide/PA-files/PAR-10-003.html). This letter is not mandatory, but strongly encouraged because it allows NCI staff to estimate the potential review workload and plan the details of the review in advance. The letter of intent should be sent electronically or by mail to the NCI Program Officer/Director at the following address:

Rajeev K. Agarwal, Ph.D.
Program Director
Translational Research Program (TRP)
Division of Cancer Treatment and Diagnosis (DCTD)
National Cancer Institute (NCI)
National Institutes of Health (NIH)
6116 Executive Boulevard, Suite 700
Bethesda, MD 20892-8347 (regular mail)
Rockville, MD 20852 (express/courier mail)
Tel: 301-496-8528
Fax: 301-402-5319
Email:agarwalraj@mail.nih.gov

Applicants should also be aware that competitive revision awards (supplements) to SPORE applications are very rare and require extremely compelling situations. Therefore, these Guidelines do not include instructions for the preparation of a competitive revision application. SPORE grantees who wish to submit a competitive revision application should speak first with their Program Officer in the TRP.

Finally, NCI SPORE applications must follow all relevant NIH policies regarding protection of human subjects from research risks; inclusion of women, minorities and children in clinical research; monitoring of data and safety of all clinical trials; vertebrate animals; human embryonic stem cells; and resource sharing as indicated in the PHS 398 instructions. Failure to do so may result in deferral of the review or return of the application without review.

The process for submitting a SPORE application is described in detail in these Guidelines. All NCI SPORE applications, including new, renewal, and resubmitted applications, must be received on or before the dates stated in PAR-10-003. The original application and three copies must be sent to the NIH Center for Scientific Review (CSR) at the address provided in the PHS 398 form. Two copies of the application must also be sent directly to the NCI Referral Office at the address shown below:

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

One of the two copies of the application sent to the NCI Referral Office may be a CD with a bookmarked PDF file. All appendix material must be prepared as bookmarked PDF files on a CD following the instructions in the PHS 398 form and included in the package with the two copies sent to the NCI Referral Office on the receipt date.

NCI SPORE applications will be grouped for review by NCI Special Emphasis Panels based on scientific areas of the proposed research and the number of applications received for a particular receipt date.

The NIH continues to evolve policies governing all extramural awards, including NCI SPORE grants. Applicants are strongly encouraged, therefore, to obtain the latest policy and procedure information as the first step in preparing a new or renewal SPORE application. Further information and guidance may also be obtained from any of the NCI Program Officers in the Translational Research Program (http://trp.cancer.gov).

SUMMARY OF CHANGES IN THIS REVISION OF THE NCI SPORE GUIDELINES

This page provides only a summary of the changes and revisions in these updated Guidelines for NCI SPOREs. Detailed information is presented in the appropriate sections of these Guidelines below and in PAR-10-003, Specialized Programs of Research Excellence (SPOREs) in Human Cancer for Years 2010, 2011 and 2012 (P50) (http://grants.nih.gov/grants/guide/PA-files/PAR-10-003.html).

As the final stage of the NIH Enhancing Peer Review initiative, the structure and page limits for ALL NIH grant applications are changing beginning as of January 25, 2010 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-149.html). Therefore, the structure and page limits for NCI SPORE applications are also changing. These updated Guidelines summarize the changes and provide instructions to applicants about how to prepare SPORE applications in the new format. There are significant changes in the instructions and requirements for preparing the following sections of the SPORE application:

New format for Biographical Sketches
All Biographical Sketches must now include a Personal Statement addressing why your experience and qualifications make you particularly well suited for your role(s) in the SPORE. In addition, NIH encourages applicants to limit the list of selected publications to no more than 15, based on the most recent, the most important, and/or the most relevant to the work proposed in the program.

New format and new page limits for Program Overview section
The Program Overview section of the application has been restructured to include one page for an Introduction to a resubmission, one page for Overall Specific Aims of the SPORE and 30 pages for Overall Research Strategy.

New Program Organization and Capabilities (POC) Section
This new section of the SPORE application includes information about the scientific and administrative leadership of the SPORE; institutional commitment; integration within the SPORE, including the relationship of the SPORE to the Cancer Center and/or institution(s) in which it functions and how SPORE research projects and cores will be integrated with existing Cancer Center/institutional resources (e.g., use of clinical data and safety management systems, biostatistical cores, etc.); cancer patient population; collaborations within the SPORE community; and collaborations with outside entities including NCI-supported clinical trials mechanisms; data management; and planning and evaluation activities. The POC may have one page for an Introduction to a resubmission application, and 12 pages for the discussion of the above items.

New format and new page limit for Projects
All research projects in a SPORE application must be organized and formatted according to the instructions in the PHS 398 form for R01 applications. Therefore, there may be one page for an Introduction to a resubmission application, one page for Specific Aims, and 12 pages for the Research Strategy.

New format and new page limit for Shared Resource Core
All Shared Resource Cores in a SPORE application may have one page for an Introduction to a resubmission application, one page for Specific Aims, and 12 pages for the Shared Resource Core Services Plan.

New format and new page limit for Developmental programs (Developmental Research Program (DRP) and Career Development Program (CDP))
The DRP and CDP in a SPORE application each may have one page for an introduction to a resubmission, one page for Specific Aims, and 12 pages for the developmental plans.

Other changes:

Requirement for Advisory Boards

In the past, advisory boards have been strongly encouraged. Now, an External Advisory Board consisting of appropriate experts who are not affiliated with either the SPORE or the SPORE institution(s) **is required** and should be addressed under Planning and Evaluation in the new POC section of the application. Internal/Institutional Advisory Boards are still strongly encouraged.

Intellectual Property Management Plan Requirement

An Intellectual Property Management Plan (IPMP) is no longer required as part of the submitted SPORE application since it is not evaluated or scored by the peer reviewers. It is, however, required prior to award, and should be submitted to the NCI Program Officer. For further instructions, see section IIIC8.

Submission of Appendix Materials

All Appendix materials must be prepared as PDF files (using no higher than PDF version 1.4) and sent on a CD <u>at the time of submission of the application with the two copies of the application to the NCI Referral Office</u>.

REMINDERS

Communication with the NCI Translational Research Program (http://trp.cancer.gov) about the intent to submit a SPORE application is strongly suggested at least 4 to 6 months before the projected submission date and a letter of intent is requested 4 weeks before the receipt date.

The receipt dates for all NCI SPORE applications, including new, renewal, or resubmitted applications, are shown in PAR-10-003 and in Section VIII A of these Guidelines. The original application and three copies must be **received** by the NIH Center for Scientific Review application receipt office by the indicated dates. Two paper copies of the application or one paper copy and a CD with a PDF file of the application should be sent to the NCI Referral Office by the receipt date. A CD containing PDF files of all Appendix materials should be sent with the copies of the application to the NCI Referral Office.

I. INTRODUCTION

The SPORE (P50) grant is for support of a collaborative, multi-project, interdisciplinary, and often multi-institutional translational research program involving strong leadership and a number of independent investigators, basic scientists and clinical/applied scientists, who are dedicated to developing and applying new approaches to the prevention, early detection, diagnosis, and treatment of human cancers. A SPORE includes a diverse group of projects connected by their organ-site or cancer type translational focus. The SPORE as a whole, including the translational research projects, the shared resource cores (COREs), the developmental research program, and the career development program, should produce a synergistic effort that will allow progress in improving cancer outcomes for human cancer patients to occur at a greater rate than if each project were pursued separately.

These Guidelines provide:

- Definitions, background, and policies for National Cancer Institute (NCI) SPORE grant applications.

- Instructions for the preparation of new, competing renewal, and resubmitted SPORE grant applications.

- Review criteria and a description of the peer review process for NCI SPORE grant applications.

II. DEFINITIONS and IMPORTANT URLs for GRANT POLICIES

Career Development Program (CDP) –A required element within the SPORE that uses funds (a minimum of $50,000/year) to support junior faculty or established investigators who wish to develop or refocus their careers on translational cancer research. Each awardee's project should not exceed two years and junior awardees should be assigned a mentor or advisor.

Developmental Research Program (DRP) – An important component of the SPORE, with a minimum budget of $50,000 per year from the NCI, which supports pilot projects of a limited duration. DRP pilot projects may be collaborative both inside and outside the SPORE community. Although DRP projects do not have to be translational, DRP projects with translational potential may become full projects during the non-competitive years with the approval of the External Advisory Board and the NCI Program Official.

Grants Management Specialist – the NCI official who serves as the focal point for all business-related activities associated with the negotiation, award, and administration of grants.

Letter of Intent – a nonbinding notification submitted to NCI staff by a Principal Investigator indicating intent to submit an application.

Multiple PD/PI - More than one Program Director/Principal Investigator (PD/PI) may NOT be designated by the applicant organization to direct the overall SPORE. However, each individual research project must have at least two co-Project Leaders: one basic and one clinical/applied co-leader.

National Cancer Advisory Board (NCAB) – a Presidential-appointed chartered committee that advises the Secretary, Department of Health and Human Services (DHHS) and the Director, NCI. The NCAB is composed of both scientists and lay members, performs the second level of review of grant applications, and advises on matters related to the policies, mission, and goals of the NCI. The members include outstanding authorities knowledgeable in relevant programmatic areas that are especially concerned with the health needs of the American people.

<u>NCI Program Director</u> – the NCI scientist administrator responsible both for the development of scientific initiatives and for the scientific management of research programs sponsored by the NCI. This person serves as the focal point for all science-related activities associated with the negotiation, award, and administration of grants. This person is also known as the NCI Program Officer or Official.

<u>P50</u> – the NIH activity code which identifies a SPORE application or grant.

<u>Principal Investigator</u> – the person designated by, and responsible to, the applicant/awardee institution for the scientific and administrative direction and proper conduct of all aspects of the P50 SPORE grant.

<u>Project</u> – a research component of the SPORE application having a separate, detailed budget.

<u>Project Co-Leaders/Core Directors</u> – the investigators (basic and clinical or applied) responsible for the scientific direction and conduct of an individual research project or of a shared resource core component of a SPORE. There must be at least two for each research project and one or more for each shared resource core.

<u>R01</u> – the NIH activity code that identifies an individual, investigator-initiated research project application or grant.

<u>Scientific Review Officer (SRO)</u> – the NCI scientist administrator responsible for the organization, management, and documentation of the initial peer review process for applications.

<u>Shared Resource Core (CORE)</u> – a separately budgeted component in a SPORE that provides essential facilities or services to at least one of the proposed research projects. Also known as CORES, they may include other analytical or non-hypothesis driven research activities designed to enhance a service.

<u>Special Emphasis Panel (SEP)</u> – a group of scientific experts convened for a specific peer review of submitted applications.

<u>SPORE Grant (P50)</u> – the Specialized Programs of Research Excellence is a Specialized Center grant mechanism, for the support of a multi-project, interdisciplinary, and often multi-institutional research program. The NCI SPORE program was initiated through a special appropriation from Congress in Fiscal Year 1992 in order 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. The focus is on organ-site specific translational research or translational research that involves highly related groups of human malignancies. SPORE grants include support for common shared resource cores required for the conduct of the component research projects and require a developmental research program as well as a career developmental research program. A key aspect of the SPORE program is collaboration between each funded SPORE and other SPOREs and/or other NCI-funded research programs.

Summary Statement – the official record of the evaluation of the application and the recommendations of the SEP.

<u>Important URLs for Grants Policy</u>

- Updated Instructions Regarding Inclusion of Publications as Appendix Materials: http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-06-051.html
- NCI Web Site: http://www.cancer.gov/
- Extramural Funding Opportunities: http://deainfo.nci.nih.gov/funding.htm
- NCI Notices Related to Initiatives: http://deainfo.nci.nih.gov/extra/notices/index.htm
- NIH Office of Extramural Research (OER) Peer Review Policy and Issues: http://grants.nih.gov/grants/peer/peer.htm
- PHS 398 Form and Instructions: http://grants2.nih.gov/grants/funding/phs398/phs398.html

- NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects: http://grants.nih.gov/grants/peer/hs_review_inst.pdf
- Guidance on Research Involving Human Specimens: http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf
- NIH Data Sharing Policy and Implementation Guidance: http://grants1.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm
- NIH Guidance on Research Involving Human Embryonic Stem Cells: http://stemcells.nih.gov/policy/guidelines.asp
- NIH Policy on Resubmission (Amended) Applications http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html
- NIH Funding Opportunity Announcement: http://grants.nih.gov/grants/guide/pa-files/PAR-10-003.html

III.   SPORE (P50) FUNDING MECHANISM

A. Introduction

The Specialized Program of Research Excellence (SPORE) was 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 SPOREs to achieve translational goals, including the support of the following features: multiple translational research projects; co-leadership on all projects; specialized shared resource cores; flexibility to terminate and initiate new research projects without additional peer review; programs to develop pilot projects as well as to foster the development of translational scientists; and opportunities to combine resources and expertise between SPOREs and other NCI funded mechanisms to test new technologies and human applications in order to advance translational cancer research.

B. SPORE Definition of Translational Research

For the SPORE program, 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. SPORE translational research projects may involve the use of any cellular, molecular, structural, biochemical, genetic, and/or other appropriate experimental approaches.

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 for SPOREs.

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 human cancer outcomes. Investigators who question whether their research projects meet the above definition of translational research and/or the expectations of this program are advised to consult with NCI program staff in the Translational Research Program (TRP). A current listing of TRP program staff can be found at http://trp.cancer.gov.

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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 SPOREs

In addition to their focus on organ-specific human cancer, such as breast cancer, or highly related groups of human cancer types, for example gastrointestinal cancers, 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 within 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 replaced by a project with translational focus.

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 impact 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 translational potential to be initiated. While the team of scientists that participates in the SPORE may remain 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 available 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. Similarly, investigators may not concurrently submit both a P01 and a P50 application requesting support for the same projects/activities. Potential overlaps will be evaluated by NCI staff prior to review; submitted applications may be returned without review if they do not conform to NIH policies or if they fail to meet the minimum requirements of the SPORE Program.

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 the 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.

8. **Intellectual Property Rights**

Each SPORE must develop an intellectual property management plan (IPMP) which addresses evaluation, protection, and commercialization of solely or jointly owned SPORE inventions, including any patenting and licensing strategies. This plan should address all proposed SPORE projects. Although the IPMP will not be included in the application or evaluated during the peer review process, it must be submitted to NCI program staff prior to award. Therefore, all applicants are strongly encouraged to begin development of their IPMP while they are developing the projects.

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 IPMP 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 IPMP, 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 Translation Research Program of the NCI.

9. **Participation in the NCI Translational Science Meeting and Other Workshops**

    i.   Annual NCI Translational Science Meeting (TSM)

         SPORE Directors and selected investigators will be expected to participate in an annual translational science meeting organized by the NCI to share research results with other translational researchers funded by NCI mechanisms such as SPOREs, P01s, R01s, U01s, etc. Other goals of this meeting are to share materials, assess progress, and 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 Overview. 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 TSM can be requested in either the Administrative Core (if proposed) or in the projects of the SPORE (but not in both).

    ii. Additional Inter-SPORE and other NCI/NIH Network Meetings

         SPORE investigators are also expected to attend additional meetings each year that are 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 (no more than $5,000 in direct costs) may be requested within the Administrative Core and/or projects to support attendance at these meetings.

    Because of the collaborative nature of the SPORE program, an unwillingness or consistent inability of a PI or SPORE group to attend these required meetings may be basis for termination of the grant.

10. **If a SPORE application originates from an institution that is supported by an NCI Cancer Center Support Grant (CCSG; P30), the following are also expected:**

    i.   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.

    ii. 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.

    iii. 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.

iv.   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 fulfillment of the requirements of the SPORE. The SPORE should also use the IRB(s) and DSMB(s) as well as clinical resources available throughout the Cancer Center, whenever applicable.

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.   Institutional and individual

Applications may be submitted by U.S., 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).

Foreign institutions may not submit a SPORE application. However, U.S. institutions may propose consortium agreements with foreign institutions 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.

2.   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 applicant institution that submits the SPORE application must receive a formal written agreement(s) from the other participant organization(s) which clearly delineates in what specific manner the participating institution plans to demonstrate a commitment to the SPORE, as well.

The primary institution (as well as any participating institutions) is strongly encouraged to demonstrate 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 application. Up to $50,000 of the SPORE direct costs budget per year may 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 in the Administrative Core, if proposed, or in another appropriate project or core if an Administrative Core is not proposed. 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.

3. 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.

4. 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 counts only 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 0.6 calendar months level of effort contributed as a project co-leader, co-investigator, or core director); they cannot only serve as mentors within the proposed Career Development Program or be the project leader of a proposed Developmental Research project. **Applicants should confirm with TRP staff that they meet the minimum research base before preparing an application and again directly prior to submission of the application.**

E. 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:

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

ii.   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 tumors for molecular targets or blood samples for early detection biomarkers). 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 and if it is feasible to complete that aim within the 5-year funding period. A project(s) proposed in a 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 Translation Research Program if they have any questions concerning this essential requirement.*

iii. 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. There are **NO** exceptions to this requirement. 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.

iv.   For many organ sites, particularly the major malignancies, 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 and must be maintained throughout the entire term of the award.

Cancer site SPOREs (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 understudied 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 the 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 Network.

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 TRP program staff.
**   Indicates whether applications **require** a project focused on early detection, screening, prevention, or population science.

> v.   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.
>
> vi.   Research projects involving **HUMAN SUBJECTS** must adequately address the protection of human subjects from risks, the overall benefit of the study to participants, and 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). 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.
>
> 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 and 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.

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 Resource Cores

SPORE applications **must** include a biospecimen/pathology shared resource core and may include other shared resource cores that provide administrative, laboratory and/or clinical facilities, equipment, and/or services to be shared by one or more research projects and the developmental programs.   Administrative, clinical, and biostatistical cores are strongly encouraged. All proposed SPORE cores must include a budgetary request. Shared resource cores may include non–hypothesis-driven research activities provided that the research is designed to improve core services.

The shared resource cores within the SPORE should not duplicate any shared resource facilities that are already available to the research group. If a proposed core appears to duplicate other facilities at the applicant institution(s), justification should be provided along with an explanation for why these institutional resources cannot be used for the SPORE activities.

For a SPORE application originating from an institution that is supported by an NCI Cancer Center Support Grant (P30), a list of existing Cancer Center Shared Resources/Cores should be included as part of the institutional resources in the Overall Program Environment section, along with a brief description of each that includes staffing, commitments and capabilities and any fees charged for its use. Where practical, use should be made of the Internal Review Board, Data and Safety Monitoring Boards (s), as well as clinical resources available throughout the Cancer Center. Whenever there is dependence on Institute-wide Core Resources, a letter of agreement from the Core Manager/Director should be included.

If any of the participating institutions has two or more ongoing SPORE awards, the application must address in the POC section and/or in the relevant core sections how related (e.g., specimen banking) activities are coordinated across all SPOREs, as well as within the Cancer Center. For example, it might be anticipated that a request to support a Specimen Core at an institution with a CCSG and substantial ongoing SPORE support will 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 overlap with ongoing CCSG and SPORE cores. It should be the objective of all involved core directors to make sure that specimen-related, biostatistical, bioinformatics, and clinical activities are performed in a cost effective and coordinated manner.

If the SPORE will benefit from a funded institutional, local, state, or national resource/consortium, the funded resource should be described in the relevant sections of the Program Overview, POC, and/or the Overall Program Environment sections of the application. The use of this pre-existing resource will be evaluated as part of the institutional commitment and/or the collaborative interactions component of the application.

For competing renewal applications, use of core facilities and services by projects and the developmental programs during the current funding period should be clearly documented. A list of joint publications, including investigators from both the projects and the cores, should also be included for the core.

i.   Biospecimen/Pathology Core (Required)

Each SPORE must have a dedicated core for collecting and distributing human specimens related to the cancer site(s) specified for the SPORE grant. 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. Appropriate informatics capability for tracking, as well as linkage to clinical and follow-up data sets, should be demonstrated. Pre-analytical considerations should be addressed, and applicants are encouraged to describe the informatics system to be used for detailed annotation of parameters of collection and preservation of specimens. The specimen core informatics should also include the essential pathological, clinical, and family history information needed for conducting a wide range of translational research activities. Networking with informatic systems at other sites, e.g. other SPOREs, is encouraged. Whenever possible, informatics systems should be caBIG [http://cabig.cancer.gov] compatible. 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 and development activities, such as analytic validation of assays, quality control, and establishment of new methods, may also be included if they are designed to improve core services for the benefit of the SPORE.

The 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 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.

ii.   Other Cores (Optional)

Additional shared resource cores (e.g., administrative, clinical, biostatistical, animal, etc.) may also be proposed that are supportive of and provide essential services to at least one SPORE research project. These cores may also include other analytical or non-hypothesis driven research activities designed to enhance core services. For Administrative Cores (if included in the SPORE), the services to be provided may include fiscal management, clerical support, manuscript preparation, meeting organization, data management, and quality control. The Administrative Core may include the budget for the required External Advisory Board described in the POC section of the application (see Section V, of these Guidelines) and any proposed internal advisory activities. If an Administrative Core is not proposed, the POC section of the application should clearly delineate how coordination, management, and communication functions will be accomplished within the SPORE, and the budget for the advisory board(s) should be included in another appropriate component of the application.

3.   **Developmental Research Program (DRP)**

Each SPORE must allocate a significant effort to support pilot projects that take maximum advantage of new research opportunities in the organ site or group of related cancers that are the focus of the SPORE. The pilot projects may be collaborative among scientists within one or more SPOREs, or with scientists outside the SPORE community. High risk/high payoff pilot projects are especially encouraged. These pilot projects do not need to reach a human endpoint during the project period as do full projects. The application should describe the proposed institutional process for funding pilot projects that could generate feasibility data. New applicants may supply a short description of eligible projects as examples. Competing renewal applicants should supply track records of awarded pilot projects, and short descriptions of progress and major achievements in the DRP.

As a required component of a SPORE, a DRP must be maintained throughout the entire term of the grant. A minimum of $50,000 direct costs per year from NCI must be requested for a DRP. Matching funds of $50,000 or more are also generally promised by the parent institution. Most DRPs have a commitment of $100,000 to $300,000 direct costs per year, including the contribution(s) made by the parent and/or consortium institutions. These funds are intended to remain flexible and to support studies of a limited duration, usually 2 years or less.

With the approval of the SPORE's External Advisory Board and the NCI TRP Program Director, DRP studies may become full projects as long as they have translational research potential within the SPORE. DRP funds should be used for research activities and cannot be used for the purchase of any large equipment. 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.

4.   **Career Development Program (CDP)**

The SPORE must demonstrate a consistent and significant commitment to a career development program (CDP) in translational research. As a required element of the SPORE, the CDP must be maintained throughout the entire term of the funding period. Funds from this program may be used to support junior faculty or established investigators who wish to develop or refocus their careers on translational research. This program is not a training program and does not support pre- or post-doctoral fellows, either pre-clinical or clinical. However, advanced post-doctoral fellows who provide a letter from an institution

stating that the candidate will be joining its faculty within the year are eligible for this program. 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 the program to support the salary and research costs of candidates with outstanding potential in translational research. The application should describe the number and types of positions (junior faculty, established investigators, and eligible advanced fellows) that will be made available, the criteria for eligibility and selection of candidates, and the selection process, including special efforts to recruit qualified women and minorities. New SPORE applicants should provide short descriptions of potential candidates, the names and research activities of translational science mentors, and the process for monitoring progress of the candidates. Renewal applicants should provide this information in addition to their past performance on recruiting women and minorities, and the track records of awardees supported (publications, subsequent grants awarded, and faculty positions held) by the CDP program. Similar to the DRP, support of a CDP awardee should not exceed two years.

A financial contribution of $50,000 or more direct costs per year from the parent and/or other institutions is encouraged in order to show commitment to the SPORE. Funds from the CDP should be used 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. POC

The SPORE must address its organization and capabilities, including the organizational, administrative, and scientific management of the SPORE. Further, the application should also explain how coordination and communication among the different projects and programs, shared resource cores and participating institutions will be achieved at the overall program level. Additionally, institutional commitment, integration within the SPORE and the institution, availability of cancer patient population, collaborations with other SPOREs within and outside the institution as well as interactions with NCI and NIH networks, data management, and planning and evaluation activities must also be addressed.

IV. ADVANCE COMMUNICATIONS with NCI STAFF

A. Initial Communications with NCI Staff

Each prospective SPORE applicant is strongly advised to schedule a pre-application consultation with NCI TRP program staff. The consultation should be scheduled at least 4 to 6 months in advance of the application due date and is intended to help the Principal Investigator (along with one or more of his/her intended co-investigators) understand the Program and its translational objectives, and discuss strategies for preparing a competitive application. NCI staff will clarify the intent of the guidelines and current NCI budget allocations, and describe the peer-review process. The following are examples of items that NCI staff find most helpful to guide applicants during pre-application sessions:

1. A brief description of the background and proposed responsibilities of the SPORE Director and key senior leaders of the SPORE;

2. 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;

3. A brief description (1-2 pages) of the proposed translational research projects, along with their specific aims and the names of project co-leaders;

4. Estimated budgets for each component (i.e., full projects, resources, developmental/career programs) of the anticipated SPORE application; and

5. A list of active peer-reviewed research grants, cooperative agreements, and contracts that form the research base of the scientific leaders of the SPORE.

Principal Investigators for resubmitted and renewal applications have also found it useful to schedule a pre-application discussion with TRP staff, since program and review policies may have changed since the previous submission.

B. Letter of Intent

Although it is not required and does not enter into the review of an application, all prospective applicants are requested (see PAR-10-003) to submit a Letter of Intent at least 30 days prior to the receipt date for the application. The Letter of Intent should include the following information:

- Descriptive title of proposed application and a list of titles for the anticipated components of the SPORE
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of the funding opportunity (PAR)

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 the applications are submitted. The Letter of Intent should be sent electronically or by mail to the NCI Program Director/Officer at the following address:

Rajeev K. Agarwal, Ph.D.
Program Director
Translation Research Program (TRP)
Division of Cancer Treatment and Diagnosis (DCTD)
National Cancer Institute (NCI)
National Institutes of Health (NIH)
6116 Executive Boulevard, Suite 700, MSC 8347
Bethesda, MD 20892-8347 (for regular mail delivery)
Rockville, MD 20852 (for courier/express delivery)
Email: agarwalraj@mail.nih.gov

SPORE applicants are exempt from the requirement to seek approval six 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). Applicants, however, must adhere to the **budgetary cap restrictions** of the SPORE program as outlined below in Sections V.A.7 and 8, and V.D. to avoid return of the application without review.

V. SPECIAL INSTRUCTIONS for PREPARATION of NCI SPORE (P50) APPLICATIONS

General instructions for the preparation of a grant application are contained in the U.S. Department of Health and Human Services Public Health Service Grant Application (PHS 398) (Rev. 11/2009). The following additional instructions are specifically for multi-project NCI SPORE P50 applications.

A. Face Page
(PHS 398 Form Page 1; Instructions for PHS 398, Part 1.Section 4).

Type "**SPORE**" in the top left hand corner of the face page immediately above the words "GRANT APPLICATION." **Check the "yes" box in Item 2 and enter PAR-10-003, "Specialized Programs of Research Excellence (SPOREs) in Human Cancer for Years 2010, 2011 and 2012 (P50)."** Complete all other items on the face page of the application according to the PHS 398 instructions. This is page 1 of the application; all succeeding pages should be numbered consecutively.

Reminder: Multiple PD/PIs are not permitted for the SPORE grant (Item 3).

Items 7 and 8: Although there is no indirect cost budget cap, by NCI policy, all competing SPOREs (both new and renewal applications) are subject to a **total cost budget cap of $2.5 million.** Total costs include all direct and indirect costs from all participating institutions. Consortium indirect costs must be included in the total costs. Applications with requests exceeding this limit will be returned to the applicant without peer review. In non-competing years, budget requests can exceed the cap for annual cost-of-living increases (less than or equal to 3% of direct costs).

B. Description/Project Summary, Performance Sites and Key Personnel
(PHS 398 Form Pages 2 and Form Page 2-continued; Instructions for PHS 398, Part 1. Section 4)

Follow instructions in the PHS 398 instructions for completing the Project Summary, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells.

The Project Summary/Description serves as a succinct and accurate description of the overall SPORE when it is separated from the application. State the SPORE's broad, long-term objectives and specific aims. State the contribution of each component project and shared resource core to the translational research goals of the SPORE. The second component of the Description is **Relevance**. Using no more than two or three sentences, describe the relevance of the work proposed in the overall SPORE to **public health**. Use plain language that can be understood by a general, lay audience.

Under Performance Sites, list the applicant institution and all other sites where work proposed in the SPORE will be conducted. The names of involved institutions should be spelled out in full for the first mention with the acronym in parenthesis. The acronym may be used subsequently. The Key Personnel list for the entire SPORE should begin with the PD/PI, , followed alphabetically by all leaders/directors, co-leaders, co-investigators, consultants and consortium collaborators involved in all projects, developmental programs, and shared resource cores, whether receiving salary or not, who will provide effort and/or significant intellectual input into the proposed research. List other personnel who will be other collaborators or consultants under "Other Significant Contributors."

C. Table of Contents

Instead of using the Table of Contents page in the PHS 398 form, which is primarily for single project R01 applications, use PHS 398 Continuation Pages to prepare a Table of Contents following the format shown in Appendix A of these SPORE Guidelines.

A detailed Table of Contents that enables reviewers to find specific information readily is very important. Identify **projects** by <u>number</u>, title, and co-project leader names. Identify **shared resource cores** by <u>letter</u>, title, and core director names. Do not include unnumbered pages, and do not use suffixes, such as 5a, 5b, for pages or for projects. Identify the Developmental Research Program as such and not by a number or letter, and identify the Career Development Program as such and not by a number or letter, as well. For renewal/competing continuation or resubmitted/amended applications, renumber all projects and shared resource cores in sequence even if an existing or previously reviewed project or shared resource core is discontinued or deleted. Deleted Component(s) should be identified in the Program Overview section as described below.

D. Budget for Overall SPORE
(PHS 398 Instructions (Part 1, Section 4)

Follow the instructions closely in preparing a detailed composite budget for all requested support for the first year. PHS Form Page 4: Detailed Budget for Initial Budget Period should be used for the first year requested budget. A summary budget for the entire proposed period of support should be prepared using Form Page 5. In each Form, the composite budgets should be summarized by project, shared resource core and developmental program in the different expense categories, i.e., personnel, equipment, and supplies.

Summarize the distribution of effort of all key personnel on each project and shared resource core. This information can be presented in a tabular form such as that shown in Appendix B: Sample Table of Distribution of Professional Effort and placed after all of the budget requests as shown in the sample Table of Contents in Appendix A.

Reminder: Budget requests for renewal/competing continuation SPORE grant applications must also not exceed a total cost (direct plus indirect cost) of $2.5 million.

E. Biographical Sketch and Research Support Information
(PHS 398 Biographical Sketch Format Page; Instructions for PHS 398, Part 1, Section 4)

Biographical sketches are required for all key personnel and all consultants participating in the projects and shared resource cores. Place all the Biographical Sketches together in one section following the overall budget for the program. Place the biographical sketch of the Principal Investigator first, followed by the biographical sketches of all other personnel in alphabetical order. It is helpful if each person is identified by listing the project, shared resource core or developmental program in the upper left corner of the biographical sketch

Follow the instructions on the new "Biographical Sketch Format" page closely. Following the educational block, complete sections A, B, C and D as directed in the PHS 398 instructions:

1. <u>Personal statement</u>. Briefly describe why your experience and qualifications make you particularly well-suited for your proposed role(s) in the SPORE (e.g., PD/PI, Project Leader/Shared Resource Core Director, and participating investigator).

2. <u>Positions and Honors</u>. List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

3. <u>Publications</u>. NIH encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. Each investigator may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research.

Articles should be cited as described in the PHS 398 Citation format. Note that copies of publicly available publications are not acceptable as Appendix material.

4. <u>Research Support</u>. List both selected ongoing and completed research projects for the past three years. Follow the instructions provided in the PHS 398 document.

F. Program Overview

The Program Overview section should summarize the overall goals and research strategies for the entire SPORE. Page limits for each section are given below.

1. **Introduction to the Overall Application:** (Resubmission applications only) **One page limit.**

2. **Overall SPORE Goals and Specific Aims: One page limit.**
    State the organ site cancer(s) to be studied and succinctly list the specific objectives and goals of the SPORE as a whole. Summarize the expected outcomes(s) of the SPORE as a whole, including the impact that the results of the proposed translational research will have on prevention, early detection, diagnosis and/or treatment of organ-site specific cancer.

3. **Overall Research Strategy: (Thirty page limit)**

    Organize the overall Research Strategy Section in the specified order and using the instructions provided below. Start each section with the appropriate section heading: Overall Significance, Overall Innovation, and Overall Approach. Preliminary studies (for new applications) and overall progress (for renewal applications) should be included in this section as well. This section should be used to discuss the overall translational strategies that will be employed in the SPORE to reach human endpoints within the five-year funding period. In addition, PIs of renewal applications should succinctly address the most significant translational research achievements in the current funding period of support and their potential impact on human cancer. Renewal applications should also discuss the use of the SPORE's flexibility to drop projects that are not meeting translational research milestones and replace those projects with new, promising projects during the current funding award period.

    i.   Overall Significance
         a. Explain the importance of the proposed translational goals, including the overarching problems or critical barriers to translational progress in the organ site(s) that the proposed SPORE addresses.

         b. Explain how the SPORE as a whole will improve scientific knowledge, technical capability, and/or clinical practice in prevention, detection, diagnosis or treatment of cancer in the specific organ site(s).

         c. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive translational research for the organ site(s) will be changed if the overall aims are achieved.

    ii. Overall Innovation
         a. Explain how the overall SPORE challenges and seeks to shift current translational research or clinical practice paradigms.

         b. Summarize novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used in the projects and/or shared resource cores.

     c.   Summarize how the SPORE as a whole will refine, improve, or provide new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions in translational cancer research.

  iii. Overall Approach
     a.   Summarize the global strategies, methodologies, and analyses that will be used to accomplish the overall specific aims and objectives of the SPORE.

     b.   Address potential problems, alternative strategies and benchmarks for success in achieving the aims of the overall SPORE.

     c.   If any of the proposed projects or shared resource cores is in the early stages of development, explain how the SPORE as a whole will establish strategies to enhance their feasibility and manage high risk aspects of the work.

     d.   Discuss the collaboration of applied researchers (e.g., clinical researchers, epidemiologists) with basic investigators in the design and implementation of translational research that is most likely to have an impact on human cancer.

     e.   Explain how the proposed research projects, developmental programs, and shared resource cores will, together, address the overall goals and aims of the SPORE more effectively than if the projects were done independently.

     f.   Explain how each shared resource core component is justified and will provide centralized high quality services to the SPORE as a whole and produce an economy of effort and/or save overall costs compared to each project in the SPORE performing its own tests, assays, animal derivations, clinical studies, etc.

As applicable, also include the following information as part of the Overall Research Strategy, keeping within the three sections listed above, Significance, Innovation, and Approach:

Preliminary Studies (for New Applications)

For new applications, summarize the preliminary studies that led to developing the SPORE application; separate more detailed preliminary studies sections are included in the individual research projects and shared resource cores.

Progress Report (for Renewal Applications)

For renewal applications, summarize the major achievements of the overall SPORE in the current funding period; separate more detailed progress reports should be included in the individual research projects and shared resource cores. Discuss new research opportunities or collaborative studies that have emerged from SPORE research in the current funding period.

Explain any significant changes to the program during the current funding period, including the use of the SPORE "flexibility option", and any new directions proposed in the new funding period. For renewal and resubmission applications, include new, continuing, completed, and discontinued projects, indicating the previous number/letter of each component, as a summary of changes in the SPORE since the last review. Explain the decision to discontinue or substantially modify previous projects or shared resource cores and/or to propose new projects or shared resource cores, and how that

affects the overall SPORE. Discuss how recommendations of the External Advisory Board, Internal Advisory Board (if any), and the SPORE leadership have influenced the modification, discontinuation, or initiation of any projects or shared resource cores.

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

4.   SPORE-Related Publications

List all publications and accepted manuscripts which have resulted from the SPORE grant. Using an asterisk, denote each publication that is a result of formal collaborations among different projects within the SPORE, with other SPOREs, or with other funded NCI networks, such as the NCI Cooperative Groups or the Early Detection Research Network (EDRN). For publicly available citations, URLs or PMC submission identification numbers should accompany the full reference. Copies of these publications may no longer be included as appendix material.

5.   Literature Citations

Each citation should include names of all authors, full title, name of book or journal, volume, pages and year of publication.

G. Program Organization and Capabilities (POC) - Twelve page limit (PHS 398 Continuation Pages)

1.   Introduction: (Resubmission applications only) One page limit.

Briefly address how any changes made to the SPORE address the main weaknesses and problems noted in POC in the previous review.

2.   Succinctly address each of the following items (twelve page limit).

i.   **Leadership**: Discuss the leadership qualifications, both scientific and administrative, and the time commitment of the Principal Investigator for the overall successful conduct of the SPORE. Detail the plans for the organizational, administrative, and scientific management of the SPORE program. Describe and/or diagram the chain of authority for decision making and administration within the program.

ii. **Institutional Commitment**: Discuss the institutional commitment to the SPORE in the form of facilitating the research objectives of the SPORE by providing support for recruitment of scientific talent, providing discretionary resources to the SPORE director, assignment of specialized research space, cost sharing of resources, and other assurances proposed by the applicant institution.

iii. **Integration within SPORE and the Institution**: Provide a narrative or table showing how the proposed shared resource cores will be used by the proposed SPORE projects and how the SPORE integrates with existing Cancer Center/institutional resources (e. g., use of clinical data and safety management systems, biostatistics cores, etc.) Explain how coordination and communication among the different projects and programs, shared resource cores and participating institutions will be achieved at the overall program level. [Note: SPORE projects are not required to interact with each other.]

iv. **Cancer Patient Population**: Describe the access to cancer patients and populations for conducting current and projected therapeutic, prevention, detection, and control research within the SPORE and collaborating institutions. For competing renewal applications, document the accomplished translational goals, including evidence of human subject enrollment on clinical/population research studies during the past funding period.

v. **Collaborations**: Discuss planned or ongoing collaborations both within the SPORE community and with outside entities including NCI-supported clinical trial mechanisms such that translational research efforts can move forward rapidly and efficiently.

vi. **Data Management**: Describe the development and use of bioinformatics capabilities of the SPORE as they relate to the Cancer Center, institution, or activities of other NIH/NCI initiatives for overall data management.

vii. **Planning and Evaluation Activities**: Discuss the planning and evaluation of SPORE activities, e.g., the evaluation of the translational research productivity of existing projects and shared resource cores, the discontinuation of projects of low productivity and their replacement with new, more promising projects, and the initiation of activities in response to important translational research opportunities including the establishment of new collaborations. Describe the establishment of the required External Advisory Board and the recommended Internal Advisory Board (if proposed). Describe the membership or areas of expertise for each group, as well as the role of each group in the planning and evaluation processes.

H. Required Statements and Letters of Support

Place all institutional statements and letters of support relative to the overall SPORE after the Program Organization and Capabilities section.

I. Overall Program Environment and Resources
(Resources Format Page PHS 398)

Briefly summarize the overall institutional environment and resources that are relevant to effective implementation of the SPORE. This may include NCI-supported clinical and laboratory facilities, participating and affiliated units, patient population, geographic distribution of space and personnel, consultative resources, and relevant collaborations with investigators currently funded under other mechanisms. Detailed Resources for each specific project and shared resource core proposed should be provided within those sections as described below in Section J. Individual Research Projects and Section K. Shared Resource Cores.

Describe any special equipment, laboratories, patient populations, and collaborations within the program that enhance the overall potential for success of the program.

J. Individual Research Projects

All projects must have at least two project co-leaders (one basic and one clinical or applied), and a budget. Number the projects as 1, 2, 3, etc. Separately numbered subprojects (i.e., such as Subprojects 3A and 3B) are not allowed. Subcontract services or other activities should be included in the project or core they support, and should not be numbered as separate subprojects. A sample Table of Contents outline for a project is included in Appendix A of these Guidelines.

1. **Title Page**

Do not use the PHS 398 Face Page for individual projects. Use PHS 398 Continuation Pages. Clearly denote the project number, the title of the project and the project co-leaders' names and professional degree(s).

2. **Description/List of Key Personnel** (PHS 398 Form Page 2a and b).

   The title of "Principal Investigator" is reserved for the Principal Investigator of the overall SPORE. The leaders of individual projects should be referred to as "Project Leaders or Co-Leaders."

3. **Omit the PHS 398 Table of Contents form.** There should be only one overall Table of Contents at the beginning of the application.

4. **Detailed Budget** and **Budget for Entire Proposed Period of Support** (PHS 398   Form Pages 4 and 5) Follow instructions in the PHS 398 form Part 1, Section 4).

   A detailed budget is required for the first year and a budget summary for the future years. In the upper left–hand corner of the initial year and total budget forms, identify the project or shared resource core. Follow the instructions in the PHS 398 form (Sections 4.4 and following) closely in preparing the budgets for individual projects and shared resource cores.

   The budget justifications should be explicit. State the role/proposed contribution of all proposed personnel and clearly explain and justify other categories of expenses, including any increases or decreases for future years.

   If collaborative efforts or "purchased services" involving other institutions or organizations are anticipated, itemize all costs associated with such third-party participation, including any applicable indirect costs, on separate budget pages and enter the total under the "Consortium/ Contracted Costs" direct costs budget category. For details, refer to "Consortium Agreements," available on the Web at http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm.

   The budget pages for subcontracts should be identified by project or shared resource core and the name of the subcontract institution. They should be placed in the application in sequence after the main budget pages for the project or shared resource core.

   Reminder: The total budget (direct and indirect) for the SPORE must not exceed $2.5 million for the first year and $2.5 million plus increments for cost of living for each subsequent year of the funding period.

5. Do not include **Biographical Sketches** in the projects, since they are grouped following the Overall Budget for the SPORE (see Section V. E. of this guide).

6. **Resources**: (PHS 398 Resources Format Page). Follow the instructions on the PHS 398 Resources Format Page.

   Identify the facilities to be used for the project (laboratory, clinical, animal, computer, office, other). If appropriate, indicate their pertinent capacities and capabilities, relative proximity and extent of access by the project. Describe only those resources that are directly applicable to the proposed work in the project. Provide information about any Other Resources available to the project (e.g., institutional machine or electrical shop or reagents, information, personnel in other projects or shared resource cores in the program) and the extent to which they will be available to the project.

Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport within the program). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements within the program or outside of the program.

List only those resources specific to the individual project. If there are multiple performance sites, describe the resources available at each site.

Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about Select Agents must be described within that section of the Research Plan, 5.5.11 (Select Agent Research)

7. **Research Plan**: (PHS 398 Continuation Pages)

For each research project, follow the PHS 398 instructions for preparing a research project grant. Do not exceed the specified page limits. All tables, graphs, figures, diagrams, and charts must be included within the page limit.

i. <u>Introduction to the Project</u> (Resubmission applications only). Do not exceed one page.

ii. <u>Specific Aims</u>. Do not exceed **one page**.

iii. State concisely the translational goals of the proposed project and summarize the expected translational outcomes(s), including the impact that the results of the project will exert on the human disease site(s) involved. List succinctly the specific objectives of the project, e.g., to test a stated hypothesis, to generate new hypotheses relevant to translational research, to solve a specific problem that has yet been unsolved in the field, to challenge an existing paradigm or clinical practice, to address any critical barrier(s) to progress in the field of translational cancer research, or to develop new technologies, screening methods, or biomarkers appropriate for testing in human cancer patients or populations at risk for cancer.

iv. <u>Research Strategy</u>. Do not exceed **12 pages** for all parts of the Research Strategy section, <u>including</u> the Preliminary Studies (for New Applications) and Progress Report (for Renewal Applications).

Organize the Research Strategy in the specified order, using the instructions provided below. Start each section with the appropriate section heading. Experimental details should be cited using the Bibliography and References Cited section and need not be detailed in the Research Strategy.

NOTE: Provide clear and specific cross references to information in other sections of the application (such as the Personal Statement in the Biosketches; power calculations or recruitment and retention strategies for participants in clinical trials in the Human Subjects section; or methods for derivation of animal strains or power calculations for animal experiments in the Vertebrate Animals section) so reviewers can find all information necessary for evaluation of the project easily.

a) Significance
   • Explain the importance of the problem or the critical barrier to progress in translational cancer research that the proposed project addresses.

- Explain how the proposed translational science project will improve scientific knowledge, technical capability, and/or clinical practice in the organ site(s) studied.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive organ site research will be changed if the proposed aims are achieved.

b) Innovation

- Explain how the project challenges and seeks to shift current translational research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s)
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

c) Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed elsewhere include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the specific stated aims and the overall aim of reaching a human end-point within the five year funding period.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion of the use of Select Agents should be included within the Research Plan as designated in the PHS 398.

As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach:

Preliminary Studies for New Projects. For new projects, include information on Preliminary Studies as part of the Approach section. Discuss the preliminary studies, data, and/or experience of the co-leaders of the project that are pertinent to the project.

Progress Report for Renewal Applications. For renewal applications, provide a Progress Report as part of the Approach section. Provide the beginning and ending dates for the period covered since the last competitive review.

Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions that will be taken. A list of publications, manuscripts accepted for publication, patents, and other printed materials should be included in the next section and is not included in the 12 page limit for the Research Strategy section.

8. **Progress Report Publication List and Bibliography and References/Literature Cited**
   (PHS 398 Continuation Pages: Instructions for PHS 398, Section 5.5)

   For publicly available citations, URLs or PMC submission identification numbers should accompany the full reference. Copies of these publications may no longer be included as appendix material. In either case, the names of all authors, full title, name of book or journal, volume, pages, and year of publication should be listed.

   Publications related to progress in the project. List all publications and accepted manuscripts which have resulted from the research conducted during the current funding period. Using an asterisk, denote each publication that is a result of collaborations within the SPORE, with other SPOREs, or with other funded NCI networks, such as the NCI Cooperative Groups or the Early Detection Research Network (EDRN). Copies of these documents are not to be included in the Appendix material. Each citation should include names of all authors, full title, name of book or journal, volume, pages and year of publication.

   Personnel Reports are not required for renewal applications.

9. **Human Subjects** (Refer to PHS 398 Part I. Item 4 Human Subjects Research and PHS 398 Part II: Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan)

   Address all six required points thoroughly. Power calculations justifying the number of subjects required for the proposed studies, and plans for recruitment and retention of subjects should be included in the appropriate sections of the Human Subjects narrative. Although this section has no specific page limit, be succinct.

   If clinical trials are proposed in any year, describe the plans for monitoring data and safety of the trials.

10. **Inclusion of Women, Minorities and Children** Follow the instructions in the PHS 398 form. Include the required Targeted/Planned and Inclusion Enrollment Table for each clinical study proposed.

11. **Vertebrate Animals** (Refer to Instructions for PHS 398, Part 1, Section 5.5.10.)

    Address all five required points relating to use and care of vertebrate animals. Procedures involved in derivations of new animal strains and power calculations justifying the number of animals required should be included in the appropriate sections of the Vertebrate Animals narrative. Although this section has no specific page limit, be succinct.

12. **Select Agent Research**

    (Follow the Instructions for PHS 398, Part 1, Section 5.5.11)
    http://www.cdc.gov/od/sap/docs/salist.pdf

13. **Multiple PD/PI Leadership Plan**

    Not applicable.

14. **Consortium/Contractual Arrangements**

    Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s).

15. **Letters of Support**
    (PHS 398 Continuation Pages: Instructions for PHS 398, Part 1, Section 5)

    Attach appropriate letters specific to the project detailing the nature and extent of participation. Group Biographical Sketches for consultants or collaborators with the other SPORE personnel directly after the Overall Program Budget.

16. **Resource Sharing Plans(s)**
    (PHS 398 Continuation Pages)

    Follow all instructions in the PHS 398, Part 1, Section 5 for addressing:

    - Data Sharing Plans
    - Sharing Model Organisms
    - Genome-Wide Association Studies (GWAS)

17. **CHECKLIST**

    Do not include a separate Checklist for each project. For multi-institutional projects, provide all checklists at the end of the completed application. Clearly indicate to which institution each Checklist applies.

K. Shared Resource Cores
(PHS 398 Continuation Pages)

The leaders of Shared Resource Cores should be referred to as Core Directors

To aid in the review process, it is suggested that a narrative or table showing the estimated or actual proportional use of shared resource cores by each project be included in the application after the table showing the distribution of professional effort within the program. (See Appendix C: Sample Table of Distribution of Core Resources).

For each shared resource core component, follow instructions for the Individual Research Project, as described above and in the Instructions to the PHS 398, Part 1, Sections 4.2 through 5.5. The general format for a shared resource core follows that of a project except for the Research Plan. A sample table of contents outline for sections of a shared resource core application is provided in Appendix A of these Guidelines.

1. **Title Page**

    Do not use the PHS 398 Face Page for shared resource cores. Use PHS 398 Continuation Pages. Clearly denote the shared resource core letter, the title of the core, and the core director's name and professional degrees.

2. **Description/List of Key Personnel**
    (PHS 398 Form Page 2a and b).

    Provide a summary of the services, facilities, equipment, etc, that the shared resource core will provide, and which projects in the program the shared resource core will serve.

3. Omit the PHS 398 Table of Contents form.

4. **Detailed Budget** and **Budget for Entire Proposed Period of Support**

(PHS 398 Form Pages 4 and 5) Follow instructions in the PHS 398 form (Part 1, Section 4), and the instructions for project budgets above.

5. **Biographical Sketch**

   Do not include Biographical Sketches in the shared resource cores, since they are grouped following the Overall Budget for the SPORE (see section V.E. of these Guidelines.)

6. **Resources**
   (PHS 398 Resources Format Page)

   Follow the instructions on the PHS 398   Resources Format Page and that given in Section J above for projects. List only those resources specific to the shared resource core.

7. **Shared Resource Core Services Plan**

   Do not exceed the specified page limits. All tables, graphs, figures, diagrams, and charts must be included within the page limit.

   i.   Introduction to the Shared Resource Core for resubmission applications **(Do not exceed one page.)**

   ii.   Specific Aims **(Do not exceed one page.)**

   iii. Core Services Strategy (Do not exceed **12 pages** for the Core Services Strategy including Preliminary Data and Progress Report/Summary of Services Provided in the Current Funding Period)

   Biospecimen/Pathology Core

   Describe the plans for collecting and distributing human cancer site-specific and/or related specimens, including fixed tissue, frozen tissue, paraffin blocks, slides, preserved cells, serum, plasma, urine, sputum samples, and other body fluids, as appropriate for the cancer site. Describe the plans for achieving detailed annotation of parameters of collection and preservation that are pertinent to the preanalytic and analytic considerations of potential SPORE studies as well as essential pathological, clinical, and family history information needed for conducting a wide range of translational research activities. Describe the informatics that will be used for tracking specimens, as well as linkage to clinical and follow-up data sets. Networking with informatics systems at other SPORE sites is encouraged, but is not required. Address development, acquisition, storage, and usage of standardized reference specimens and materials, as applicable, and any other services related to the analysis of specimens (e.g., tissue microdissection, immunohistochemistry) that will be provided. Describe and justify any research activities to improve core services and how they will benefit the SPORE.

   Provide a plan 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. Renewal 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.

   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.

Describe the facilities and/or services that will be provided by the shared resource core, and provide the rationale for centralizing them in the core, rather than including them in individual projects. Indicate why the shared resource core is an essential part of the SPORE, and how provision of the proposed services will facilitate accomplishment of the proposed goals and objectives of the SPORE as a whole. Address plans for prioritization of services (if necessary).

If an <u>Administrative Core</u> is proposed, costs to cover the travel of (up to) 10 investigators per SPORE to the annual NCI Translational Science Meeting and other workshops can be requested within this core. In addition, any requests for discretionary funds (up to $50,000 direct costs per year) should also be included within the Administrative Core; institutions are encouraged to match this request.

If a <u>Clinical Core</u> is proposed, the application also 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.

As applicable, also include the following information as part of the Core Services Strategy, keeping within the 12 page limit:

Preliminary Studies for New Applications
Summarize the preliminary studies that support the ability of the core to provide the proposed services

Progress Report/Summary of Services in Current Funding Period
For renewal applications, use of the core facilities and services by projects and developmental programs during the current funding period should also be clearly documented. 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.

8. **List publications stemming from completed shared resource core activities in the current funding period as described above for Projects.**

9. **Include Items in the PHS 398 instructions Part 1 Section 5 as appropriate.**

L. Developmental Research Program (DRP)
(PHS 398 Continuation Pages)

Follow instructions for the Individual Research Projects, as described above and in the Instructions to the PHS 398, Part 1, Sections 4.2 through 5.5. The general format for the DRP follows that of a project except for the Research Plan. A sample table of contents outline for sections of the DRP is provided in Appendix A of these Guidelines.

1. **Title Page**

Do not use the PHS 398 Face Page for the DRP. Use PHS 398 Continuation Pages. Clearly denote the Developmental Research Program, and the DRP's leader or co-leader's name(s) and professional degrees.

2. **Description/List of Key Personnel** (PHS 398 Form Page 2a and b)

3. Omit the PHS 398 Table of Contents form.

4. **Detailed Budget** and **Budget for Entire Proposed Period of Support**
    (PHS 398 Form Pages 4 and 5)

    Follow instructions in the PHS 398 form (Part 1, Section 4), and the instructions for project budgets above.

    The 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 per year 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 and $300,000 direct costs per year, including the contribution(s) made by the parent and/or consortium institutions. DRP funds should be used for research activities and cannot be used for the purchase of any large equipment.

5. **Biographical Sketch**

    Do not include Biographical Sketches in the DRP, since they are grouped following the Overall Budget for SPORE (see section V.E. of these Guidelines.)

6. **Resources**
    (PHS 398 Resources Format Page)

    Follow the instructions on the PHS 398   Resources Format Page and that given in Section J above for projects. List only those resources specific to the DRP.

7. **DRP Plans and/or Examples**. **Do not exceed the specified page limits.**

    All tables, graphs, figures, diagrams, and charts must be included within the page limit.

    i.   Introduction to the DRP for resubmission applications (Do not exceed one page.)

    ii.   Specific Aims (Do not exceed **one page**.)

    iii. DRP Plans for the SPORE with examples of types of projects being considered (Do not exceed **12 pages** for the DRP Plans, including samples and Progress Report/Summary in the Current Funding Period)

         Clearly describe the process for solicitation of DRP projects and the institutional review process for funding pilot projects that generate feasibility data. These funds are intended to remain flexible and to support studies of 2 years or less. The expectation is that successful feasibility studies that have translational potential will replace full projects that are not progressing satisfactorily toward their translational research objectives within the SPORE.

         New applications should describe the methods to be used to set up the DRP within the SPORE and the process to be established for the continuous reviewing and funding of

the pilot projects based on quality and importance to the overall SPORE's goal. New applicants may also supply a short description of eligible projects as examples. Competing renewal applicants should include their track records of funding pilot projects, methods of monitoring and assessing ongoing pilot projects, and short descriptions of other potentially eligible projects.

8. List publications stemming from the DRP in the current funding period as described above for Projects.

9. Include Items in the PHS 398 instructions Part 1 Section 5 as appropriate.

M. Career Developmental Program (PHS 398 Continuation Pages)

Follow instructions for Individual Research Projects, as described above and in the Instructions to the PHS 398, Part 1, Sections 4.2 through 5.5. The general format for the CDP follows that of a project except for the Research Plan. A sample table of contents outline for sections of the CDP is provided in Appendix A of these Guidelines.

1. **Title Page**

    Do not use the PHS 398 Face Page for the CDP. Use PHS 398 Continuation Pages. Clearly denote the Career Development Program, and the CDP's leader or co-leader's name(s) and professional degrees.

2. **Description/List of Key Personnel** (PHS 398 Form Page 2a and b)

3. Omit the PHS 398 Table of Contents form.

4. **Detailed Budget** and **Budget for Entire Proposed Period of Support**
    (PHS 398 Form Pages 4 and 5)

    Follow instructions in the PHS 398 form (Part 1, Section 4), and the instructions for project budgets above.

    The CDP, 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 per year MUST be proposed for a CDP. Matching funds of $50,000 or more by the parent institution are also encouraged. CDP funds should be used to support research activities, including partial salary support for the candidate, research personnel, supplies, travel, and/or other expenses, and cannot be used for the purchase of any large equipment.

5. **Biographical Sketch**

    Do not include Biographical Sketches in the CDP, since they are grouped following the Overall Budget for SPORE (see section V.E. of these Guidelines.)

6. **Resources**
    (PHS 398 Resources Format Page)

    Follow the instructions on the PHS 398 Resources Format Page and that given in Section J above for projects. List only those resources specific to the CDP.

7. **CDP Plans and/or Examples**. **Do not exceed the specified page limits**. All tables, graphs, figures, diagrams, and charts must be included within the page limit.

    i.   Introduction to the CDP for resubmission applications (Do not exceed one page.)

    ii.   Specific Aims (Do not exceed **one page**)

    iii. CDP Plans for the SPORE with examples of types of candidates being considered (Do not exceed **12 pages** for the CDP Plans including examples, Progress Report/Summary in the Current Funding Period)

Clearly describe the plans for this program including the policies, criteria, and processes for selecting candidates (e.g., advanced post-doctoral fellows, junior faculty, and established investigators), including the special efforts that will be made to recruit qualified women and minorities. The plan should include the number and types of positions that will be made available, the criteria for eligibility and selection of candidates, a description of the selection process, and the process for mentoring or advising junior level candidates or monitoring the progress of all candidates. New applicants should provide a short description of types of potential candidates, as well as the names and research activities of mentors/advisors.** Renewal applicants should provide this information in addition to their past performance on recruiting women and minorities and the track record of awardees supported on the SPORE. Support of a CDP awardee should not exceed 2 years.

8.   List publications stemming from the CDP in the current funding period as described above for Projects.

9.   Include Items in the PHS 398 instructions Part 1 Section 5 as appropriate.

N.   Appendix Materials and PDF Files of Submitted Applications

Follow the standard instructions in the PHS 398 form for limits on what may be submitted as Appendix materials for each project, shared resource core, DRP, and CDP (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-07-018.html) and for preparing the Appendix materials. Each project, shared resource core, DRP, and CDP in the SPORE is equivalent to an R01-type application for the purposes of allowable Appendix materials.

All Appendix Materials for paper applications submitted on the PHS 398 form MUST be submitted as bookmarked PDF files on CDs. A summary listing of all the items included in the Appendix is encouraged, but not required. When including a summary, it should be the first file on the CD.

Use a separate file for each component (project, shared resource core, DRP or CDP) and name the file with the component name. Follow the standard instructions for preparing the CDs:

- Use PDF format only. The files should be prepared as PDF version no higher than 1.4 for compatibility with NIH programs and software.
- Where possible, applicants should avoid creating PDF files from scanned documents. NIH recommends producing the documents electronically using text or word-processing software and then converting the document to PDF format. Scanned document images should be checked for legibility.
- Label each disk with the date, Principal Investigator's Name, Grant Number (if available), grant title, and applicant institution.
- If burning CD-ROM disks on a Mac, select the ISO 9660 format.
- Do not use compression techniques for the electronic files.
- Do not use password protection, encryption, digital signature and/or digital certification in the PDF files.

*** This wording corrects the intent of the original version of the 2010 guidelines.*

NCI SPORE applications are scanned by central NIH offices to produce black and white images and black and white double sided copies for the reviewers. Figures in the application that do not reproduce well in black and white may be included in the Appendix. However, all figures included in the Appendix must be included in the application, although they may be reduced in size in the application. Images not included in the application cannot be included in the Appendix.

If your application contains a large number of color illustrations or charts and graphs that will not reproduce well in black and white, you may also submit a CD with a bookmarked PDF file of the entire application as one of the two copies of the application sent to the NCI Referral Office on the due date. Such CDs will be accepted only at the time of application submission. The PDF file should be bookmarked at major subdivisions of the application so that reviewers can navigate through the file and find individual components easily. The files should be saved as PDF version no higher than 1.4 for compatibility with NIH programs and software.

For materials that cannot be submitted on CD (e.g., medical devices, prototypes, video tapes), applicants should contact the Scientific Review Officer for instructions.

Appendix materials should be included with the copies of the application sent to the NCI Referral Office on the receipt date.

VI. SPECIAL INSTRUCTIONS FOR PREPARATION OF RESUBMITTED (AMENDED) APPLICATIONS

Beginning with new and competing renewal applications submitted for the first time on or after January 25, 2009, the NIH will allow only one resubmission/amendment (A1) (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html). However, an application first submitted prior to January 25, 2009 will be allowed two resubmission/amended applications. NOTE that all resubmission/amended applications must use the most current PHS 398 form and be prepared in the new application format with the page limits and structure described in these Guidelines.

The receipt dates for resubmission/amended applications are the same as for new and competing renewal applications (see PAR 10-003).

There is no longer a specific time limit for resubmission of an application. However, a lengthy hiatus between the initial submission and the resubmission may necessitate extensive modification of the research goals and research plans due to significant advances in the field in the intervening period. Principal Investigators and their institutions need to exercise their best judgment in determining the advisability of submitting a resubmitted/amended SPORE application after a significant amount of time has elapsed.

Prepare a resubmitted/amended application according to instructions provided in Section V of these Guidelines. <u>A resubmitted/amended application will be returned without review if substantive changes are not clearly apparent and identified</u>.

A.   Each time an application is submitted for review, a new Letter of Intent is requested (but not mandatory) to the TRP 4 weeks in advance of the submission due date. See Section IV – Advance Communication with NCI Staff.

B.   The Table of Contents should be adjusted to include a listing for the "Introduction to the Resubmitted/Amended Application" in the Program Overview before the Overall SPORE Goals and Specific Aims. Similarly, an "Introduction to the Resubmitted/Amended Application" should be inserted before the Specific Aims page for the individual projects, shared resource cores, DRP, and CDP.

1. The "Introduction to the Resubmitted/Amended Application" section within the SPORE Overview may not exceed **one page** and should provide a general summary of the overall additions, deletions, and changes that have been made to the application as a whole to address the overarching issues raised in the previous review. References to specific statements in the previous summary statement are not necessary.

2. Each resubmitted project, shared resource core, DRP and CDP should include an "Introduction to the Resubmitted/Amended Application" that delineates in greater detail the changes made in that specific component of the application to address the issues raised in the previous review. The Introduction for each individual component (project, core, DRP, and CDP) of the SPORE should be placed before the Specific Aims for that component and may not exceed **one page**. References to specific statements in the previous summary statement are not necessary.

C. Incorporate a discussion of any work done since the previous review into the Preliminary Results/Progress Report sections of the Program Overview as well as all resubmitted projects, resubmitted shared resource cores, DRP, CDP, and POC.

D. Throughout the application, amended portions or passages must be clearly identified to facilitate the review of the amended aspects of the application. The preferred method is to use a vertical line in the right margin to mark amended areas of the application. An easily differentiable font, such as italics, of the size required in the PHS 398 form, also may be used. Neither grayed background nor strikeout of the old text should be used since they make the application difficult for the reviewers to read.

It is important to read through the entire application before submission to ensure that all sections of the resubmitted application, including biographical sketches, Program Overview, Program Organization and Capabilities, Developmental Research Program, Career Developmental Program, Project and Core descriptions, specific aims, research strategy sections, literature cited, human subjects and animal sections, and budgets and budget justifications, etc., have been correctly and properly updated.

VII. SPECIAL INSTRUCTIONS for REVISION/COMPETING SUPPLEMENT APPLICATIONS

As stated in the Foreword, requests for supplemental funding for SPOREs are rare and may be awarded only in unusual and very compelling circumstances. Instructions for submission of a competitive revision application are therefore not given here and those awardees who wish to submit a competitive revision application are encouraged to speak first with their Program Officer at the TRP.

VIII. APPLICATION SUBMISSION PROCESS

A. Specific application due dates are given in PAR-10-003. The receipt and review schedules for all SPORE applications submitted to the NCI, including all new, renewal, and resubmitted/amended, are presented in the table below. Incomplete applications will be deferred to the next review cycle or administratively withdrawn and returned to the applicant without review. All competing renewal applications should be submitted in a timely fashion to avoid a possible gap in support for the SPORE.

Letter Of Intent	Application Receipt	Peer Review	Council Review	Earliest Start Date
Dec 28, 2009	Jan 28, 2010	May/June 2010	Oct 2010	Dec 2010
April 20, 2010	May 20, 2010	Sep/Oct 2010	Jan 2011	April 2011
Aug 21, 2010	Sep 21, 2010	Jan/Feb 2011	May 2011	July 2011
Dec 20, 2010	Jan 20, 2011	May/June 2011	Oct 2011	Dec 2011
April 20, 2011	May 20, 2011	Sep/Oct 2011	Jan 2012	April 2012
Aug 20, 2011	Sep 20, 2011	Jan/Feb 2012	May 2012	July 2012
Dec 20, 2011	Jan 20, 2012	May/June 2012	Oct 2012	Dec 2012
April 22, 2012	May 22, 2012	Sep/Oct 2012	Jan 2013	April 2013
Aug 20, 2012	Sep 20, 2012	Jan/Feb 2013	May 2013	July 2013

B.   General instructions for submission of an NCI SPORE Grant Application are described in the PHS 398 (Part I Section 3). Applicants are strongly encouraged to include a cover letter with the original application. The letter is only for internal agency use and will not be shared with peer reviewers. Place the cover letter at the beginning of the original application only. The cover letter should include:

   1.   Application title
   2.   Funding Opportunity Announcement (FOA) number and title.
   3.   The organ site or related cancers to be studied.
   4.   For late applications, a justification for why the application should be accepted after the stated receipt date. (See NOT-OD_06-086, NIH Policy on Late Submission of Grant Applications, and NOT-OD-07-026, NIH Policy on Late Submission of Grant Applications – Clarification for Multiple PI Applications and New Submission/Receipt Dates)

C. Packing and submission of the application and copies.

   Mail the **original** and **three** identical, single-sided copies of the complete application to the NIH Center for Scientific Review (CSR) using the address label included in the PHS 398 application kit. DO NOT BIND/CLIP SECTIONS OF THE APPLICATION SEPARATELY since this will cause problems with processing and scanning/duplication of the application. Use rubber bands or string to package an individual application as one document. Applications must be sent by U.S. mail or by commercial carrier. Personally delivered packages will not be accepted by the CSR mailroom.

   Center for Scientific Review
   National Institutes of Health
   6701 Rockledge Drive, Suite 1040
   MSC 7710
   Bethesda, MD 20892-7710 (for United States Postal Service (USPS) Express or Regular Mail)
   Or
   Bethesda, MD 20817 (for Express/Courier/Non-USPS delivery)

   Send **two** identical, single-sided copies of the original application or (optionally) **one single-side copy and one** CD with a PDF version of the application, under separate cover to:

Referral Officer
Program Coordination and Referral Branch
Office of Referral, Review and Program Coordination
Division of Extramural Activities
National Cancer Institute
6116 Executive Blvd., Room 8040A, MSC 8329
BETHESDA, MD 20892-8329 (for U.S. Postal Service express or regular mail)
Rockville, MD 20852 (for non-USPS delivery)
301-496-3428
301-402-0275 (FAX)
ncirefof@dea.nci.nih.gov

IX. REVIEW PROCEDURES

A. Policies

The NCI Scientific Review Officer (SRO) serves as the Designated Federal Official (DFO) with legal responsibility for managing the review and ensuring that the review is conducted according to relevant laws, regulations, policies, and established NIH and NCI policies and procedures. The SRO provides guidance and direction with respect to review policies, procedures and criteria; the functions of the NCI staff; conflict of interest policies; implications of the Privacy Act; the need for confidentiality of the proceedings; the necessity of addressing gender, minority, and children representation in clinical study populations; and other policy and logistical matters. During the review, the NCI program director serves as a resource, as needed, concerning the history and development of the SPORE program, changes in program direction for resubmitted and renewal applications, and other relevant programmatic matters.

- The NCI is committed to the conduct of impartial, high-quality peer review of grant applications submitted by the scientific community and to the maintenance of an objective review process.

- The Research Programs Review Branch, Division of Extramural Activities, NCI, which is responsible for managing the peer review of NCI SPORE applications, is organizationally independent from the NCI extramural program units. The Research Programs Review Branch has responsibility for and autonomy in, the conduct of initial review activities.

- The conduct of peer review of NCI SPORE applications shall be in all particulars consistent with, and subject to, NIH and PHS peer review practices and policies.

- NCI review staff members are responsible for managing the scientific and technical review of SPORE applications, including the selection of reviewers; management of SEPs; and the documentation of review panel findings and recommendations.

- The responsibility for communications between the applicant and NCI staff changes during the various phases of the application process. Prior to submission of the application, NCI TRP staff members are the appropriate contact. From submission of the application until the peer review has been completed, all contacts should be made through the SRO. Following the peer review, TRP staff members again become the contact for communications with the applicant.

- Efforts are made to avoid both real and apparent conflict of interest in review of SPORE applications. In addition, the confidentiality of both review materials and reviewer deliberations is maintained. Direct contact between applicants and reviewers is prohibited. Instead, any questions or concerns should be brought to the attention of appropriate NCI staff as indicated above.

- To maintain the focus of the peer review process on scientific merit, previous and current pay lines and funding policies are not discussed, and, in fact, are not relevant.

B. Application Receipt and Referral

SPORE applications, like all other PHS grant applications, are received and processed initially by the NIH Center for Scientific Review (CSR) and are assigned to NCI. The NCI referral office subsequently assigns the application to the SPORE program area, the TRP. Finally, RPRB review staff group the SPORE applications for review based on scientific content and recruit appropriate reviewers for each Special Emphasis Panel (SEP) .

C. Application Administrative Review

Upon receipt, the SRO reviews the application for conformance to NIH policies and NCI SPORE Guidelines. If there are administrative or policy deficiencies that can be resolved easily post-submission, the SRO will contact the Principal Investigator with the remedial action necessary. If there are extensive deficiencies in the structure, organization or format of the application, or the application fails to address required NIH policies in ways that cannot be resolved quickly, the application will be returned to the applicant without further consideration. The applicant may submit a complete application for a later receipt date.

D. Review Format

All review panels are constituted as SEPs. The SEP reviewers evaluate and score projects, shared resource cores, DRP, CDP, and POC, and assign an overall impact/priority score to the entire SPORE application.

The SEP membership will include (a) senior investigators, many of whom have experience with SPORE grants, and who can view the proposed science from an overall translational science perspective, and (b) specialists for specific scientific areas. Key members of the previous review panel will be included for continuity of review of resubmitted/amended applications. In organizing the review panel membership, conflicts of interest, either real or apparent, will be managed according to NIH policy.

The SEP meeting date will be determined by the NCI SRO according to the availability of the reviewers and NCI review staff.

The SEP will convene in a face-to-face meeting in the Washington, DC, metropolitan area or elsewhere at the convenience of the reviewers. The SRO will provide an introductory orientation on NIH and NCI review policies and procedures and administrative and logistic matters relating to the review. Then, each application will be evaluated by the reviewers. The reviewers will evaluate and rate each project and shared resource core component, the two developmental programs, and POC, and then evaluate the overall SPORE. The review panel will then assign the final overall impact/priority score to the SPORE application.

NCI SROs prepare the summary statement using the minimally edited reviewers' comments as well as summaries of the discussion prepared by selected SEP members and/or the SRO.

E. Communications with the Principal Investigator

Prior to the review, the SRO will contact the Principal Investigator to obtain background information relevant to the application and names of investigators collaborating with the members of the applicant group and other investigators who may be in conflict with the group. Applicants may

suggest types of expertise that are required to review the application. However, **neither the SRO for the review nor the TRP program director assigned to the application may accept names of specific potential reviewers from any member of the applicant group either directly or indirectly.**

The SRO will provide a deadline for submission of a small amount of supplemental data that can be forwarded to the reviewers electronically. This deadline generally will be several weeks prior to the review so that all reviewers have adequate time to study and evaluate the information. Major changes in scope of the projects or shared resource cores cannot be accepted after submission of the application.

F. Communications with NCI Staff

Shortly after receipt of the applications, the SRO contacts appropriate NCI TRP staff to discuss programmatic issues related to the review of submitted applications and for recommendations for prospective reviewers, where appropriate. However, all review-related communications with actual or potential reviewers are through the SRO.

G. Selection of Reviewers

The size and composition of each SEP review panel will be determined by the particular details of the applications to be reviewed. It is the responsibility of the SRO to make these determinations based upon thorough understanding of the work proposed in the applications and consultation with NCI TRP staff and other NCI review staff, as appropriate. The review panel members are recruited based on the scientific areas, methods and approaches proposed in the applications grouped for review each review cycle. The SEPs convened for SPORE reviews therefore change every review cycle.

The roster for each SEP will reflect the areas of expertise required to review all applications grouped for review by that SEP. Because all SPORE applications are required to reach a human endpoint within 5 years of the funding period, one or more patient/consumer advocates will be included in the review group. These individuals, who have full scoring privileges, will address clinical or population-based study issues related to protection, recruitment and retention of human subjects in the proposed research. The SEP roster will be available on the NIH Web site (http://era.nih.gov/roster/#sep) approximately 30 days before the review meeting.

In identifying prospective qualified reviewers, the SRO takes full advantage of many available resources, including existing databases of experienced reviewers, lists of grantees and contractors, and consultation with recognized authorities in the scientific community. The SRO, as well as TRP staff, will identify reviewers who, because of collaboration, affiliation, bias or other issues, should be excluded from the review. **As noted above, applicants are prohibited from suggesting names of prospective reviewers.**

The Chairperson of the review panel will generally be a senior investigator experienced in the review of complex multidisciplinary applications and generally knowledgeable in the scientific areas to be reviewed. The Chairperson has responsibility for ensuring that each application receives a fair discussion and that the reviewers adhere to the SPORE review criteria and the NCI SPORE scoring guidelines. Each application will have an assigned Discussion Leader who will briefly introduce the application by summarizing the research scope, goals and objective of the proposed SPORE and providing a brief description of each proposed project and shared resource core for the review panel. The Discussion Leader will also draft a summary of the committee discussion of the overall SPORE for inclusion in the summary statement.

X.   REVIEW CRITERIA

The mission of the NIH is to support science in the pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Peer review of NCI SPORE applications emphasizes a synthesis of two major aspects of the SPORE application: (1) review of the merit of each individual research project and shared resource core and (2) review of the overall program as a collaborative translational research effort including the developmental programs (DRP and CDP) and the POC.

The review criteria for both the overall program and the individual projects are Significance, Investigators, Approach, Innovation, and Environment (NIH Guide Notice **NOT-OD-09-025**, December 2, 2008 – see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-024.html). The sections below give more detail about how these review criteria are applied to the overall program and to the individual projects. The review criteria for shared resource cores, the developmental programs and the POC are also listed below.

Each of the review criteria will be addressed and considered in assigning the overall impact/priority score, and weighted as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, an investigator may propose to carry out important work that by its nature is not innovative, but is essential to advance a field.

A. <u>Review Criteria for the Overall Program</u>

Overall Impact: Reviewers will provide an overall impact/priority score on the standard NIH 9-point scale (1=exceptional; 9=poor)) to reflect their assessment of the likelihood that the SPORE as a whole will exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria listed below and additional review criteria listed in section X.D. below (as applicable). Although the overall impact/priority score is not meant to be a formulaic calculation, the scientific projects and their associated shared resource cores should be weighted approximately 70% of the total overall score and the developmental programs and the POC approximately 30% of the total overall score. An overall scoring tool that takes the 70/30 weighting into consideration will be provided to the reviewers by the SRO.

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

- **Significance**: Does the program as a whole address an important translational research problem or a critical barrier to progress in the field? If the aims of the program are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the program change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

- **Investigators/Overall Program Leadership**: Are the PI, collaborators, and other researchers well suited to the program? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? Do the investigators have

complementary and integrated expertise for proposed collaborations; are their leadership approach, governance and organizational structure appropriate for the SPORE? Are the qualifications and experience of the PI and other senior scientists appropriate for the work proposed? Do they provide effective scientific and administrative leadership, as demonstrated by selection of individual projects for scientific excellence and translational feasibility? Have they established effective developmental programs for pilot studies as well as for building careers in translational research in organ-site specific cancers? Is the commitment of the PI and other senior investigators adequate?

- **Innovation**: Does the overall program challenge and seek to shift current research or clinical practice paradigms in the context of translational research for a particular organ site by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? Does the SPORE seek out high risk/high payoff projects that are based on solid preclinical preliminary studies, and that have a good chance of achieving a human endpoint within the five year funding period?

- **Approach**: Are the overall strategies, methodologies, and analyses, including biostatistical methods well-reasoned and appropriate to accomplish the specific aims of the SPORE? Are potential problems, alternative strategies, and milestones for success presented? If there are projects in the early stages of development, will the overall strategy establish feasibility and will particularly risky aspects be managed so that the 5 year goal of a human endpoint can be achieved? What is the overall quality of the projects and the adequacy of services provided by the shared resource cores (if proposed)? In the case of multiple institutions involved in a single SPORE, is there an adequate plan for communication among investigators to achieve the goals of the grant? For renewal applications, has there been adequate progress during the current funding period and have the projects reached a human endpoint or are they about to? Is there evidence of effective use of SPORE COREs? Are the plans for 1) protection of human subjects from research risks, and 2) Inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

- **Environment**: Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional commitment to the SPORE, support, equipment and other physical resources available to the program adequate for the project proposed? If more than one institution is involved in the SPORE, in what way will the institutions act synergistically to implement the goals of the SPORE?   Will the program benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

B. Review Criteria for Individual Research Projects

Reviewers will provide an impact score for each project that reflects their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria listed in Section X.D below (as applicable). A project does not need to be strong in all categories to be judged likely to have major scientific impact.   For example, a project that by its nature is not innovative may be essential to advance a field.

1. **Significance**: Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims

change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. **Investigators**: Are the Project co-Leaders, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative with other groups, do the investigators have complementary and integrated expertise; are their leadership approaches, governance and organizational structures appropriate for the project?

3. **Innovation**: Does the project challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research (e.g. gene therapy specifically for one type of cancer) or novel in a broad sense (e.g. molecular targeting a pathway known to be used in many different cancers)? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

4. **Approach**: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Are the plans for (1) protection of human subjects from research risks and (2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

5. **Environment**: Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

6. **Additional Criteria for SPORE Research Projects**

   i.   Significance. Does this study address an important translational research goal or barrier for this particular organ site or the related group of organs?

   ii. Investigators. Is there adequate evidence of co-leadership of the project by basic and applied/clinical investigators in the conception, design, and proposed implementation of the project?

   iii. Innovation. Is the project original and innovative in the context of translational research for the organ site(s) involved?

   iv. Approach. Will the research achieve a human end-point within five years? Is it likely the study will be completed within the project period? If the project is ongoing and has changed research direction, is there appropriate rationale for the new approach?

C. <u>Review Criteria for Shared Resource Core(s) (If applicable)</u>

Each Shared Resource Core must provide essential functions or services for at least one project.

1.   Biospecimen/pathology CORE (required)

- 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 information, 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 these analyses were critical to the success of SPORE projects and are worthy of continued support, if requested.

- Is there sufficient evidence of experienced personnel dedicated to the activities of specimen collection, annotation, quality control, storage, distribution, and analysis? Is there sufficient oversight of the collection of initial and follow-up clinical information, data entry, and maintenance of database and computer networks? 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 that the investigators within the projects are working closely with those of the CORE to meet project objectives?

- Is the proposed plan for augmenting and/or complementing any existing specimen resource supported by a Cancer Center Support Grant (CCSG; P30 grant mechanism) or other funding mechanism(s) adequate? 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?

2.   Other shared resource cores will be evaluated based on the following criteria:

- Is the proposed Shared Resource Core well matched to the needs of the overall SPORE? Does it provide essential facilities or services for one or more scored research projects? For renewal applications, a demonstrated use of each CORE by SPORE projects during the previous funding period is critical and should be detailed.

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

- What is the overall quality of the proposed core services? Are there adequate quality control processes proposed for the facilities or services provided by the Shared Resource Core (including procedures, techniques, and quality control)? What are the criteria for prioritization and usage of Shared Resource Core products and/or services?

- Are the qualifications, experience, and commitment of the Shared Resource Core Director(s) and other key personnel adequate and appropriate for providing the proposed facilities or services?

- Will the proposed shared resource core(s) provide cost effective services to the SPORE? Are there adequate plans to augment and/or complement an existing shared resource supported by an NCI Cancer Center Support grant (P30), if applicable?

- Is the environment for the shared resource core adequate to support the program as proposed?

D. Review Criteria for the Developmental Research Program (DRP)

- Will the proposed plan for the DRP attract new ideas and pilot studies within and/or outside of the SPORE institution(s)? Is the plan for periodic review and funding of a spectrum of pilot projects, as well as for promoting pilot projects with translational research potential to full projects within the SPORE, adequate?

- For renewal applications, did the DRP generate a strong publication record? Were any high-risk/high-impact projects funded through the DRP? Did data produced by the DRP lead to success in the competition for outside funds? Did any DRP projects reach translational potential and become full SPORE projects? Was funding from DRP used for collaborative projects with other institutions/programs?

E. Review Criteria for the Career Development Program (CDP)

- Does the proposed plan for the CDP describe how promising candidates for independent careers (academic, industrial, governmental) in translational cancer research will be selected? Is the recruitment, retention and communication with awardees adequately described? For renewal applications, are the research activities, independent grant awards, publication(s), and promotion/current status of individuals who have been supported by the CDP described? The proposed plan for the CDP may include the promotion of outstanding career development projects to full projects within the SPORE and the continued support and integration of successful awardees as project co-leaders or co-investigators.

- Does the proposed plan address how the investigators will seek out and include qualified women and minorities in the program?

- Does the proposed plan address periodic review of the CDP awardees and the role of mentors/advisors?

F. Review Criteria for Overall Program Organization and Capabilities (POC)

- Leadership: Are the scientific qualifications, involvement, leadership and time commitment of the PI sufficient for requirements of the proposed SPORE?

- Institutional Commitment: Is the institutional commitment for facilitating the research objectives of the SPORE (e.g., special facilities, recruitments, discretionary funding) documented and sufficient?

- Integration within the SPORE and the Institution: Are the activities of SPORE projects and proposed COREs integrated? Does the entire SPORE integrate with the existing cancer center/institute (e.g., use of clinical data and safety management systems, biostatistical and other COREs, etc.)? Is there evidence of or plans for coordination and communication across all components of the SPORE and among all participating institutions at the overall SPORE level?

- 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 SPORE? For competing renewal applications, documentation of accomplished translational goals, including evidence of human subject enrollment on clinical/population research studies (if applicable) during the current funding period should be provided.

- Collaborations: Is there a plan for or evidence of interactions with other SPOREs, NIH/NCI programs and/or other organizations? Is sharing of information, participation in committees, or collaboration on other activities of mutual interest evident and sufficient? For competing renewal applications, are there contributions and outcomes from the NCI Translational Science Meeting and other related SPORE or NIH/NCI meetings during the term of the award?

- Data Management: Are the plans for and/or track record of the overall data management and/or bioinformatics capabilities of the SPORE as they related to the Cancer Center, institution, and/or activities of other NIH/NCI initiatives sufficient for the requirements of the proposed SPORE?

- Planning and Evaluation of Activities: Are the plans for and/or track record of evaluating the translational research productivity of existing projects and COREs adequate for the requirements of the proposed SPORE? Are the plans for and/or track record of use of advice from internal and external advisors sufficient? For competing renewal applications, is there evidence that the flexibility available to the SPORE has been used effectively?

G.   As applicable for the overall program, each research project, developmental program, and shared resource core proposed, reviewers will consider **the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items:**

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

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

Inclusion of Women, Minorities, and Children. When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

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

Resubmission Applications. When reviewing a Resubmission application (formerly called an amended application), the reviewers will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal Applications. When reviewing a Renewal application, the reviewers will consider the progress made in the last funding period.

- Has adequate progress been made in both projects and shared resource cores since the previous competitive review?

- Were the previous specific aims accomplished, and are the proposed research goals logical extensions of work during the current funding period?

- Has scientific collaboration occurred, as indicated by joint publications and new collaborative aims and/or projects?

- Is there adequate justification for adding new projects and/or deleting previous components?

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

H. Additional Review Considerations

As applicable for the overall program, each research project and shared resource core proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

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

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

Applications from Foreign Organizations. SPORE applications from foreign organizations are not permitted. However, if a component of the SPORE is from a foreign organization, reviewers will assess whether the project or resource presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Resource Sharing Plans. Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable:

1. Data Sharing Plan (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm);

2. Sharing Model Organisms (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html); and

3. Genome Wide Association Studies (GWAS) (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html).

I. Scoring

All components of the SPORE (Research Projects, Program Organization and Capabilities, Developmental Programs, and Shared Resource Cores) are scored numerically using the standard NIH 9-point (1 =exceptional; 9=poor) scoring scale. Any of these components can be rated Not Recommended for Further Consideration (NRFC) if the reviewers consider the component completely unsatisfactory.

For each discussed application, a final numerical impact/priority score from 1 (exceptional) to 9 (poor) will be given by each eligible SEP member (those without conflicts of interest). Each reviewer's overall impact/priority score will reflect his/her evaluation of the overall impact that the SPORE as a whole is likely to have on the research field(s) involved, rather than a simple average of the reviewer's scores for the projects, the shared resource cores, the developmental programs, and the POC .

The final overall Impact/Priority score will be weighted as follows:

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

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

Reviewers will focus on the scored projects, shared resource cores, developmental programs and the POC of the program, excluding any components not recommended for further consideration, in assigning the final overall impact/priority score. However, inclusion of components of poor quality will be considered evidence of poor judgment by the Principal Investigator(s) and the program senior leadership. Reviewers do not have the option to select only the better components of the SPORE to improve the overall impact/priority score.

If an application has many major weaknesses and therefore is likely to have low impact relative to all SPORE applications normally received by the NCI, the review panel may chose to expedite the discussion or to not discuss the application. An application can be not recommended for further consideration if it lacks significant and substantial merit; does not have four scored projects, a scored Specimen/Pathology shared resource and scored developmental programs; or

presents serious ethical problems in the protection of human subjects from research risks, use of vertebrate animals, biohazards, and/or select agents.

XI. SUMMARY STATEMENT

The summary statement is the official record of the review of the application. The summary statement includes administrative information about the application, the final overall impact/priority score if the application was discussed, codes for the committee's determination of the adequacy of protections for human subjects and animal welfare, and several narrative sections conveying the opinions and recommendations of the reviewers assigned to the application. The summary statement for applications discussed during the review meeting will include a Resume and Summary of Discussion, an Overall Critique section summarizing the strengths and weaknesses of the Overall Program, summary paragraphs listing the strengths and weaknesses and the final impact score/rating of each project and shared resource core, and resumes for human subjects, vertebrate animals and other additional review criteria, which are prepared by the SRO.

The summary statement will also contain the criterion scores and the essentially unedited critiques from each of the reviewers assigned to the projects and shared resource cores (if applicable) proposed in the application. Applicants should note that some reviewers may not have updated their critiques after the review meeting to reflect their final opinions after the discussion. However, the overall Resume and Summary of Discussion, the Overall Critique section, and the summary paragraphs prepared by the SRO will reflect the final opinions of the review committee.

For applications that are not discussed during the meeting, the summary statement may not include an Overall Critique section, but it will include the individual reviewers' criterion scores for projects along with the essentially unedited critiques for all projects and shared resource cores.

The SRO prepares the summary statements as soon as possible after each review meeting. Each summary statement is released as soon as it is completed. Depending on the number of applications that were reviewed in each SEP, summary statements are usually completed within 6 weeks after the review meeting, and all summary statements will be released no later than two months prior to the next receipt date to provide sufficient time for applicants who may need to resubmit the application. The Principal Investigator(s) can access the summary statement through the NIH eRA Commons (http://commons.era.nih.gov) after it has been finalized and released by the SRO.

The summary statement will be transmitted to the NCAB for second level peer review, to the NCI official file and to the appropriate NCI staff.

XII. AWARD

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

Following review by the NCAB, scored applications are considered for funding by the NCI. When an award is made, it is the policy of NCI that meritorious projects reviewed as part of the SPORE be funded as part of the SPORE even though other funding may be available. Duplicate funding will not be awarded.

NCI program staff may administratively delete funding or reduce the duration of support for components of SPOREs that are judged by peer review to be less meritorious and/or nonessential to the conduct of the SPORE.

XIII. QUESTIONS

Questions related to NCI SPORE review may be directed to:

Referral Officer
Program Coordination and Referral Branch
Office of Referral, review, and Program Coordination
Division of Extramural Activities (DEA)
National Cancer Institute (NCI)
6116 Executive Boulevard, Room 8041, MSC 8329
Bethesda, MD 20892 (for U.S. Postal Service express or regular mail)
Rockville, MD 20852 (for non-USPS delivery)
Telephone: (301) 496-3428
FAX: (301) 402- 0275
Email: ncirefof@dea.nci.nih.gov

APPENDIX A

SAMPLE TABLE OF CONTENTS

SECTION I

Face Page
Description, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors
and Human Embryonic Stem Cells
Table of Contents
Detailed Summary Budget for SPORE Initial Budget Period
Budget for Entire Proposed SPORE Period Direct Costs Only
Table of Distribution of Professional Effort in the SPORE
Table of Percentage Distribution of Shared Resource Core Effort To Projects
Biographical Sketches and Research Support Information

SECTION II

Program Overview
Introduction to the Overall Application (for resubmission applications)
Overall Program Goals and Specific Aims
Overall Research Strategy
- Overall Significance
- Overall Innovation
- Overall Approach
- Program Related Publications
- Literature Citations

Program Organization and Capabilities (POC)
Introduction to the Program Organization and Capabilities (for resubmission applications)
    POC Issues
- Leadership
- Institutional Commitment
- Integration within the Institution
- Cancer Patient Population
- Collaborations
- Data Management
- Planning and Evaluation Activities
- Other issues relating to coordination, communication, administration, and scientific
  management of the SPORE Program.

Institutional Statements and Letters of Support

Individual Research Project 1
- Title Page (Title, Project Co-Leaders Names, Degrees)
- Description, Performance Sites, Senior/Key Personnel, Other Significant Contributors,
  and Human Embryonic Stem Cells
- Detailed Budget for Initial Budget Period
- Budget for Entire Proposed Period of Support

- • Resources
- • Detailed Budget for First 12-Month Period for Any Included Consortium/Subcontract Arrangement
- • Budget Estimate for Each Year of Any Included Consortium/Subcontract Arrangement
- • Resources for Consortium/Subcontract Arrangement
- • Research Plan
  - o Introduction to Resubmission Application (if applicable)
  - o Specific Aims
  - o Research Strategy
- • Progress Report Publication List (for Renewal Applications)
- • References/Literature Cited
- • Human Subjects
  - o Inclusion Enrollment Report (Renewal Applications Only)
  - o Protection of Human Subjects
  - o Inclusion of Women and Minorities
  - o Targeted/Planned Enrollment Table
  - o Inclusion of Children
- • Vertebrate Animals
- • Select Agent Research
- • Consortium/Contractual Arrangements
- • Letters of Support
- • Resource Sharing Plan(s)

Shared Resource Core Component A
- • Title Page (Title, Core Director(s) Name(s), Degree(s))
- • Description of Core Service Plan, Performance Sites, and Key Personnel
- • Budget for the First 12-Month Period
- • Budget Estimate for Each Year of Requested Support
- • Resources
- • Shared Resource Core Services Plan
  - o Introduction to Resubmission Application (if applicable)
  - o Specific Aims
  - o Core Services Strategy
- • Progress Report Publication List and Bibliography (for Renewal Applications)
- • References/Literature Cited
- • Human Subjects
  - o Inclusion Enrollment Report (Renewal Applications Only)
  - o Protection of Human Subjects
  - o Inclusion of Women and Minorities
  - o Targeted/Planned Enrollment Table
  - o Inclusion of Children
- • Vertebrate Animals
- • Select Agent Research
- • Consortium/Contractual Arrangements
- • Letters of Support
- • Resource Sharing Plan(s)

Developmental Research Program
- Title Page (Title, DRP Leader, Name, Degree)
- Description, Performance Sites, Key Personnel
- Detailed Budget for Initial Budget Period
- Budget for Entire Proposed Period of Support
- Resources
- Detailed Budget for First 12-Month Period for Any Included Consortium/Subcontract Arrangement
- Budget Estimate for Each Year of Any Included Consortium/Subcontract Arrangement
- Resources for Consortium/Subcontract Arrangement
- DRP Plans for the SPORE
  - Introduction to Resubmission Application (if applicable)
  - Specific Aims
  - DRP Plans for the SPORE with examples of types of projects being considered for new applications and a track record of funded pilot projects, ongoing pilot projects and other potentially eligible projects for renewal applications.
- List of Publications
- Human Subjects
  - Inclusion Enrollment Report (Renewal Applications Only)
  - Protection of Human Subjects
  - Inclusion of Women and Minorities
  - Targeted/Planned Enrollment Table
  - Inclusion of Children
- Vertebrate Animals
- Select Agent Research
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plan(s)

Career Developmental Program
- Title Page (Title, CDP Leader, Name, Degree)
- Description, Performance Sites, Key Personnel
- Detailed Budget for Initial Budget Period
- Budget for Entire Proposed Period of Support
- Resources
- Detailed Budget for First 12-Month Period for Any Included Consortium/Subcontract Arrangement
- Budget Estimate for Each Year of Any Included Consortium/Subcontract Arrangement
  Resources for Consortium/Subcontract Arrangement
- CDP Plans for the SPORE
  - Introduction to Resubmission Application (if applicable)
  - Specific Aims
  - CDP Plans for the SPORE with examples of types of candidates being considered for new applications and a track record with numbers and types of candidates recruited, ongoing projects and potential candidates for renewal applications.
- List of Publications
- Human Subjects

- o   Inclusion Enrollment Report (Renewal Applications Only)
- o   Protection of Human Subjects
- o   Inclusion of Women and Minorities
- o   Targeted/Planned Enrollment Table
- o   Inclusion of Children
- Vertebrate Animals
- Select Agent Research
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plan(s)

Checklist(s) - Include a Checklist for each participating institution

APPENDIX B

SAMPLE TABLE of

DISTRIBUTION OF PROFESSIONAL EFFORT (%) IN THE SPORE

Participating Investigator	Project 1	Project 2	Project 3	Project 4	Core A	Core B	Core C	Application Total
Dr. A. (Principal Investigator)	20*		15		15*			50
Dr. B.						10*		10
Dr. C.		25*	10				20*	55
Dr. D.				30*				30
Dr. E.	30		30*					60
Dr. F.						30		30
Dr. G.		25					25	50
Dr. H.							25	25
Dr. I.				50				50

*Project Leader/Core Director

First lines should be reserved for project and core directors; other investigators should follow thereafter.

APPENDIX C

SAMPLE TABLE of

PERCENTAGE DISTRIBUTION OF SHARED RESOURCE CORE EFFORT TO PROJECTS

Project	Project 1	Project 2	Project 3	Project 4	DRP	CDP	Total (100%)
Core A: Administration	15	15	15	15	20	20	100
Core B: Biospecimen/Pathology	30	5	10	30	20	5	100
Core C: Biostatistics and Bioinformatics	5	40	5	10	20	20	100