GUIDELINES FOR THE PROGRAM PROJECT (P01) OF THE NATIONAL CANCER INSTITUTE

December 2006

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FORWARD

These Guidelines for the Program Project Grant (P01) of the National Cancer Institute are intended as a resource for prospective applicants and for reviewers of NCI Program Project applications. The Guidelines dated January 2006 are effective for all P01 applications submitted February 1, 2006, and later.

Program Projects constitute one of the major extramural research mechanisms supported by the National Cancer Institute (NCI). The NCI has found the P01 grant mechanism to be particularly effective and highly productive, especially in areas where interdisciplinary collaboration and specialized core resources are needed to achieve a larger objective than can be supported through the traditional single project R01 grant.

Submitting and reviewing a P01 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 encouraged to discuss their ideas with relevant NCI program staff prior to the submission of a formal application. Individuals should contact the NCI Referral Officer in the Division of Extramural Activities (DEA), NCI (e-mail: ncidearefof@dea.nci.nih.gov or 301-496-3428) for assistance in identifying appropriate NCI program areas and program staff.

Applicants must obtain approval from the NCI at least 6 weeks before the anticipated submission of a P01 application (including resubmitted/amended applications and requests for supplemental funds) requesting $500,000 or more in direct costs in any single year [NIH Guide to Grants and Contracts, dated October 16, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html)].

In addition, for Type 2 (renewal/competing continuation) applications budget requests for direct costs for the first requested year must not exceed an increase of 20 percent over the direct costs awarded in the last noncompeting (Type 5) year. Details of the restrictions on budget requests are provided at this Web site: http://deainfo.nci.nih.gov/flash/NCIPolicy_p01_escalation.htm. To determine the base for calculation of the maximum allowed increase in the first renewal year, the Principal Investigator is strongly advised to contact appropriate NCI program staff for assistance.

It is a requirement that NCI P01 applications be prepared according to the instructions described in this document. The instructions for NCI application formatting refer to current procedures outlined in the Application for a Public Health Service Grant, PHS 398 (Rev. 5/01) as well as the latest changes in policies governing the submission, review, and award of NCI P01s (see http://grants.nih.gov/grants/funding/phs398/phs398.html) (see http://grants.nih.gov/grants/oer.htm). Applications not prepared using this or later versions of the PHS 398 application kit or not adhering to the instructions for preparation contained in this document may be returned without review.

Applications involving clinical research must meet the NIH requirement for addressing the protection of human subjects from research risk; the inclusion of women, minorities, and children in the study populations; plans for data and safety monitoring (for research involving clinical trials)) and plans for model-organism sharing. Expected accruals must be presented in tabular form for each clinical study proposed. Applicants should refer to the information in this document and the PHS 398 instructions. Failure to provide such information will result in the application being returned as nonresponsive or deferral of review until adequate information is provided.

Investigators submitting an NIH application requesting research support of $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why data sharing is not possible. This requirement is a reaffirmation of the NIH policy endorsing expedited translation of research results into knowledge, products, and procedures to improve human health. Applicants

should refer to the policy statements provided by the NIH Office of Extramural Research (http://grants2.nih.gov/grants/policy/data_sharing/index.htm).

The NIH continues to evolve policies governing all extramural awards, including Program Projects. Applicants are strongly encouraged, therefore, to make certain to obtain the latest policy and procedure information as the first step in preparing a new or renewal P01 application. Updated information and additional copies of the P01 Guidelines may be obtained over the Internet by accessing the Home Page of the National Cancer Institute Division of Extramural Activities at: http://deainfo.nci.nih.gov/awards/P01.htm. Further information and guidance may also be obtained from the NCI Referral Officer (see contact information below). For current grantees, information may be obtained from your NCI Program Director.

Referral Officer
Division of Extramural Activities
National Cancer Institute
6116 Executive Blvd., Room 8041
BETHESDA, MD 20892-8329
Rockville, MD 20852 (for courier delivery)
301-496-3428
301-402-0275 (FAX)
ncirefof@dea.nci.nih.gov

The process for submitting an NCI P01 application is different from that for most grant applications. All NCI P01 applications, including new, resubmitted/amended, revised/supplemental, and competing renewal applications, must be submitted on or before the P01 receipt dates—January 25, May 25, or September 25. 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 be sent directly to the NCI Referral Office at the address above.

BEGINNING WITH APPLICATIONS SUBMITTED FOR THE FEBRUARY 1, 2006, RECEIPT DATE, NCI IS UNDERTAKING A PILOT STUDY OF A SINGLE-TIER REVIEW PROCESS FOR P01 APPLICATIONS. APPLICATIONS ON RELATED TOPICS WILL BE REVIEWED TOGETHER IN LARGE (UP TO 10 APPLICATIONS) CLUSTERS AND SCORED BY A SPECIAL EMPHASIS PANEL (SEP) ENCOMPASSING APPROPRIATE EXPERTISE. APPLICATIONS WILL BE GROUPED BASED ON COMMONALITY OF SCIENTIFIC RESEARCH AREAS AND GENERAL TECHNICAL APPROACHES. ALTHOUGH THE THREE NCI P01 CHARTERED COMMITTEES WILL NOT MEET AS THE SECOND TIER OF REVIEW DURING THE PILOT STUDY, COMMITTEE MEMBERS WILL BE INCLUDED IN THE SEPS. TELECONFERENCES WITH APPLICANTS WILL NOT BE CONDUCTED AS PART OF THE REVIEW PROCESS.

SUMMARY OF CHANGES

This page is a summary only. Detailed information is presented in the appropriate section.

Changes Made in the December 2006 Guidelines

Changes in Receipt Dates for P01 Applications

- In November, 2006, the NIH announced changes in receipt dates for all applications (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-001.html). Therefore, effective January 2007, the receipt dates for all NCI P01 applications are **January 25, May 25, or September 25**.

Changes in Policy Relating to Appendix Materials

- In November, 2006, the NIH announced a change in policy regarding appendix materials that may be submitted with grants applications (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-07-018.html). These policies also apply to NCI P01 applications. These changes also apply to NCI P01 applications. Appendix materials may be submitted in PDF format on CDs in lieu of paper copies. Appendix materials **should not be submitted with the NCI P01 application on the receipt date**. The SRA for the review will give applicants a specific deadline for submitting appendix materials and late-breaking information. (See section V.J of these Guidelines for more information on submitting appendix materials.)

Changes in Terminology

As the NIH transitions to the new electronic SF 424 R&R application form, there has been a change in terminology to make the terms used at NIH congruent with terms used throughout the Federal government. These changes have been incorporated into these updated Guidelines.

Former Term	New Term
Revised/Amended	Resubmission
Competing continuation	Renewal
Progress Report	Continuation
Competing supplement	Revision

Changes Made in the May 2006 Guidelines

Changes in NCI P01 Policies Regarding Resubmitted/Amended Applications

- Resubmitted/amended P01 applications which have had one or more projects funded since the previous submission must have at least two unfunded projects in order to qualify for submission of the P01.
- The funded project(s) will not be discussed or scored separately during the review of the P01 application; instead, they will be considered under the Environment and Integration review criteria for the Overall Program.
- If the P01 is to be awarded, funded projects will be folded into the P01 at the awarded budget levels and for the remaining awarded years of support.
- Accelerated peer review of resubmitted/amended applications has been discontinued.

Changes in Review and Scoring Process

Beginning with applications submitted for the February 1, 2006, receipt date:

- All NCI P01 applications will be reviewed in large (up to 10 applications) clusters.

- Applications will be reviewed by Special Emphasis Panels (SEPs) which will include members of the NCI P01 Parent Committees and other appropriate reviewers.
- The SEP will discuss and score projects, cores, and the Overall Program, and assign the final priority score for each application.
- The SEP will have the option to streamline the review and unscore applications with low merit.
- Telephone conferences with applicants during the review will be discontinued.
- Program leadership will be reviewed under Overall Program Investigators.
- Integration will be reviewed as part of the Overall Program.
- Appendix D shows the Special Emphasis Panels (SEPs) that will review P01 applications and the topic areas for each SEP as of February 2006. The number of SEPs and their topic areas may be modified to accommodate the number of applications or other factors.

REMINDERS

- Communication with the NCI Referral Office via a Letter of Intent is required at least 6 weeks before the projected submission date so that internal NCI approval can be obtained. This requirement also applies to resubmitted/amended applications. If the application is not submitted on the anticipated receipt date, a new Letter of Intent is required for the next receipt date.
- **All** NCI P01 applications are to be submitted January 25, May 25, or September 25.
- The original application and three copies must be sent to the Center for Scientific Review.
- Two copies must be sent to the NCI Referral Office.

I. INTRODUCTION

The Program Project (P01) grant is a mechanism for the support of an integrated, multiproject research program involving a number of independent investigators who share knowledge and common resources. This type of grant has a well-defined central research focus involving several disciplines or several aspects of one discipline. The individual projects should be interrelated such that the research proceeds synergistically so that research progress proceeds at a greater rate; hence, they are expected to result in a greater contribution to program goals than if each project were pursued separately.

These Guidelines provide:

- Definitions, background, and review criteria for National Cancer Institute (NCI) P01 grant applications.
- Descriptions of the peer review process used for the evaluation of P01 grant applications.
- Instructions for the preparation of new, competing renewal, revised/supplemental, and resubmitted/amended P01 grant applications.

II. DEFINITIONS and IMPORTANT URLs for GRANT POLICIES

Awaiting Receipt of Application (ARA) – an internal NIH document submitted to CSR by NCI staff to indicate willingness to accept an application (a) requesting $500,000 or more in direct costs in any year, or (b) for programmatic relevance.

Core – a separately budgeted component that provides essential facilities or services to two or more of the proposed research projects.

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.

National Cancer Advisory Board (NCAB) – a Presidential-appointed chartered advisory committee to the Secretary, Department of Health and Human Services (DHHS), and the Director, NCI, composed of both scientists and lay members, which performs the final advisory review of grant applications and advises on matters of significance 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.

P01 – the NIH activity code which identifies a Program Project application or grant.

Principal Investigator – the one person designated by, and responsible to, the applicant/awardee institution for the scientific and administrative direction and proper conduct of all aspects of the P01.

Program Director – the NCI scientist administrator responsible for the development of 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.

Program Project Grant (P01) – an assistance award for the support of a broadly based multidisciplinary research program that has a well-defined central research focus or objective. It

may also include support for common supporting resources (cores) required for the conduct of the component research projects. Interrelationships between projects are expected to result in a greater contribution to the program goals than if each project were pursued separately.

Project – a research component of the P01 application having a separate detailed budget.

Project Leader/Core Director – the investigator responsible for the scientific direction and conduct of an individual research project or of a core component of a P01.

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

Scientific Review Administrator (SRA) – the NCI scientist administrator responsible for the organization, management, and documentation of the initial review process for applications.

Special Emphasis Panel (SEP) – an advisory group of scientific experts convened for a specific review or collection of reviews.

Summary Statement – the official record of the evaluation and recommendations of the scientific review panel.

Important URLs for Grants Policy

- 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

III. PROGRAM PROJECT (P01) FUNDING MECHANISM

The P01 grant is intended solely for the support of multidisciplinary or multifaceted research programs having a strong central theme. There are several features that distinguish P01 grants from other assistance mechanisms: Each project within a P01 is similar to the traditional research grant application in the sense that each is reviewed for scientific merit compared to a standard of quality in a broader scientific discipline. However, a component project also is evaluated within the context of the special collaborative interrelationships and environment required for a P01. Interaction between projects should be such that the acquisition of knowledge is accelerated or of a quality beyond that expected from the same projects conducted separately, without combined

leadership or a common theme. Individual investigators may apply their specialized research capabilities to basic research projects, clinical research projects, cancer control, and cancer prevention research projects or combinations of such projects as they relate to the focused, central theme of the overall P01. Thus the P01 funding mechanism offers a special way to achieve research synergy through the sharing of personnel, facilities, equipment, data, ideas, and concepts.

Each application should include a sufficient number of scientifically meritorious projects to promote an effective collaborative effort among the participating investigators. To be eligible for an award, a P01 must consist of a minimum of three scientifically meritorious projects. Conversely, the P01 should not be so large that it exceeds the scientific and administrative leadership capability of the Principal Investigator, or that it loses a tight focus. Applicants should realize that the larger the program, the greater the likelihood that some components will be of lower quality. The inclusion of projects of lower quality or of peripheral relationship to the central theme will have a negative impact on the overall evaluation. The maximum number of research projects recommended, therefore, is six. Plans to submit applications with more than six projects should be discussed with the appropriate NCI Program Director. Alternatively, investigators considering research programs with a larger number of projects should consider submission of separate more focused P01 applications each containing fewer projects. Please note that division of projects into subprojects in order to designate additional key investigators or to fragment the experimental approach is not permitted.

Applications may include projects by NIH intramural investigators. However, since funds for such a project will come from the NCI intramural budget, the application should not include a requested budget for such a project. Otherwise, applications should not include projects or core components for which no funds are requested, such as for projects which are already funded. For competing (Type 2) renewal/competing continuation applications for which a former project is now supported by another award mechanism (i.e., a separate R01 grant) but will continue to collaborate with the P01, the Program Overview section of the application and relevant projects may refer to the other non-P01 projects/activities to emphasize a greater institutional research environment, resources, and support. Letters of collaboration from the separately funded investigators should also be included in the application.

However, resubmitted/amended P01 applications may include one or more projects that were in the original P01 application but which have subsequently been awarded as a separate grant (i.e., an R01 grant) during the course of the resubmission process for the P01. The Principal Investigator should indicate within the Program Narrative which project(s) have been awarded funds. All resubmitted/amended applications must include at least two unfunded projects. In this case, NCI policy is that the funded project(s) will not be discussed or scored during the review, but will be considered under the Environment and Integration review criteria for the Overall Program and that the funded project(s) will be folded into the P01 award at the awarded budget levels and period of support. The application should contain a statement signed by all investigators agreeing to these stipulations.

Finally, P01 applications may not include requests for unspecified funds (seed money) for developmental projects, or for training.

A P01 application may contain one or more core component(s), each with a separate budget, for administrative or research support services that are required for and shared solely within the P01. Core components should be important to the overall success of the program, and each core must serve at least two projects. Core components also may include research designed to improve core services. If a P01 grant application originates from an institution that is supported by an NCI Cancer Center Support Grant (P30), or there are Special Programs of Research Excellence (SPORE) (P50) on related research topics, a list of existing Cancer Center Shared Resources/Cores and SPORE resources and cores should be provided. If cores proposed within the P01 application

duplicate existing institutional resources, clear and substantive justification should be provided for such duplication. Instead, funds may be requested to supplement existing facilities in accordance with the needs of the P01.

Central to the quality of a P01 is the leadership of the Principal Investigator and the other senior participating investigators. The Principal Investigator of the P01 should be an established scientist with a strong record of accomplishment who is substantially committed to, and exercises the responsibility for the scientific leadership, integration, and administration of the entire P01. The Principal Investigator need not serve as a project leader or core director. The component projects should be directed by investigators who are experienced in the conduct of independent research as evidenced by grant awards and publications and whose backgrounds and interests relate sufficiently to one another to allow for integrated group pursuit of the proposed P01 goals and objectives. There is one designated project leader and one designated core director for each project and core. This named person is the one responsible for overall management and coordination of the component.

IV. ADVANCE COMMUNICATIONS with NCI STAFF

A. Initial Communications with NCI Staff

Research groups planning to submit a P01 application have found it useful to establish advance communications with relevant NCI staff. Such communications should begin at least 3 months before the submission date.

Specific issues that might be discussed include:

- The theme or focus of the P01;
- The size and scope of the program and the optimal number of projects;
- The rationale for choosing the P01 mechanism for support of the planned research;
- For each project within the program, the tentative title, name of the project leader, and a brief summary of goals and relationship to the central theme;
- A brief description of the core component(s) and how each one supports the overall program;
- The estimated budget for the program. NOTE: If the budget for a competitive renewal application exceeds 120 percent of the last budget period, the application may be returned if NCI approval has not been obtained and documented;
- The methods to be used to stimulate communication and interaction among program participants;
- Other related support; and
- For competing renewal applications, an identification of components to be discontinued and new components that might be added to the P01.

B. Letter of Intent

Applicants must obtain approval from the NCI at least 6 weeks prior to the anticipated submission of any P01 grant application, including requests for supplemental funds, requesting $500,000 or more in direct costs in any one year (NIH Guide to Grants and Contracts, dated October 16, 2001 [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html]. **This rule also applies to resubmitted/amended applications and applications that have been delayed to a later submission date.**

An informative Letter of Intent, as described below, will assist NCI staff in preparing the ARA, the NIH internal document required for such approval, in a timely manner. Communications about intent to submit a P01 application should be with personnel in the NCI Referral Office. If the application is received without prior staff concurrence and an ARA filed it will be returned to the applicant without review. All applications including resubmitted/amended applications must have this permission 6 weeks in advance of the planned receipt date. If application submission is delayed, a new communication to the NCI Referral Office must be made to update NCI staff regarding the intent to submit the application.

Although the Letter of Intent is not binding either for the planned submission date or for final detailed research content, the information provided also allows NCI review staff to estimate the potential review workload and to avoid conflict of interest in the review. Therefore, the Letter of Intent should include at a minimum:

- The names of the Principal Investigator and key personnel;
- A descriptive title of the potential application and a list of titles for the anticipated components of the P01;
- Identification of the organization(s) involved; and
- Announcement (if any) to which the potential application is responsive.

Descriptions for the program, projects, and core are also very helpful.

Letters of Intent should be sent to:

Referral Officer
Division of Extramural Activities
National Cancer Institute
6116 Executive Blvd., Room 8041
BETHESDA, MD 20892-8329
Rockville, MD 20852 (for courier delivery)
301-496-3428
301-402-0275 7(FAX)
ncirefof@dea.nci.nih.gov

Electronic transmission of the Letter of Intent is acceptable. The Referral Office will send a copy to the Chief, Research Programs Review Branch, and to the appropriate NCI program director. If you have previously been in communication with an NCI program director, please provide that person's name in the letter and forward him or her a copy of the letter.

V. SPECIAL INSTRUCTIONS for PREPARATION of PROGRAM PROJECT APPLICATIONS

General instructions for the preparation of the P01 grant application are contained in the Grant Application Form PHS 398 (Interim Revision 4/2006). Please note that the instructions provided in the PHS 398 document are designed primarily for traditional research project (R01) applications. P01 applications require additional information as outlined below. Clear and concise organization of the document is essential to the efficient study and review of the application. Page limitations are presented in the PHS 398 instructions; these should be followed closely for each individual project and core unless otherwise noted. In particular the font recommendations must be followed. Page limitations for the sections relating to the overall program are noted under the specific categories.

Use the current PHS 398 forms and instructions as provided in the PHSPHS 398 Interim Revision (4/2006). When submitting the application, please attach a cover letter that includes the following information: the institute (NCI) which has agreed to accept the application (see NIH Policy), the

name of the NCI program director, and response to a Program Announcement or RFA (if applicable).

A. Face Page (PHS 398 Form Page 1; Instructions for PHS 398, Part 1.Section I C1).

Type "PROGRAM PROJECT" in the top left-hand corner of the face page immediately above the words "GRANT APPLICATION." Complete all items on the face page of the application as in a traditional research grant application. This is page 1 of the application; all succeeding pages should be numbered consecutively.

B. Description, Performance Sites and Key Personnel (PHS 398 Form Pages 2 and Form Page 2-continued; Instructions for PHS 398, Part 1. Section I-C2).

Form Page 2 is now two pages (Form Page 2 and Form Page 2-continued) which include five sections: Description, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells.

The Description is meant to serve as a succinct and accurate description of the proposed work when it is separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the program. Clearly state the contribution of each component to the overall theme and goals. The second component of the Description is **Relevance.** Using no more than two or three sentences, describe the relevance of this research 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 described in the research plan will be conducted. The Key Personnel for the entire P01 should begin with the Principal Investigator and then list alphabetically all project and core leaders, coleaders, coinvestigators, and consultants and consortium collaborators, whether receiving salary or not, who will provide effort and/or significant intellectual input into the proposed research. List under "Other Significant Contributors" other personnel who will be other collaborators or consultants. The names of involved institutions should be spelled out in full for the first mention with acronym in parenthesis. The acronym may be used subsequently.

To aid in the review of the application, include information concerning the distribution of effort of all key personnel on each project and core. This could be presented in a tabular form such as that shown in Appendix B: Sample Table of Distribution of Professional Effort, NCI P01 Guidelines.

C. Table of Contents (PHS 398 Research Grant Table of Contents Form Page 3; Instructions for PHS 398, Part 1. Section 1-C3.)

Replace the PHS 398 Form Page 3 with a detailed table of contents that enables reviewers to find specific information readily. Identify projects by number, title, and responsible investigator. Identify cores by letter, title, and responsible investigator. A sample Table of Contents is included at the end of these Guidelines as an example of how the order and format of the application could be organized (see Appendix A, NCI P01 Guidelines). For renewal/competing continuation or resubmitted/amended applications, renumber all projects and cores in sequence if an existing or previously reviewed project or core is discontinued or deleted.

D. Overall Budget for Program Project

The PHS 398 Instructions (Part 1, Sections 1-C4 and 1) should be followed closely in preparing a detailed composite budget for all requested support for the first year using of the PHS 398

application. 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: Budget for Entire Proposed Period of Support of the PHS 398 application. The composite budgets should summarize all project/core expenses by category, i.e., personnel, equipment, and supplies.

Budget requests for direct costs for renewal/competing continuation P01 grant applications must not exceed an increase of 20 percent over the direct costs to be awarded in the last noncompeting (Type 5) year. The Principal Investigator is encouraged to contact NCI program staff for assistance in preparing budgets. (http://deainfo.nci.nih.gov/flash/NCIPolicy_p01_escalation.htm).

E. Biographical Sketch and Other Research Support Information (PHS 398 Biographical Sketch Format Page; Instructions for PHS 398, Part 1, Section I-C6)

Follow the instructions on the "Biographical Sketch Format" page. Biographical sketches are required for all **key** personnel participating in individual projects and cores and for all consultants. In arranging the biographical sketches, the Principal Investigator should be listed first, with other key personnel in alphabetical order. Each sketch may not exceed four pages. For publicly available citations, URLs or NIH PubMed Central (PMC) submission identification numbers may accompany the full reference. **NOTE**: Copies of these publications **may no longer** be included as appendix material. Information on other support beyond that required in the biographical sketch should not be submitted with the application. Specifically, do not list award amounts or person months in projects, nor address potential scientific and/or budgetary overlap.

It is the policy of the NCI that meritorious projects reviewed as part of the P01 be funded as part of the P01 even though other funding (e.g., in the form of an R01 grant) may be available.

F. Program Narrative: Overall Program Project (PHS 398 Continuation Pages)

The narrative for the P01 should provide explicitly the required information in the order noted below. Efforts should be made to keep the narrative as concise as possible. **Typically, eight to twelve pages are sufficient.**

1. **Goals and Significance:** Present the general scientific or medical area to be studied, the overall long-term objectives of the research described in this application, and any hypotheses to be tested. In addition, the overall significance of the research effort should be described. In particular, the importance of the research to public health should be stated.

2. **Theme and Integration:** A P01 is a confederation of interrelated research projects. It is important to establish the programmatic theme in this section and to address the issue of the integration of components, delineating how each individual component benefits from and contributes to the overall P01. A diagram illustrating the interactions between components, accompanied by explanatory text, may be helpful to reviewers.

3. **Research Plan:** This section delineates the research effort as a whole and explains the strategic approach to the problem, briefly mentioning each project as it relates to the overall P01. Descriptions of prior collaborative efforts among investigators in the group, as well as the sequence of events leading to the current application, may also be included in this section. It is important to discuss the advantages expected from a group effort, e.g., how the projects are mutually reinforcing, how collectively they further the goals of the proposed research, etc.

4. **Preliminary Studies (For New Applications):** This section should focus on ongoing research and current accomplishments of the investigators relative to the proposed studies. More detailed preliminary reports should be included separately under each individual project. Items to be included are:
   - A summary of major accomplishments attributed to the participating investigators that relate to the overall theme of the P01.
   - A list of all publications and manuscripts accepted for publication already produced by the interaction(s) of the participating investigators.

5. **Progress Report (Renewal/Competing Continuation Applications):** The Progress Report should describe achievements in the current funding period. Separate progress reports are included in the individual research projects, so the information in the program narrative should focus on the overall P01 rather than reiterating information provided in each component. Items to be included are:
   - A summary of major accomplishments that can be attributed to the P01 grant. Accomplishments involving more than one project should be noted.
   - A list of all publications and completed manuscripts that have resulted from the P01 grant. With an asterisk, denote each publication that is a result of formal collaborations among different projects within the program. For publicly available citations, URLs or PMC submission identification numbers may accompany the full reference. Copies of these publications **may no longer be included** as appendix material.
   - A list of project and core components in tabular form (by title, investigator, and previous number/letter) that denotes which projects have been discontinued or completed since the last review. Also indicate which projects are continuing, are new, or are substantially modified. Explain the decision to discontinue, substantially modify, or start new projects.

6. **Institutional Environment and Resources:** Briefly describe the institutional environment and resources that are relevant to effective implementation of the P01. This may include statements about 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.

7. **Organization and Administrative Structure:** Several kinds of information are required in this section:
   - Describe in detail, and by diagram, the chain of authority for decision making and administration, beginning at the level of the Principal Investigator. Include investigators responsible for individual components (project leaders) and how the projects are planned, coordinated, and evaluated. If internal or external advisory groups are to be used, list the membership and describe the role of each.
   - List in a separate table all paid and unpaid consultants and their institutional affiliations.
   - Describe relationships between the P01 and other research, academic, and administrative units of the institution (such as centers, institutes, departments), and the central administration.

8. **Literature Cited:** List complete literature citations at the end of the program narrative. Each should include names of all authors, full title, name of book or journal, volume, pages and year of publication.

G. Individual Research Projects (Research Plan, Instructions for PHS 398, Part I, Section I-C7)

Describe each project **in sufficient detail to enable reviewers to judge the scientific merit**

based on information in the application. Be explicit enough to enable experts in other areas to follow the main objective of the project. All projects are to have a single theme, project leader, and budget. 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.

1. Title Page (PHS 398 Continuation Page). Clearly denote the project number, the title of the project, the project leader's name, and educational degrees.

2. Description/List of Key Personnel (PHS 398 Form Page 2a and b). The title of "Principal Investigator" is reserved for the director of the overall application. The directors of individual projects should be referred to as "project leaders" and directors of cores should be referred to as "core directors."

3. Omit the PHS 398 Table of Contents form.

4. Detailed Budget (PHS 398 Form Pages 4 and 5; Instructions for PHS 398). A detailed budget is required for the first year and a budget summary for the future years. The budget justifications should be explicit, including those for any increases or changes for future years.

   In the upper left–hand corner of the initial year and total budget forms, identify the project or core. The PHS 398 Instructions (Sections 1-C4 and 1-C5) should be followed closely in preparing the budgets for individual projects and cores. 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 core and the name of the subcontractual institution. They should be placed in the application in sequence after the main budget pages for the project or core.

5. Biographical Sketches and Other Support are grouped elsewhere in the application (see section V. E. of this guide).

6. Resources (PHS 398 Resources Format Page). Follow the instructions on the PHS 398 Resources Format Page. List only those resources specific to the individual project or core.

7. Research Plan: (PHS 398 Continuation Page; Instructions for PHS 398, Part 1, Section I-C7 items a–d). Do not exceed 25 pages for items a–d. All tables, graphs, figures, diagrams, and charts must be included within the 25-page limit.

   a. Specific Aims. One page is recommended.
   b. Background and Significance. Two to three pages are recommended.
   c. Preliminary Studies/Progress Report. Six to eight pages are recommended.

      A progress report must be provided for competing renewal applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application's specific aims and their status relative to completion. Discuss any changes in the specific aims as a result of budget reductions or outcome of research results. Discuss the importance of the findings.

Include the complete references to appropriate publications and manuscripts accepted for publication (This last item is not part of the page limitations).

For resubmitted/amended applications, inclusion of progress attained since the previous submission is appropriate.

d. Research Design and Methods. Limited by the 25 page maximum for items a–d.

The following specific categories of information are not part of the 25-page maximum but, nevertheless, should be written succinctly:

8. Human Subjects Research (PHS 398 Continuation Pages; Instructions for PHS 398, Part 1, Section I-C7e, item e).

   For P01s that involve human subjects, applicants must address (a) the protection of human subjects from research risk, (b) the inclusion of women, minorities, and children in the study population, and (c) the plan for data and safety monitoring (for projects involving any type of clinical trials), in accordance with information provided in the ANIH Instructions to Reviewers For Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications@ (http://grants.nih.gov/grants/peer/hs_review_inst.pdf).

   For P01s that involve NIH-defined clinical research, investigators must report ethnic/racial enrollment in TABULAR form, as specified in the PHS 398 application. There must be a Data and Safety Monitoring Plan for ALL clinical trials. The Plan should be commensurate with the potential risk to subjects in the trial. All Phase III clinical trials require a full Data and Safety Monitoring Board. Deficiencies in the application with respect to these issues will be considered in evaluating the research approach, and may impact on the recommended scientific merit rating of individual projects and the overall application.

9. Vertebrate Animals (PHS 398 Continuation Pages; Instructions for PHS 398, Part 1, Section I-C7, Item f).

   NIH policy no longer requires Institutional Animal Care and Use Committee (IACUC) approval of the proposed research before NIH peer review of an application. See PHS policy section on Vertebrate Animals and http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-064.html. See also the Just-In-Time-Policy.

10. Literature Cited (PHS 398 Continuation Pages; Instructions for PHS 398, Part 1, Section I-C7, Item g). List complete literature citations at the end of each project. Each citation must include the names of all authors, full title, name of book or journal, volume, pages, and year of publication. See format example at the end of sample R01 grant application: http://www.niaid.nih.gov/ncn/grants/app/app.pdf.

11. Consortium/Contractual Arrangements (PHS 398 Continuation Pages; Instructions for PHS 398 Part 1, Section I-C7, Item h). Follow instructions in the PHS 398 form.

12. Resource Sharing (PHS 398 Continuation Pages; Instructions for PHS 398 Part I, Section IC7, Item i).

    Data Sharing Plan: Investigators seeking $500,000 or more in direct costs in any year must include a brief one-paragraph description of how final research data will be shared, or explain why data sharing is not possible. Applicants are encouraged to discuss their data sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See Data-Sharing Policy or http://grants1.nih.gov/grants/policy/data_sharing/index.htm.

Sharing Model Organisms: Regardless of the amount requested, all NIH applications proposing development of new, genetically modified variants of model organisms and related resources are expected to include a specific plan for sharing these organisms or state why such sharing will be restricted or not possible. The term "model organism" includes mammalian models (such as the mouse and rat) and non-mammalian models (such as budding yeast, roundworm, Arabidopsis, fruit fly, zebrafish, frog, etc). Examples of model organisms for which sharing plans are expected when new, genetically modified organisms are developed are posted on the NIH Model Organisms for Biomedical Research Web site: http://www.nih.gov/science/models.

13. Consultants (PHS 398 Continuation Pages; Instructions for PHS 398, Item j). List consultants specific to this project but external to the P01. For each consultant, include within the application a letter of support detailing the nature and extent of participation.

14. Do not include a checklist for each project. For multi-institutional projects, summarize checklist information on one checklist page with components indicated.

15. If a Personnel Report is submitted with a renewal/competing continuation application, the Personnel Report Forms should be identified by project/core and grouped at the end of the application.

H. Cores (PHS 398 Continuation Pages; Instructions for PHS 398)

The cores of a P01 may include laboratory and clinical facilities, equipment, and services that will be shared by two or more projects of the P01. A core may also include support for administration, such as the costs of fiscal and business management, consultant, secretarial, and clinical services associated with the P01, unless these items are included in the institution's indirect cost rate.

1. Title Page. (Form PHS 398 Continuation Page) Clearly denote the core letter, the title of the core, and the core director's name and educational degree(s). If there is to be more than one core component, prepare a separate section for each core (i.e., Core A, Core B, etc.).

2. For each core component, follow the specific instructions for the individual Research Project, Section V above. In place of Item G. 7, Research Plan, describe the role of the core component as a resource to the P01 as a whole. The core service plan should the background and rationale for the inclusion of the core. The application should present a clear description of the methods and services to be provided, how they will be prioritized if necessary, and (if appropriate) a discussion of human subjects protection and inclusion, as well as a data safety monitoring plan. Cores may contain non–hypothesis-driven research activity, provided that the research is designed to improve core services. For competing renewal applications, a progress report/summary of services in the current funding period should be provided. This may include reference to publications from the completed research effort. Clearly present the facilities, resources, and professional skills that the core component provides.

   For Administrative Cores (if included in the P01), the services to be provided may encompass such functions as fiscal management, clerical support, manuscript preparation, meeting organization, data management, and quality control and planning/evaluation. The latter may include plans to establish internal and/or external advisory committees. If an Administrative Core is not part of the P01, these issues must be discussed under "Organization and Administrative Structure" in the Program. In all cases, there should be

cross reference between the "Organization and Administrative Structure" and the "Administrative Core" so that there is complete information regarding plans about program administration and administrative cores services. (see Section V, F.7 of these Guidelines). In particular, the application should include a discussion of the decision-making processes involved in the program and the planned mechanisms for promoting communication and collaboration among program investigators. This information is relevant to the Program as an Integrated Effort.

3. To aid in the review process, it is suggested that a table showing the estimated or actual proportional use of this core component by each project be included in the application. (See Appendix C: Sample Table of Distribution of Core Resources). Justify each core component by discussing ways in which these centralized services improve quality control, produce an economy of effort, and/or save overall costs compared to their inclusion as part of each project in the program.

4. The resources (or cores) within the P01 should not duplicate any available shared core facilities available to the research group. If duplication is necessary, justification should be provided along with an explanation about why these institutional resources cannot be used for the P01 activities. For a P01 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. P01 funds can be requested to augment preexisting P30 Cancer Center or other such resources in order to direct these core support activities towards more effectively fulfilling the needs of the P01. 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.

5. For a competing renewal application, summarize core activities carried out during the preceding performance period.

I. Appendix Materials for Projects and Cores **(Procedures differ from PHS 398 Instructions)**

Do not submit appendix materials with the application. The SRA for the review will give applicants a specific deadline for submitting appendix materials and late-breaking information.

In November, 2006, the NIH published new limits on Appendix materials for all applications submitted on or after January 3, 2007. These new instructions can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-07-018.html. Each project and core in the P01 should be considered equivalent to an R01-type application for the purposes of allowable Appendix materials. An applicant has the option of submitting appendix material as paper copies or as an electronic media format or a combination thereof. If paper copies are submitted, they should be collated in sets by project or core with a cover sheet listing the contents of the collated set. The format for the appendix material can be discussed with the review SRA.

The electronic media format for the NCI P01 Appendix is a CD clearly labeled with the applicant name, application number, and sponsoring institution. All documents should be converted to PDF format. The CD should be formatted by Project and Core with a well-developed list of Bookmarks to indicate different folders and folder contents. If there are illustrations that will not be legible in the black and white copy of the application produced for reviewers by the central NIH print shop, these illustrations may be submitted as PDF attachments under the appropriate project and core. You may view the scanned image of the application to assess its completeness and quality of reproduction by logging onto the NIH eRA Commons.at https://commons.era.nih.gov/commons/.

One copy of the CD should be submitted to the SRA in a well-protected mailing container. NCI staff will make copies of the material on the CD to send to the reviewers. Therefore, the contents of the CD must not be "copy protected" in any way.

Applicants are cautioned **not** to use the Appendix to circumvent the page limitations of the Research Plan. An application that does not observe the relevant policies and procedures may be delayed in the review process.

For P01s submitted in response to an RFA, the appendix material should be submitted with the application.

VI. SPECIAL INSTRUCTIONS FOR PREPARATION OF RESUBMITTED/AMENDED APPLICATIONS

NIH allows two resubmissions/amendments (A1 and A2) of an application. There is no longer a time limit for resubmission of these applications. However, it is worth noting that a lengthy hiatus between the initial submission and resubmission may necessitate extensive modification of the research goals and research plan due to significant advances in the scientific field in the intervening period, and the relevance of the previous review critiques may be reduced. Principal Investigators and their institutions need to exercise their best judgment in determining the advisability of submitting a resubmitted/amended application after a significant amount of time has elapsed.

As described in Section III, resubmitted/amended P01 applications may include one or more projects that were in the original P01 application but which have subsequently been awarded as a separate grant(s) (i.e., an R01 grant) during the course of the resubmission process. However, all resubmitted/amended P01 applications must include at least two unfunded projects to be accepted for review. Funded projects will be discussed only in terms of the Environment and Integration of the Overall Program. The funded project(s) will be folded into the P01 award at the awarded budget levels and period of support. The application should contain signed agreements from all investigators to these stipulations.

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

A. Each time an application of greater than $500,000 in first-year direct costs is submitted for review, a **new** Letter of Intent must be sent to the NCI Referral Officer 6 weeks in advance of the submission due date. See Section V – Advance Communication with NCI Staff.

B. Acceptance of a resubmitted/amended application automatically withdraws the prior application.

C. The Table of Contents should be adjusted to include a listing for the "Introduction to the Resubmitted/Amended Application" before the Program Narrative. Similarly, add an "Introduction to the Resubmitted/Amended Application" should be inserted before the Research Plan for the individual projects and cores.

1. The "Introduction to the Resubmitted/Amended Application" section for the overall program should not exceed 3 pages and should provide a general summary of the additions, deletions, and changes that have been made for the overall program.

2. In each project and core, preceding the Research Plan, provide an introduction that delineates in greater detail the changes made in the research plan. This new section should not exceed 3 pages for the individual component.

D. Incorporate in the Progress Report/Preliminary Results a discussion of any work done since the previous review.

E. Throughout the application text, 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 left 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 because of reproduction of the application and page limits. The application should be assessed for completeness of text updating, correctness of figure labeling, and other editorial details.

VII. SPECIAL INSTRUCTIONS for REVISION/COMPETING SUPPLEMENTAL APPLICATIONS

Requests for supplemental funds may be submitted only for grants with at least 2 years of support remaining in the current award. Conversely, a revision/supplemental application is not accepted before the original application is awarded funding. The request for supplemental funds needs to have a well-founded basis: unexpected costs and/or pursuance of an unanticipated scientific opportunity; continuation of a currently funded project/core; or inclusion of a new project/core relevant to the goals of the funded program. It should contain sufficient detail to permit an adequate evaluation of the requested expansion of the overall P01. A revision/supplemental application will not be accepted if (a) it is to restore administrative cuts or (b) it does not fit within the theme of the existing P01 or extend the program's scope.

If the request for supplemental funds exceeds $500,000, applicants must obtain approval from the NCI by sending a letter of intent to the NCI Referral Office at least 6 weeks prior to the anticipated submission date. Consultation with the program director of the original application may precede the submission of a revised/competing supplement application. (See Section IV – Advance Communication with NCI Staff.)

All the information requested in these Guidelines (Section V above) should be included in the application, but adjusted to the requirements of the supplement as follows:

A. Face Page (PHS 398 Form Page 1; Instructions for PHS 398, Part 1, Section I-C1)

Type "PROGRAM PROJECT" in the top left–hand corner of the face page immediately above the words "GRANT APPLICATION." Complete all items on the face page of the application as in a traditional research grant application. This is page 1 of the application; all succeeding pages should be numbered consecutively. The Principal Investigator of the funded P01 must be the Principal Investigator for the revised/supplemental application. The Title should include the grant number of the parent grant.

B. Description, Performance Sites and Key Personnel (PHS 398 Form Pages 2 and Form Page 2-continued; Instructions for PHS 398, Part 1. Section I-C2)

The Description should state very concisely the overall goals of the entire P01. Emphasis should be placed on the purpose and contribution that the proposed studies, services, or equipment/facilities will make to the overall theme and goals. Under Performance Sites, list the applicant institution and all other sites where work described in the research plan will be conducted. Key personnel for the entire P01, including consultants and consortium collaborators, if any, should be listed alphabetically. Investigators added specifically for the supplemental funds request should be identified by an asterisk (*) with annotation.

C. Table of Contents (PHS 398 Research Grant Table of Contents Form Page 3; Instructions for

PHS 398, Section I-C3) Follow the Table of Contents as instructed in the PHS 398 and construct the format as needed to reflect the complexity of the revision/supplemental application.

D. Detailed Budget Request Initial Budget Period (PHS 398 Form Page 5; Instructions for PHS 398, Section 1-C4)

The PHS 398 Instructions (Part 1, Sections 1-C4 and 1) should be followed closely in preparing a detailed composite budget for all requested support for the first year and subsequent years of the requested supplemental funding. 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: Budget for Entire Proposed Period of Support of the PHS 398 application. If the supplemental funds request is related to more than one project or core, each component should have separate budget requests and justifications. These secondary budgets should be associated with the specific component.

Immediately after the supplemental funds budget summary tables and justifications, present a detailed composite budget table for all years of the current P01 award (Form Page 5). Label the composite budget table page in the upper left hand corner: CURRENT PROGRAM BUDGET.

F. Biographical Sketch and Other Research Support Information (PHS 398 Biographical Sketch Format Page; Instructions for PHS 398, Part 1, Section I-C6) Follow the instructions on the "Biographical Sketch Format Page." Biographical sketches are required only for the P01 Principal Investigator and for individuals whose efforts are newly included in the request for supplemental funds. In arranging the biographical sketches, the Principal Investigator should be listed first, with other personnel in alphabetical order. Each biosketch may not exceed four pages and should be prepared according to PHS 398 instructions.

G. Program Narrative: Overall Program Project (PHS 398 Continuation Pages)

The program narrative for a request for revision/supplemental funds application should summarize briefly the overall theme and research goals of the funded program; provide justification for requesting additional supplemental funds; and summarize the progress made in each funded project and core including numbers of publications and identification of completed aims. Typically, four or five pages are sufficient for the Overall Narrative.

H. Format for the Research Plan

Requests for supplemental funds can be for a new project or core, continuation of a currently funded project/core, an opportunity to follow a new research lead, provision of additional core support, or special equipment to achieve certain program goals. The format for the Research Plan will vary depending on the purpose of the request for revision/supplemental funding.

For each application, a one-page introduction should be inserted at the beginning of the Research Plan that describes the nature of the request; the relevance of the newly proposed research/new resources to the entire P01; and how the funds will influence the specific aims, research design, and methods of the current grant.

1. Request for new or continuing project/core. The Revision/Competing Supplement application format should follow the instructions as described for a project or core for a new P01 application (See Section V.G.1 or Section V.H.1). Note: A separate Description page describing the project or core is not needed. Instead, the Introduction should provide the information normally provided in the Description. If a new research project is proposed or if funds are sought for continuation of a currently funded project, the research plan should

include rationale for how the new/continuing project will augment the funded program. The body of the application should contain sufficient information from the original grant application to allow evaluation of the proposed new or extended project in relation to the goals of the original application. Biographical Sketches and Other Support should be included only for newly added personnel.

If the request is for continuation of a project or core funded for a period less than the overall program, it is important that those factors contributing to the recommendation for a reduced funding period are addressed. Progress reports and key preliminary data should be provided, as well as justification for the time extension.

2. Additional funds for existing project/core. Special requests for unique opportunity or additional resources should include a clear justification for the request based on recent research findings. Requests for funds to purchase equipment to support research effort should also include verification of the requested cost.

3. If the revision/supplemental application relates to a specific line of investigation presented in the original application that was not recommended for support by the previous review panel, the application must respond to the criticisms in the prior Summary Statement.

   Two copies of the application should be sent to the NCI Referral Office. The original document and three copies should be sent to the Center for Scientific Review. Appendix material should not be submitted with the application; the SRA for the review will provide a specific deadline for submission of appendix materials.

VIII. APPLICATION SUBMISSION PROCESS

A. Receipt deadlines and review schedules for all P01 applications submitted to the NCI, including all new, competing renewal, resubmitted/amended, and revised/supplemental applications, 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 program. Please note that the NCI Executive Committee has reaffirmed that applicants must submit competing renewal applications only on the originally scheduled submission date (ordinarily 9 months prior to the end date of the award), to ensure applications are considered for funding with their proper cohort and to conserve NCI staff resources. Therefore, the Division of Extramural Activities will defer to the appropriate later round(s), the review of all renewal applications submitted prematurely.

Advance Communication with NCI Referral Office*	Receipt Date for Applications	Initial Review**	NCAB Review	Earliest Possible Start Date
December 10	January 25	May/June	September	December 1
April 10	May 25	September/October	February	April 1
August 10	September 25	January/February	June	July 1

*Applicants must obtain approval from the NCI by sending a Letter of Intent to the NCI Referral Office, if the application has a requested budget in excess of $500,000 direct costs in any year. This notification must be repeated each time the application is submitted or if the application is delayed to a subsequent review cycle.
**Requests For Applications announcements for P01s may prescribe different Letter of Intent, receipt, and review dates.

B. Mail the original and three 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 SECTIONS OF THE APPLICATION SEPARATELY since this will cause problems with processing the application in the CSR. Use rubber bands or string to package an individual application. Applications must be sent by U.S. mail or by commercial carrier. Personally delivered packages will not be accepted by the CSR mailroom.

C. In addition, send two complete copies under separate cover to:

Referral Officer
Division of Extramural Activities
National Cancer Institute
6116 Executive Blvd., Room 8114
BETHESDA, MD 20892-8329
Rockville, MD 20852 (for courier delivery)
301-496-3428
301-402-0275 (FAX)
ncirefof@dea.nci.nih.gov

It is to the advantage of the applicant to be certain that the Referral Office copies are submitted separately. This allows NCI staff to direct early attention to such issues as review scheduling and avoidance of conflict of interest in the review.

D. **Do NOT send appendix material with the application**. The SRA will provide a deadline for submission of appendix materials. (See Section V.I of these Guidelines.)

E. For applications submitted in response to a specific Request for Applications (RFA), the RFA label available in the 5/01 revision of Application Form 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. **NOTE:** RFAs may have specific formatting instructions, application due dates, or eligibility requirements which supersede these Guidelines.

IX. REVIEW PROCEDURES

A. Policies

The SRA 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 SRA provides guidance and direction with respect to review procedures and criteria; the need for a well-documented review; 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. The NCI program director serves as a resource, as needed, concerning the history and development of the program, changes in program direction, and other relevant program 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, which is responsible for managing the peer review of NCI P01 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 shall be in all particulars consistent with, and subject to, NIH and PHS peer review practices and policies.
- Review staff members are responsible for managing the scientific and technical review of P01 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 extramural program staff members are the appropriate contact. From submission of the application until the initial peer review has been completed and the application scored, all contacts should be made through the SRA. Following the peer review and assignment of the priority score, program staff members again become the contact for communications with the applicant.
- Efforts are made to avoid both the fact and appearance of conflict of interest in obtaining advice concerning P01 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 integrity of the peer review process in its focus on scientific merit, current pay lines and funding policies are not discussed.

B. Application Receipt and Referral

Program Project applications, like all other PHS grant applications, are received and initially processed by the NIH Center for Scientific Review (CSR). Following the current National Cancer Institute referral guidelines, the application is assigned to NCI. The NCI referral office subsequently assigns the application to a program area. Finally, RPRB review staff assign the application to a particular cluster SEP SRA who manages the review. Applications that do not meet the referral guidelines for NCI programs are referred to another NIH institute.

C. Application Administrative Review

Upon receipt, the SRA reviews the application for conformance to NIH policies and NCI Guidelines. If the deficiencies can be resolved easily post-submission, then the Principal Investigator is notified and remedial action is taken. If the deficiencies are extensive or cannot be resolved quickly, the application will be returned to the applicant without further consideration.

D. Review Format

Beginning with applications submitted for the February 1, 2006, receipt date, the NCI is undertaking a pilot study of reviewing P01 applications in large clusters (up to 10 applications) in a one-tier, "paper only" review process. Teleconferences with applicants will not be conducted. Thus, the success or failure of an application will depend on how well the application text conveys the intent, merit, and impact of the proposed research. Applications must be complete as submitted so that they can be reviewed without communication between the applicant and review groups.

During the pilot study period, all review panels will be constituted as Special Emphasis Panels. The SEP reviewers will evaluate and score projects and cores, and assign the overall priority score to each application.

Each SEP will review up to 10 applications in a general research area. Applications will be grouped based on commonality of scientific research areas and general technical approaches. New, competing renewal, resubmitted/amended and revision/supplemental applications will, therefore, be reviewed together. P01 SEP Review Group Descriptions are in Appendix D. Applications will be assessed according to a standard of P01 quality as defined in the P01 review criteria.

The SEP membership will include senior investigators who can view the proposed science in a global perspective, specialists for specific scientific areas, and members of the three NCI P01 chartered review committees. Key members of the previous review panel will be included for continuity of review of the resubmitted/amended applications. In organizing the review panel membership, conflicts of interest, either real or perceived, will be avoided.

The SEP meeting date will be determined by the NCI SRA according to the availability of suitable Chairpersons and senior investigators. Applicants will be asked to provide a cell phone number and/or e-mail address so that they can be reached in the rare instance that a critical question must be addressed for the review to proceed.

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 SRA will provide an introductory orientation on NIH and NCI review policies and procedures and administrative and logistical matters relating to the review. Then, each application will be evaluated by the reviewers. The reviewers will have the option to streamline the review and unscore applications with low merit. For applications that are discussed fully, the reviewers will discuss and rate each project and core component, then discuss the overall program. The review panel will assign the final overall priority score to the application.

NCI SRAs will prepare the summary statement using the minimally edited reviewers' comments and summaries of discussion prepared by selected SEP members and/or the SRA.

E. Communications with the Principal Investigator

The SRA will contact the Principal Investigator to obtain background information relevant to the application and names of investigators in collaboration with the members of the applicant group and other investigators who may be in conflict with the group, and to request the number of collated copies of appendix materials required for the review. The SRA also may contact the Principal Investigator to discuss the specific disciplines or specialty areas of expertise that the PI feels are required to review the application properly. However, **NIH policy prohibits either the SRA or the program director assigned to the application from asking for or receiving names of potential reviewers from any member of the applicant group either directly or indirectly.**

Full consideration is given to valid reasons presented by the Principal Investigator requesting that a particular reviewer not be invited, but the final decision rests with the SRA responsible for the review. The Principal Investigator should discuss these issues fully with co-investigators before communicating this information to the SRA.

The SRA will provide a deadline for receipt of appendix materials and any supplemental data obtained after submission of the application. This deadline generally will be 5 to 6 weeks prior to the review so that all materials related to the application(s) can be sent as one mailing to the reviewers. Major changes in scope of the projects or cores cannot be accepted after submission of the application; submission of such information in the appendix may result in deferral of review.

Brief updates may also be sent electronically to the SRA up to 1 week before the review meeting. The SRA will forward these electronic updates to the reviewers for incorporation into their critiques and have printed copies of the information available at the review meeting.

F. Communications with NCI Staff

Shortly after receipt of the application, the SRA contacts appropriate NCI program staff and other individuals for supplemental information and recommendations for prospective reviewers where appropriate. Program and/or grants management staff members discuss with the SRA any unusual features of the application which might require additional material for reviewers, or any special problems that they anticipate in the review of the application. All review-related communications with actual or potential reviewers are through the SRA.

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 SRA to make these determinations based upon thorough review of the applications and consultation with program and review staff. In identifying prospective qualified reviewers, the SRA 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 SRA, as well as program staff, will identify reviewers who, because of collaboration, affiliation, or bias, should be excluded from the review. **As noted above, applicants are prohibited from suggesting names of prospective reviewers.** However, applicants may suggest expertise areas appropriate for inclusion in the review panel. Resubmitted/amended applications will have a core of membership from the previous review but there also will be new reviewers assigned to the application.

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 broad scientific areas to be reviewed. Each application will have an assigned Discussion Leader who has the responsibility of coordinating the discussion of that application. The review panel membership will reflect a balance in terms of experience, expertise, and specialty so as to afford peer review of the separate components as well as the overall P01s in the cluster. A consultant experienced in management and fiscal administration may be included if applications with complex consortium arrangements are to be reviewed. For applications including clinical or population-based studies, a patient advocate/consumer will be included in the review group. These individuals, who have full scoring privileges, will address 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.

X. REVIEW CRITERIA

Peer review emphasizes a synthesis of two major aspects of the P01 application: (1) review of the merit of each of the individual research projects and core components compared to a standard of quality in a related, broad, scientific discipline, and (2) review of the overall program as an integrated research effort focused on a central theme.

The review criteria for both the overall program and the individual projects are the standard NIH review criteria of Significance, Approach, Innovation, Investigators, and Environment (NIH Guide, Vol. 26, Num. 22, June 27, 1997 [http://grants1.nih.gov/grants/guide/notice-files/not97-010.html]).

The sections below give more detail about how these five criteria are applied to the overall program and the individual projects.

The goals of NIH supported research are to advance the understanding of biological systems, to improve the control of disease, and to enhance health status. In their written critiques, reviewers will be asked to comment on each of the criteria presented below in order to assess the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them 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 and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

A. Review Criteria for the Overall Program

- **Significance:** The potential of the overall program to advance knowledge in one or more broad scientific areas or fields.
- **Approach:** The overall adequacy and quality of the experimental approaches proposed in the projects, the adequacy of services provided by the cores, and the overall design of the P01.
- **Innovation:** The degree to which the overall program applies novel concepts and innovative approaches.
- **Investigators:** The qualifications of the Principal Investigator and other senior scientists to lead the P01 scientifically and coordinate all P01 activities, including:
    - The demonstrated ability of the Principal Investigator to provide effective scientific and administrative leadership, as demonstrated by selection of individual projects for scientific excellence and thematic relatedness and by promotion of effective interactions and collaborations. Although the scientific merit of the P01 is based on the overall quality of scored and rated projects and cores, any components Not Recommended for Further Consideration (NRFC) are considered in the peer review evaluation of the Principal Investigator's leadership and program administration skills.
    - The adequacy of the commitment (person months) of the Principal Investigator to the P01. There should be a specific commitment to both the scientific and administrative aspects of the P01. Though a common practice, it is not mandatory that the Principal Investigator be a project or core leader..
- **Environment:** Scientific, organizational, and administrative environment.
- **Integration:** Scientific and administrative integration of the P01, including:
    - Evidence of coordination, interrelationships, and synergy among the meritorious research projects and core components as related to the common theme of the P01.
    - The advantages or value added that could be realized by conducting the proposed research as a P01 rather than through separate research efforts.
    - The presence and quality of mechanisms for regular communication and coordination among investigators.
    - The mechanisms for quality control of the research (e.g., internal or external advisory committees).
    - For competing renewal applications, evidence of productive collaborations, such as joint publications, resulting from the P01 award.

B. Review Criteria for Projects

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- **Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

  As part of the assessment of research approach, the review group also will evaluate the involvement of human/animal subjects, the proposed plans for inclusion of minorities and members of both sexes/genders. The evaluation will be factored into the overall score for scientific and technical merit of the application.
- **Innovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area?
- **Investigators**: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the project leader and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
- **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

Projects may be "Not Recommended for Further Consideration@ (NRFC) based on seriously flawed research approach or on inclusion of research hazardous to human subjects.

(NOTE: Synergy and thematic relatedness between the projects and cores, and their significance for the program as a whole, are not discussed when rating individual projects. These characteristics are discussed and rated under the Integration review criterion when evaluating the Overall Program.)

C. Additional Review Criteria for Projects involving Human Subjects

1. Protection of Human Subjects: In conducting peer review for scientific and technical merit, the review group also will evaluate the involvement of human subjects and proposed protections from research risk relating to their participation in the proposed nonexempt research plan according to the following four review criteria: (1) Risk to subjects, (2) Adequacy of protection against risks, (3) Potential benefits of the proposed research to the subjects and others, (4) importance of the knowledge to be gained; and (5) Data and safety monitoring for clinical trials.

   For P01s that involve human subjects, reviewers will examine (a) whether the applicant has adequately addressed the protection of human subjects and (b) whether the involvement of minorities and children and the gender characteristics of the study population are scientifically acceptable and consistent with the aims of the project. Deficiencies in the application with respect to these issues will be considered in assessing merit of the research approach, and may impact on the recommended scientific merit rating of individual projects.

If human subjects are involved, applicants should consult the instructions in the PHS 398 package as well as the online: "NIH Policy and Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research" (http://grants.nih.gov/grants/funding/phs398/section_1.html) (http://grants.nih.gov/grants/funding/women_min/women_min.htm).

For P01s that involve NIH-defined clinical research, investigators must report ethnic/racial enrollment in tabular form, as specified in the PHS 398 application. For those projects that involve clinical trials, investigators must include a general description of the Data and Safety Monitoring Plan in the application. (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html)

2. Inclusion of Women, Minorities and Children: When human subjects are involved in the proposed clinical research, the review group will also evaluate the proposed plans for inclusion of minorities and members of both sexes/genders, as well as the inclusion of children in clinical research, as part of the scientific assessment of Approach criterion.

D. Additional Review Criteria for Inclusion of Vertebrate Animals

As part of the peer review process, the review panel will evaluate the proposed involvement and protection of vertebrate animals as part of the scientific assessment of Approach and Environment criteria and according to the following five points: 1) Detailed description of the proposed use of the animals; 2) Justification for the use of animals and for the appropriateness of the species and numbers proposed; 3) Adequacy of proposed veterinary care: 4) Procedures for limiting pain and distress to that which is unavoidable; and 5) Methods of euthanasia.

E. Review Criteria For Core(s)

- The utility of the core to the P01. Each core must provide essential facilities or services for two or more projects judged to have substantial merit.
- The quality of the facilities or services provided by this core (including procedures, techniques, and criteria for prioritization).
- The qualifications, experience, and commitment of the personnel involved in this core.
- The cost effectiveness of the core services.
- When appropriate, adequacy of the proposed plan to augment and/or complement an existing shared resource supported by an NCI Cancer Center Support Grant (P30).
- For an administrative core: The quality of administrative resources, the decisionmaking process for the allocation of resources and funds, and the plans for the evaluation of progress.
- Although advisory boards are not required, if they are proposed, there should be plans for meeting with them and procedures for using recommendations resulting from the meetings.

Cores may be "Not Recommended for Further Consideration@ (NRFC) based on seriously flawed research approach or on inclusion of research hazardous to human subjects or if they do not serve two or more projects or lack sufficient evidence of technical expertise and experienced leadership.

F. Additional Criteria for Competing Renewal Applications

- The progress and achievements specific to this P01 since the previous competitive review. Both continuing and discontinued projects and cores should be assessed.

- Evidence that scientific synergy has occurred as indicated by joint publications and new collaborative aims and/or projects.
- Evidence that the previous specific aims have been accomplished and that the new research goals are logical extensions.
- The previous performance and cost-effectiveness of the core(s).
- The justification for adding new projects or cores or deleting previous components.

G. Additional Criterion for Resubmitted/Amended Applications

Resubmitted/amended applications should be assessed based on the overall merit of the application as now presented. A resubmitted/amended application may be improved, the same as, or worse than the previous application.

H. Scoring

Projects are scored numerically, from 1.0 (highest merit) to 5.0 (least merit), or are not recommended for further consideration (NRFC). Cores are rated Superior, Satisfactory, or NRFC. Program Integration is rated Highly Integrated, Integrated, or Not Integrated.

Reviewers will consider all of the review criteria for Overall Program in assigning a single score for the application as a whole. Reviewers will focus on the meritorious projects and cores of the program, excluding any components not recommended for further consideration, in assigning the final overall score. However, components that are of poor quality or are not related to the main theme of the P01 will be considered evidence of poor judgment by the Principal Investigator and a deficiency in the coordination of the overall program administration. Reviewers do not have the option to select only the better components of the program to improve the overall score.

Following discussion of the Overall Program, each SEP member will privately assign a score for the application. The Overall Program may be scored numerically from 1.0 to 5.0 if it is fully discussed, unscored if the review panel judges that it has very low merit relative to all P01 applications normally received by the NCI and streamlines the discussion of the application, or not recommended for further consideration if it does not have three scored projects or posses very serious risks to human subjects.

XI. SUMMARY STATEMENT

The findings and recommendations of the reviewers are summarized in a written report called the summary statement that accurately conveys the evaluation of the P01 application. The summary statement for applications discussed fully during the review meeting will include a Resume and Summary of Discussion, an Overall Critique addressing the strengths and weaknesses of the Overall Program and summary paragraphs addressing the strengths and weaknesses of each project and core, and the essentially unedited critiques from reviewers assigned to each project and core. The individual reviewers' critiques, which were prepared prior to the review meeting, may not be updated to reflect their final opinions after the discussion.

For "unscored" applications that were not fully discussed during the meeting, the summary statement may not include a Resume and Summary of Discussion and/or Overall Critique section, but it will include the individual reviewers' essentially unedited critiques for all projects and cores.

The summary statement will be transmitted to the NCAB for advisory review, to the NCI official file and to the appropriate NCI staff. The applicant65 can access the summary statement through the NIH Commons shortly after it has been released by NCI review staff.

XII. AWARD

The award and administration of P01s 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 P01 be funded as part of the P01 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 P01s that are judged by peer review to be less meritorious and/or nonessential to the conduct of the P01.

XIII. QUESTIONS

Questions related to NCI P01 review may be directed to:

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Research Programs Review Branch
Division of Extramural Activities
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APPENDIX A

SAMPLE TABLE OF CONTENTS

SECTION I

Face Page
Description, Performance Sites, and Personnel
Table of Contents
Detailed Summary Budget for Program Project Initial Budget Period
Budget for Entire Proposed Program Project Period Direct Costs Only
Biographical Sketches

SECTION II

Overall Program Project
- Goals
- Theme of the Program Project
- Research Plan
- Progress Report/Preliminary Studies
- Institutional Environment and Resources
- Organization and Administrative Structure
- Literature Cited with complete titles and authors

Individual Research Project 1
- Title Page (Title, Project Leader, Degree)
- Description of Research Plan, Performance Sites, and Key Personnel
- Detailed Budget for First 12-Month Period
- Budget Estimate for Each Year of Requested Support Resources
- Resources and Environment
- 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
  - A. Specific Aims
  - B. Background and Significance
  - C. Preliminary Studies/Progress Report
  - D. Research Design and Methods
  - E. Human Subjects
    - Decision Table for Human Subjects Research, Protection and the Inclusion of Women, Minorities, and Children
  - F. Vertebrate Animals
  - G. Literature Cited
  - H. Consortium/Contractual Arrangements
  - I. Resource Sharing
  - J. Consultants/Collaborators

Core Component A

Title Page (Title, Core Director, Degree)
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
Core Services Plan

A. Specific Aims
B. Background and Significance
C. Progress Report/Summary of Services in Current Funding Period
D. Methods and Services to be Provided
E. Human Subjects
   Decision Table for Human Subjects Research,
   Protection and Inclusion of Women, Minorities, and Children
F. Vertebrate Animals
G. Literature Cited
H. Consortium/Contractual Arrangements
I. Consultants/Collaborators

Checklist

APPENDIX B

(SAMPLE TABLE)
DISTRIBUTION OF PROFESSIONAL EFFORT (%)
ON THIS APPLICATION

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)
PERCENTAGE DISTRIBUTION OF SCIENTIFIC CORE
RESEARCH RESOURCES TO PROJECTS

Project	Project 1	Project 2	Project 3	Project 4	Project 5	Total (100%)
Core A: Bioinformatics	20		40	40		100
Core B: Animal Maintenance	50			50		100
Core C: Administration		30	40		30	100

APPENDIX D
SPECIAL EMPHASIS PANELS (SEPs) FOR PILOT OF SINGLE-TIER REVIEW OF NCI P01s

MOLECULAR BIOLOGY SEP
- Biological, viral, physical, and chemical carcinogenesis;
- DNA replication, damage, and repair;
- Basic studies of radiation biology;
- Gene expression and regulation;
- Molecular genetics;
- Structural biology;
- Cell cycle and signaling pathways; and
- Cellular immortalization, senescence, and death pathways.

CELLULAR AND TISSUE BIOLOGY SEP
- Tumor microenvironment;
- Angiogenesis;
- Tumor cell biology;
- Basic mechanisms of tumor progression, invasion, and metastasis;
- Cellular differentiation, hematopoiesis and stem cell biology;
- Cellular and tissue organization;
- Basic studies of immune mechanisms and vaccine development, and
- Viral and microbial-host interactions.

PREVENTION, CONTROL AND POPULATION SCIENCES SEP
- Population-based studies in the areas of cancer prevention and control;
- Cancer epidemiology, risk analysis, genetic and environmental factors;
- Health services, delivery and outcomes;
- Surveillance;
- Geographic information systems, modeling and cancer trends;
- Nutrition, diet, and energy balance;
- Cancer survivorship and quality of life;
- Behavioral interventions; and
- Health informatics and cancer communications.

DISCOVERY AND DEVELOPMENT SEP
- Clinical validation of biomarkers for risk, early detection, diagnostic, prognosis, and progression;
- Discovery, development, and delivery of new therapeutics through phase 0 studies;
- Validation of novel preclinical models for anticancer drug evaluation;
- Basic, applied, preclinical, and clinical aspects of medical imaging systems and related technologies; and
- Technology development including diagnostics, genomics, proteomics, and bioinformatics.

CLINICAL STUDIES SEP
- Immunotherapy and vaccines,
- Cellular transplantation;
- Chemotherapy including chemoprevention;
- Gene therapy;
- Radiotherapy including hyperthermia and photodynamic therapy;
- Molecularly targeted therapy and
- Surgery