GUIDELINES
FOR
NATIONAL CANCER INSTITUTE
PROGRAM PROJECT (P01) GRANTS

March 2013

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FOREWORD

Program Project (P01) grants constitute one of the major extramural research portfolios of the National Cancer Institute (NCI). The NCI has found P01 grants to be particularly effective and highly productive in research areas where interdisciplinary collaboration and specialized shared resource cores are needed to achieve a larger objective than can be supported through the traditional single project (R01) research grant. These Guidelines for NCI P01 Grants are intended as a resource on NCI policies and review procedures for prospective P01 applicants and for reviewers of NCI P01 applications. These Guidelines also contain instructions for preparing and submitting a P01 application to the NCI which supplement the instructions in the PHS 398 form for applications for a Public Health Service Grant (see http://grants1.nih.gov/grants/funding/phs398/phs398.html), since the instructions in the PHS 398 form relate primarily to preparing single project R01 applications.

ALL NCI P01 APPLICATIONS MUST BE SUBMITTED UNDER NIH FUNDING OPPORTUNITY ANNOUNCEMENT PAR-12-005, National Cancer Institute Program Project (P01) Applications (*http://grants.nih.gov/grants/guide/pa-files/PAR-12-005.html*) . Applications not prepared using the current version of the PHS 398 application forms or not adhering to the format and preparation instructions contained in these Guidelines and the NCI P01 Funding Opportunity Announcements may be returned without review.

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. Prospective applicants should contact the NCI Referral Officer in the Division of Extramural Activities (DEA), NCI (e-mail: ncirefof@dea.nci.nih.gov or 301-496-3428) for assistance in identifying appropriate NCI program areas and program staff.

Referral Officer
Program Coordination and Referral Branch
Office of Referral, Review, and Program Coordination

Division of Extramural Activities
National Cancer Institute
6116 Executive Blvd., Room 8040, MSC 8329
BETHESDA, MD 20892-8329 (for U.S. Postal Service Express or Regular Mail)
Rockville, MD 20852 (for non-USPS delivery)
301-496-3428
301-402-0275 (FAX)
ncirefof@dea.nci.nih.gov

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 [see NIH Guide to Grants and Contracts, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html)]. The process for obtaining approval to submit a P01 application begins with submission of a letter of intent to the NCI Referral Officer at the address above (See Section IV of these Guidelines).

In addition, for renewal applications, direct cost budget requests for the first requested year must not exceed an increase of 10 percent over the direct costs awarded in the last noncompeting (Type 5) year. Details of the restrictions on budget requests are provided at http://grants.nih.gov/grants/guide/notice-files/NOT-CA-08-026.html. To determine the base for calculation of the maximum allowed increase in the first renewal year, the Principal Investigator is strongly advised to contact the NCI Program Director for the award for assistance.

Finally, NCI P01 applications must follow all relevant NIH policies regarding protection of human subjects from research risks; inclusion of women, minorities and children in clinical research; monitoring of data and safety of all clinical trials; vertebrate animals; human embryonic stem cells; and resource sharing as indicated in the PHS 398 instructions. Failure to do so may result in deferral of the review or return of the application without review.

The process for submitting a P01 application is described in detail in Section VIII of these Guidelines. **All** NCI P01 applications, including new, renewal, resubmitted, and revised applications, must be **received** on or before the dates stated in PAR-12-005. Note that these receipt dates are the same as the general NIH P01 receipt dates. The original application and three copies must be sent to the NIH Center for Scientific Review (CSR) at the address provided in the PHS 398 form. Two copies of the application must also be sent directly to the NCI Referral Office at the address shown above. All appendix material must be prepared as bookmarked PDF files following the instructions in the PHS 398 form and included in the package with the two copies sent to the NCI Referral Office by the receipt date.

NCI P01 applications will be grouped for review by Special Emphasis Panels based on scientific areas of the proposed research and the general technical approaches involved in the proposed work as well as the number of applications received.

The NIH continues to evolve policies governing all extramural awards, including NCI Program Projects. Applicants are strongly encouraged, therefore, to obtain the latest policy and procedure information as the first step in preparing a new or renewal P01 application. Updated information and the latest version of the NCI Guidelines for P01s may be obtained 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. For current grantees, information may also be obtained from your NCI Program Director.

SUMMARY OF CHANGES IN THIS REVISION OF THE NCI P01 GUIDELINES

The NCI P01 Guidelines have been updated throughout to include the latest NIH policies and internet links. This page provides only a summary of several key changes that affect may preparation, submission, and review of the applications. Detailed information is presented in the appropriate sections of these Guidelines below and in PAR-12-005, National Cancer Institute Program Project (P01) Applications.

New NIH Policy on Post-Submission Application Materials

Effective with applications submitted on or after September 25, 2010, the NIH policy on submission of application materials after the application due date has changed. This policy also applies to NCI P01 applications. Only certain types of materials, mostly resulting from unforeseen administrative changes in the program, such as loss of an investigator and natural disasters, and news of articles accepted for publication will be accepted. Supplemental data, late breaking research findings and new letters of support or collaboration not resulting from changes in personnel due to loss of an investigator will no longer be accepted. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-091.html for further details.

NCI P01 Receipt Dates

All NCI P01 applications, including new, resubmission, renewal and revision applications, will now be accepted on the standard NIH receipt dates for P01 applications. See PAR-12-005 and http://grants.nih.gov/grants/funding/submissionschedule.htm for more information.

Review Criteria

There was a minor re-wording of the Approach review criterion under Overall Impact:

Approach: Is the overall design of the P01, including strategies, methodologies and analyses, well-reasoned and appropriate to accomplish the specific aims of the program? What is the overall quality and potential influence of the component projects on the field(s) involved, and are the services provided by the shared resource cores (if proposed) adequate to support the program?

New NIH Policy on Not Recommended for Further Consideration

According to NIH policy, if any component of a P01 application is Not Recommended for Further Consideration (NRFC), the entire application will also be NRFC. A Project may be NRFC if is of such poor quality that it lacks significant and substantial merit, if it presents serious ethical problems in the protection of human subjects from research risks, or presents serious ethical problems in the use of vertebrate animals, biohazards, and/or select agents. Applications designated as NRFC do not proceed to the second level of peer review (National Cancer Advisory Board) because they cannot be funded.

NCI P01 Special Emphasis Panels (SEPs)

Appendix D, which showed topics typically grouped together for review, has been deleted, since it led to the mistaken impression that NCI has standing study sections for P01 review. Applications are grouped for review based on the broad areas of research proposed. There will typically be 8 – 10 applications per SEP, so there may be 3 to 5 SEPs per review round depending the number of applications received.

REMINDERS

Communication with the NCI Referral Office via a Letter of Intent is required at least **6 weeks** before the projected submission date for all P01 applications requesting more than $500,000 in any year 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.

The original application and three copies must be **received** by the NIH Center for Scientific Review application receipt office by the receipt date. Two copies of the application and all copies of the Appendix CD must be **received** by the NCI Referral Office by the receipt date.

I. INTRODUCTION

The Program Project (P01) grant is for support of an integrated, multi-project research program involving a number of independent investigators who share knowledge and common resources. Program Projects have a well-defined central research focus involving several disciplines or several aspects of one discipline.

The multi-project P01 application should be viewed as a confederation of interrelated research projects, each capable of standing on its own scientific merit, but complementary to others in the program such that the overall research is synergistic rather than additive. The individual projects should be interrelated such that the combined research efforts produce synergy and allow progress to occur at a greater rate and result in a greater contribution to program goals than if each project were pursued separately.

These Guidelines provide:

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

II. DEFINITIONS and IMPORTANT URLs for GRANT POLICIES

Awaiting Receipt of Application (ARA) – an internal NIH document submitted to the Receipt and Referral Office in the NIH Center for Scientific Review (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.

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

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

Multiple PD/PI - More than one Program Director/Principal Investigator (PD/PI) may be designated by the applicant organization to direct the overall program project. If the multiple PD/PI option is elected, each PD/PI must have a designated role within the P01. One of the PD/PIs must be designated as the "corresponding" or contact PI to coordinate the overall program and to communicate with NCI. The application must also include a Multiple PI Leadership Plan.

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

NCI Program Director – the NCI scientist administrator responsible both for the development of scientific initiatives and for the scientific management of research programs sponsored by the NCI. This person serves as the focal point for all science-related activities associated with the negotiation, award, and administration of grants.

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

Principal Investigator(s) – the person(s) 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 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 shared resource 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 shared resource core component of a P01.

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

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

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

Shared Resource Core – a separately budgeted component in a P01 that provides essential facilities or services to two or more of the proposed research projects.

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

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
- 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/2009guidelines.htm
- NIH Policy on Resubmission (Amended) Applications http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-140.html
- DHHS/OER Policy on Multiple Principal Investigators http://grants.nih.gov/grants/multi_pi/

III. PROGRAM PROJECT (P01) FUNDING MECHANISM

The P01 grant is for 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 project has specific objectives, aims, a fully developed research plan and a separate budget. However, each project in a P01 takes place in the broader environment of the overall program. In addition, strong interactions, including sharing of ideas, reagents and information, are expected among the projects in a P01, and shared resource cores may facilitate the work of the projects by providing efficient, centralized support services. Interactions among the projects and shared resource cores should allow acquisition of knowledge and research outcomes beyond what could be expected from the same projects conducted separately, without combined leadership and coordination. Individual investigators may apply their specialized research capabilities to basic science, clinical studies, cancer control and cancer prevention or combinations of such studies 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 ideas, concepts, personnel, facilities, equipment, and data.

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 effect on the overall evaluation. Therefore, the maximum number of research projects recommended 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.

Research projects currently funded by other mechanisms should not be included in a newly proposed program. Such projects may, however, submit a letter of agreement to collaborate with the P01 group. Applications may include projects by NIH/NCI intramural investigators. However, a budget for such projects should not be requested since funds to support the research will come from the NCI intramural budget. If a project(s) that was previously part of an awarded P01 will now be supported by another award mechanism (such as an independent R01) but will continue to collaborate with the P01 applicant group, the Overall Program Environment section of the renewal/competing continuation application should explicitly describe how that collaboration will occur. Letters of agreement to collaborate from the separately funded investigators should be included in the application.

Resubmitted/amended P01 applications may include one or more projects in the original P01 application that have been awarded subsequently as an independent grant (i.e., an R01 grant) during the course of the P01 resubmission process. However, to be accepted for review, all resubmitted P01 applications must include at least two unfunded projects. The Overall Program Environment section should explicitly indicate which project(s) have been awarded. NCI policy is that the funded project(s) will not be discussed or receive an impact/priority score during the review, but will be considered under the Overall Environment and Program as an Integrated Effort review criteria, and their inclusion will be considered as part of the overall impact/priority score for the application as a whole. In addition, 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.

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

Note that P01 applications may not include requests for funds for developmental projects (seed money) or for training.

Central to the quality of a P01 is the leadership of the Principal Investigator(s) and the other senior participating investigators. The NCI encourages P01 applicants to take advantage of the multiple PDs/PIs option (see http://grants.nih.gov/grants/multi_pi). This option allows, for example, the designation of any (or all) of the leaders of the individual projects or shared resource cores as a PD/PI of the overall application. If this option is used, one of the PDs/PIs must be identified as the "corresponding or contact PD/PI" who will be responsible for coordinating the entire program project and for official communications with NCI. NCI also expects that one of the PDs/PIs will be designated as the "Lead PD/PI" for coordinating the entire program.

All designated Principal Investigator(s) of the P01 should be established scientists with strong records of accomplishment who are substantially committed to, and exercise responsibility for, the scientific leadership, integration, and administration of the entire P01. The lead Principal Investigator need not serve as a project leader or shared resource 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. NCI does not allow multiple PIs for individual projects and cores within a P01 application. There should be one designated project leader for each project and one designated shared resource core director for each shared resource core who is responsible for overall management and coordination of the core.

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 well before the planned submission date.

Specific issues for discussion might 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;
- Tentative projects: Title, name of the project leader, and a brief summary of goals and

relationship to the central theme;

- Tentative shared resource core component(s) and how each supports the overall program;
- Budget estimates for the program. NOTE: If the budget for a competitive renewal application exceeds 110 percent of the last budget period, the application may be returned without review if NCI approval has not been obtained before submission and documented in the cover letter accompanying the application;
- The methods for communication and interaction among program participants and internal quality control;
- Other related support; and
- For competing renewal or resubmitted applications, an identification of components to be discontinued and new components that might be added to the P01.

B. Letter of Intent

PAR-12-005 shows that Letters of Intent are due one month prior to each P01 due date. However, **all applicants requesting $500,000 or more in direct costs in any one year** must obtain approval from the NCI at least **six weeks** prior to the anticipated submission date (NIH Guide to Grants and Contracts, 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.**

Although the Letter of Intent is not binding either for the planned submission date or for final detailed research content, the information provided will allow NCI program staff to process an Awaiting for Receipt of Application (ARA) request with the Division of Receipt and Referral in the NIH Center for Scientific Review. The Letter of Intent also is helpful to the review staff in the NCI Division of Extramural Activities in estimating the potential review workload, avoiding conflict of interest in the review, and planning for the number of Special Emphasis Panels that will need to be convened for the review cycle. Therefore, the Letter of Intent should include at a minimum:

- The names of the Principal Investigator(s) and key personnel;
- A descriptive title of the potential application and a list of titles for the anticipated components of the P01;
- Brief descriptions of the individual projects and cores, including whether clinical trials are proposed;
- Identification of all organization(s) involved;
- PAR Announcement to which the potential application is responding, and
- Suggested NCI Program Director (if known) or research area.

The Letter of Intent should be sent to:

Referral Officer
Program Coordination and Referral Branch
Office of Referral, Review, and Program Coordination
Division of Extramural Activities
National Cancer Institute
6116 Executive Blvd., Room 8040A
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/her a copy of the letter.

V. SPECIAL INSTRUCTIONS for PREPARATION of NCI PROGRAM PROJECT APPLICATIONS

General instructions for the preparation of a grant application are contained in the U.S. Department of Health and Human Services Public Health Service Grant Application (PHS 398) (Rev. 11/2009).

The following additional instructions are specifically for multi-project NCI Program Project P01 applications.

A. Face Page

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

Type "PROGRAM PROJECT" in the top left-hand corner of the face page immediately above the words "GRANT APPLICATION**." Check the "yes" box in Item 2 and enter PAR-12-005, "National Cancer Institute Program Project (P01) Applications" for number and title of the announcement.** Complete all other items on the face page of the application according to the PHS 398 instructions. This is page 1 of the application; all succeeding pages should be numbered consecutively.

If multiple PD/PIs are proposed, use the Face Page-Continued page to provide Items 3a – 3h for all PD/PIs. NIH requires one PD/PI be designated as the "contact PD/PI" for all communications between the PD/PIs and the agency. The contact PD/PI should be listed in block 3 of Form Page 1 (the Face Page), with all additional PD/PIs listed on Form Page 1-Continued. When inserting the name of the PD/PI in the header of each application page, use the name of the "Contact PD/PI, et.al." The contact PD/PI must be from the applicant organization if the PDs/PIs are from more than one institution.

B. Description/Project Summary, Performance Sites and Key Personnel

(PHS 398 Form Pages 2 and Form Page 2-continued; Instructions for PHS 398, Part 1. Section 4).

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

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

Under Performance Sites, list the applicant institution and all other sites where work proposed in the program will be conducted. The names of involved institutions should be spelled out in full for the first mention with the acronym in parenthesis. The acronym may be used

subsequently. The Key Personnel list for the entire P01 should begin with the contact PD/PI, followed by any other Principal Investigator(s) in alphabetical order, followed alphabetically by all project and shared resource core leaders, co-leaders, co-investigators, and consultants and consortium collaborators, whether receiving salary or not, who will provide effort and/or significant intellectual input into the proposed research. List other personnel who will be other collaborators or consultants under "Other Significant Contributors".

C. Table of Contents

Instead of using the Table of Contents page in the PHS 398 form, which is primarily for single project R01 applications, use PHS 398 Continuation Pages to prepare a Table of Contents following the format shown in Appendix A of these P01 Guidelines.

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

D. Budget for Overall Program Project

(PHS 398 Instructions (Part 1, Section 4)

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

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

Budget requests for direct costs for renewal/competing continuation P01 grant applications must not exceed an increase of 10 percent over the direct costs awarded in the last noncompeting (Type 5) year. The Principal Investigator is encouraged to contact NCI program staff for assistance in preparing requested budgets.

E. Biographical Sketch and Research Support Information

(PHS 398 Biographical Sketch Format Page; Instructions for PHS 398, Part 1, Section 4)

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

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

A. Personal statement. Briefly describe why your experience and qualifications make you particularly well-suited for your proposed role(s) in the program (e.g., PD/PI, Project Leader/Shared Resource Core Director, participating investigator).
B. Positions and Honors. List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.
C. Publications. NIH encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. Each investigator may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. Articles should be cited as described in the PHS 398 Citation format. Note that copies of publicly available publications are not acceptable as Appendix material.
D. Research Support. List both selected ongoing and completed research projects for the past three years. Follow the instructions provided in the PHS 398 document.

F. Program Overview (PHS 398 Continuation Pages)

The Program Overview section should summarize the overall research plan for the multi-project P01 application. Page limits for each section are given below.

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

   Briefly address how the changes made to the proposed program address the main weaknesses and problems noted in the previous review or why the proposed revision (supplement) is important to the overall program, as appropriate.

2. **Overall Program Goals and Specific Aims: One page limit.**

   State concisely the general scientific or medical area(s) to be studied. List succinctly the specific objectives and the goals of the program as a whole. Summarize the expected outcomes(s) of the program as a whole, including the impact that the results of the program will exert on one or more broad research fields.

3. **Overall Research Strategy: Twelve page limit.**

   Organize the overall Research Strategy Section in the specified order and using the instructions provided below. Start each section with the appropriate section heading: Overall Significance, Overall Innovation, and Overall Approach.

   a. Overall Significance

   - Explain the importance of the program, including the overarching problems or critical barriers to progress in the field that the proposed program addresses.
   - Explain how the program as a whole will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
   - Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive cancer research will be changed if the overall aims are achieved.

b. Overall Innovation

- Explain how the overall program challenges and seeks to shift current research or clinical practice paradigms.
- Summarize novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used in the projects and/or shared resource cores.
- Summarize how the program as a whole will refine, improve, or provide new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions in the field.

c. Overall Approach

- Summarize the global strategies, methodologies, and analyses that will be used to accomplish the overall specific aims and objectives of the program.
- Address potential problems, alternative strategies and benchmarks for success in achieving the aims of the overall program.
- If any of the proposed projects or shared resource cores is in the early stages of development, explain how the program as a whole will establish strategies to enhance their feasibility and manage high risk aspects of the work.

- Preliminary Studies (for New Applications)

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

- Progress Report (for Renewal and Revision Applications)

  For renewal/revision applications, summarize the major achievements of the overall P01 in the current funding period; separate more detailed progress reports are included in the individual research projects and shared resource cores. Explain any significant changes to the program during the current funding period, including changes resulting from significant budget reductions, and any new directions proposed in the new funding period.

4. **Program-Related Publications**

List all publications and accepted manuscripts which have resulted from the P01 grant. Using 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 should accompany the full reference. Copies of these publications may no longer be included as appendix material.

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

G. Program Integration and Management: Six page limit
(PHS 398 Continuation Pages).

- Provide a table or diagram showing all proposed projects and shared resource cores, and their relationship within the proposed program. For renewal and resubmission applications, include new, continuing, completed, and discontinued projects, indicating the previous number/letter of each component, as a summary of changes in the program

since the last review. Explain the decision to discontinue or substantially modify previous projects or shared resource cores and/or to propose new projects or shared resource cores, and how that affects the overall program integration and management.

- Explain how the proposed projects and cores will, together, address the overall goals and aims of the program more effectively than if the projects were done independently. Give specific examples of inter-project collaborations and/or shared resource core support in the proposed program. Address how information, reagents, personnel, equipment, etc., will be shared between the proposed projects and shared resource cores to create synergy within the program.
- Explain the plans for organizational and administrative management of the program. Describe and diagram the chain of authority for decision making and administration within the program. If internal or external advisory groups are proposed, list the membership or areas of expertise for each group, and describe the role of each group.
- Explain how coordination and communication among the different projects, shared resource cores and participating institutions will be achieved at the overall program level.
- Explain the plans and methods for monitoring and assessing progress in the research projects and effective use of the shared resource cores.

H. Letters of Support: Place all institutional and collaborative letters of support relative to the overall program after the Program Integration and Management section

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

Briefly summarize the overall institutional environment and resources that are relevant to effective implementation of the P01. This may include NCI-supported clinical and laboratory facilities, participating and affiliated units, patient population, geographic distribution of space and personnel, consultative resources, and relevant collaborations with investigators currently funded under other mechanisms. Detailed Resources for each specific project and shared resource core (if proposed) should be provided within those sections as described below in Section K. Individual Research Projects and Section L. Shared Resource Cores.

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

J. Multiple PD/PI Leadership Plan (Required if proposing Multiple PD/PIs):
(http://grants.nih.gov/grants/multi_pi) (Use PHS 398 Continuation Page)

For applications designating multiple PD/PIs, a leadership plan must be included. The rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team for the overall program should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts among the multiple PDs/PIs. The roles and administrative, technical, and scientific responsibilities of each PD/PI for the program should be delineated, including responsibilities for studies involving human subjects or live vertebrate animals, as appropriate. Within the multiple PD/PI Leadership Plan, applicants should retain the use of Project Leader and Core Director as the titles for individuals responsible for project or shared resource core leadership in order to be consistent across all NCI P01 applications.

If a budget allocation is planned, the distribution of resources to specific components of the program or individual PD/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Award.

K. Individual Research Projects

All projects are to have a single theme, a single designated project leader, and a 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. A sample Table of Contents outline for a project is included in Appendix A of these Guidelines.

1. **Title Page**

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

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

   The title of "Principal Investigator" is reserved for the Contact/Lead Principal Investigator of the overall application. The leaders of individual projects should be referred to as "Project Leaders" and leaders of shared resource cores should be referred to as "Core Directors." There may be only one Project Leader per project.

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

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

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

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

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

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

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

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

   Identify the facilities to be used for the project (laboratory, clinical, animal, computer, office, other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and

extent of access by the project. Describe only those resources that are directly applicable to the proposed work in the project. Provide information about any Other Resources available to the project (e.g., institutional machine or electrical shop or reagents, information, personnel in other projects or shared resource cores in the program) and the extent to which they will be available to the project.

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

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

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

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

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

1. Introduction to the Project (Resubmission or Revision [See Section VI of these Guidelines] applications only). Do not exceed **one page.**

2. Specific Aims. Do not exceed **one page.**

   State concisely the goals of the proposed project and summarize the expected outcomes(s), including the impact that the results of the project will exert on the research field(s) involved. List succinctly the specific objectives of the project, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address any critical barrier(s) to progress in the field, or develop new technology.

3. Research Strategy. Do not exceed **12 pages** for all parts of the Research Strategy section, including the Preliminary Studies (for New Applications) and Progress Report (for Renewal and Revision Applications).

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

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

(a) Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

(b) Innovation

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

(c) Approach

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

Preliminary Studies for New Applications. For new applications, include information on Preliminary Studies as part of the Approach section. Discuss the Project Leader's preliminary studies, data, and/or experience pertinent to the project.

Progress Report for Renewal and Revision Applications. For renewal/revision applications, provide a Progress Report as part of the Approach section. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes resulting from significant budget reductions. A list of publications, manuscripts accepted for publication, patents, and other printed materials should be included in the next section and is not included in the 12 page limit for the Research Strategy section.

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

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

Publications related to progress in the Program. List all publications and accepted manuscripts which have resulted from the research conducted during the current funding period. Using an asterisk, denote each publication that is a result of formal collaborations among different projects within the program. Copies of these documents are not to be included in the Appendix material.

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

Personnel Reports are not required for a renewal/competing continuation application.

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

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

   If clinical trials are proposed in any year, describe the plans for monitoring data and safety of the trials. A full Data and Safety Monitoring Board is required for all Phase III trials.

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

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

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

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

13. **Multiple PD/PI Leadership Plan: Not applicable for individual projects -** Multiple leaders are not allowed for individual projects. If the Multiple PD/PI option is used for the overall application, the Multiple PI Leadership Plan for the program as a whole should be included after the Overall Program Environment section as described above.

14. **Consortium/Contractual Arrangements**: Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s).

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

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

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

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

Data Sharing Plans

Sharing Model Organisms

Genome-Wide Association Studies (GWAS)

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

L. Shared Resource Cores (PHS 398 Continuation Pages)

A Program Project application may include shared resource cores that provide administrative, laboratory and/or clinical facilities, equipment, and/or services to be shared by two or more projects. Shared Resource Cores are not required for a P01. Shared resource cores may include non–hypothesis-driven research activities provided that the research is designed to improve core services.

To aid in the review process, it is suggested that a table showing the estimated or actual proportional use of shared resource cores by each project be included in the application after the table showing the distribution of professional effort within the program. (See Appendix C: Sample Table of Distribution of Core Resources). The Overall Research Strategy section and the Program Integration and Management sections of the application should justify each shared resource core component by discussing ways in which these centralized services will provide consistent, high-quality services; produce an economy of effort; and/or save overall costs compared to each project in the program performing its own tests, assays, animal derivations, clinical studies, etc.

The shared resource cores within the P01 should not duplicate any shared resource core facilities that are already available to the research group. If similar facilities are available at the applicant institution(s), the application should provide strong justification and explanation for why those 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 in the Overall Program Environment section. Similarly, if there are SPORE (P50) research support cores available, these should also be listed in the Overall Program Environment section. Funds may be requested to augment preexisting P30 Cancer Center or SPORE (P50) 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. Whenever there is dependence on Institute-wide Core Resources, a letter of agreement from the Core Manager/Director should be included.

For Administrative Cores (if included in the P01), the services to be provided may include 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. (**NOTE:** Neither an Administrative Core nor internal nor external advisory committees are required.) If an Administrative Core is proposed, there should be cross reference between the Program Integration and Management section and the Administrative Core so reviewers can easily find complete information regarding plans for program administration (see Section V, of these Guidelines). If an Administrative Core is not proposed, the Program Integration and Management section of the application should clearly delineate how the required coordination, management, communication, planning and evaluation functions will be accomplished within the program.

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

1. **Title Page**

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

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

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

3. Omit the PHS 398 Table of Contents form.

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

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

6. **Resources:** (PHS 398 Resources Format Page) Follow the instructions on the PHS 398 Resources Format Page and that given in Section K above for projects. List only those resources specific to the shared resource core.

7. **Shared Resource Core Services Plan**. **Do not exceed the specified page limits.** All tables, graphs, figures, diagrams, and charts must be included within the page limit.

   1. Introduction to the Shared resource core for resubmission (amended/revised) applications **(**Do not exceed **one page.)**

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

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

      Clearly describe the facilities, equipment, methods, services, etc., that will be provided by the shared resource core and how they meet the needs of two or more of the proposed

research projects in the program. Provide the rationale for centralizing the proposed services in the core, rather than including them in individual projects. Indicate why the shared resource core is an essential part of the program, and how provision of the proposed services will facilitate accomplishment of the proposed goals and objectives of the program as a whole. Address plans for prioritization of services (if necessary).

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

Progress Report/Summary of Services in Current Funding Period
Summarize the services provided to the projects during the Current Funding Period.

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

9. Include Items in the PHS 398 instructions Part 1 Section 5 as appropriate. The multiple PI option is not available for individual shared resource cores.

M. Appendix Materials and PDF Files of Submitted Applications

Follow the standard instructions in the PHS 398 form for limits on what may be submitted as Appendix materials for each project and shared resource core (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-07-018.html) and for preparing the Appendix materials. Each project and shared resource core in the P01 is equivalent to an R01-type application for the purposes of allowable Appendix materials.

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

Collect all Appendix Materials for each project or shared resource core into **ONE** PDF file. Use a separate file for each project or shared resource core, and name the file with the project or shared resource core number. Follow the standard instructions for preparing the CDs:

- Use PDF format only. The files should be saved as **Adobe Version 7** for compatibility with NIH programs and software.
- Where possible, applicants should avoid creating PDF files from scanned documents. NIH recommends producing the documents electronically using text or word-processing software and then converting the document to PDF format. Scanned document images should be checked for legibility.
- Label each disk with the Principal Investigator's Name, Grant Number (if available), grant title, and applicant institution.
- If burning CD-ROM disks on a Mac, select the ISO 9660 format.
- Do not use compression techniques for the electronic files.
- Do not use password protection, encryption, digital signature and/or digital certification in the PDF files.

NOTE: Paper NCI P01 applications are scanned by central NIH offices after receipt to produce black and white images and black and white double sided copies for the reviewers. Therefore, it is very important that color versions of figures in the application that do not reproduce well in black and white be included in the Appendix.

All figures included in the Appendix must be included in the application, although they may be reduced in size in the application. Images not included in the application cannot be included in the Appendix. For materials that cannot be submitted on CD (e.g., medical devices, prototypes, video tapes), applicants should contact the Scientific Review Officer for instructions.

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

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

The receipt dates for resubmission/amended applications are the same as for new and competing renewal applications (see PAR 12-005 or http://grants.nih.gov/grants/funding/submissionschedule.htm).

NIH allows only one resubmission/amendment (A1) (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html). As detailed in NOT-OD-10-140 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-140.html), the NIH will not accept a resubmission application that is submitted later than 37 months after the date of receipt ("receipt date") of the initial New, Renewal, or Revision application. Applications must be submitted for the dates listed in PAR-12-005. Normal late application policies (NOT-OD-08-027) will apply. If the initial submission (A0 version) was accepted late, the resubmission (A1 version) must be received within 37 months of the original due date, not 37 months after the extended receipt date for the initial application.

Although an A1 application may be submitted up to 37 months after the A0 version, such a lengthy hiatus between the initial submission and the resubmission may necessitate extensive modification of the research goals and research plans due to significant advances in the field in the intervening period. Principal Investigators and their institutions need to exercise their best judgment in determining the advisability of submitting a resubmitted/amended application after a significant amount of time has elapsed.

As described in Section III, a resubmitted/amended P01 may include one or more projects that were in the original P01 application which were subsequently awarded as a separate grant(s) (i.e., an R01 grant) during the course of the resubmission process. However, all resubmisssion/amended P01 applications must include at least two unfunded projects to be accepted for review. The funded project(s) 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 at least **6 weeks** in advance of the submission due date. See Section IV – Advance Communication with NCI Staff.

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

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

2. Each resubmitted project and shared resource core should include an "Introduction to the Resubmitted/Amended Application" that delineates in greater detail the changes made in that specific component of the application to address the issues raised in the previous review. The Introduction for each individual component of the P01 should be placed before the Specific Aims for that component and may not exceed **one page**. References to specific statements in the previous summary statement are not necessary.

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

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

It is important to read through the entire application before submission to ensure that all sections of the resubmitted application, including biographical sketches, Program Overview, Program Integration and Management, Overall Program Environment, project and core descriptions, specific aims, research strategy sections, literature cited, human subjects and animal sections, and budgets and budget justifications, etc., have been correctly and properly updated.

VII. SPECIAL INSTRUCTIONS for REVISION/COMPETING SUPPLEMENT APPLICATIONS

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 will not be accepted before the original application is awarded. 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/shared resource core; or inclusion of a new project/shared resource core relevant to the goals of the funded program. The application should contain sufficient information about the ongoing program activities 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; (b) it does not fit within the theme of the existing P01; or (c) it does not extend the scope of the ongoing awarded program.

The receipt dates for Revision/competing supplement applications are the same as those for full applications (see PAR-12-005).

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 NCI program director of the awarded grant is strongly encouraged before 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 4)

Complete all items on the face page of the application as described above in Section V. The contact Principal Investigator of the funded P01 must be the contact Principal Investigator for the revised/supplemental application, and the applicant organization must be the awardee institution. **The title of the supplement must be the same as the title 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. Sections 4 and 2.8)

The application Description should first state very concisely the overall goals of the ongoing P01and then emphasize the purpose and contribution that the proposed supplemental 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 (*).

C. **Table of Contents** (PHS 398 Research Grant Table of Contents Form Page 3; Instructions for PHS 398, Section I) Follow the example of the suggested Table of Contents in Appendix A of these Guidelines, and adapt the format as needed to reflect the complexity of the revision/supplemental application.

D. **Budget Request** (PHS 398 Form Pages 4 and 5; Instructions for PHS 398, Section 4)

The PHS 398 Instructions (Part 1, Sections 4. and 2.8) should be followed closely in preparing a detailed composite budget for all requested support for the initial year and subsequent years of the requested supplemental funding. Form Page 4: Detailed Budget for Initial Budget Period should be used for the initial 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 shared resource 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.

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

Follow the instructions on the “Biographical Sketch Format Page.” Biographical sketches should be provided 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 the Biographical Sketches for other personnel in alphabetical order.

F. **Program Overview: Currently Funded Program Project** (PHS 398 Continuation Pages)

The Program Overview for a request for revision/supplemental funds application should follow the organization and format described above in Section V. F, emphasizing the rationale for

adding the proposed new work, providing a strong justification for the proposed new work, and explaining how it will affect the overall theme, goals, objectives, aims, and research strategy of the ongoing program. Summarize the progress made in each funded project and shared resource core including numbers of publications and identify already completed aims. 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.

Unless the request for supplemental funds is very complex and involves several new projects and shared resource cores, the Program Overview section for a revision application should not require the full 12 pages.

G. **Program Integration and Management** (PHS 398 Continuation Pages)

Address the points indicated above in Section V.G for the currently funded program and indicate how the proposed supplemental activities will be integrated with the ongoing activities and how they will affect overall program management. Unless the request for supplemental funds is very complex and involves several new projects and shared resource cores, the Program Integration and Management section for a revision application should not require the full 6 pages.

H. **Overall Program Environment** (Resources Format Page PHS 398)

Address the points indicated above in Section V.H for the currently funded program and indicate any new resources that the proposed supplemental activities will bring to the program or resources that the supplemental activities will require from the ongoing program.

I. **Format for the Research Plan** (PHS 398 Continuation Pages)

The format for the Research Plan will vary depending on the purpose of the request for revision/supplemental funding.

For each new project or shared resource core proposed, follow the appropriate format described above in Section V.K or V.L. At the beginning of the Research Plan, insert a one-page Introduction 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.

If the request is for continuation of a project or core funded for a period less than the overall program, it is important to address those factors that contributed to the recommendation for a reduced funding period. Progress reports and key preliminary data should be provided to justify the time extension in addition to an explanation of the work that will be done in the continuation period.

If the revision application is requesting additional funds for an existing project or shared resource core, the Research Plan should include a clear justification for the request based on recent research findings in the project, new methodologies now available to the shared resource core, or the compelling need for additional core support for the program. Requests for funds to purchase equipment should also include verification of the cost of the equipment.

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 should address the criticisms noted in the prior Summary Statement.

VIII. APPLICATION SUBMISSION PROCESS

A. Application due dates are given in PAR-12-005 (http://grants.nih.gov/grants/guide/pa-files/PAR-12-005.html) and at http://grants.nih.gov/grants/funding/submissionschedule.htm. The 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 returned 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 that competing renewal applications should be submitted only on the appropriate submission date (ordinarily nine months prior to the end date of the award) to ensure that 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 review round the review of all renewal applications submitted prematurely.

Letter of Intent*	**Application Due Dates (see PAR-12-005 for specific date for each review cycle)****	**Initial Review**	**NCAB Review**	**Earliest Possible Start Date**
4 weeks before receipt date*	January	May/June	September	December 1
4 weeks before receipt date*	May	September/October	February	April 1
4 weeks before receipt date*	September	January/February	June	July 1

***NOTE: Applicants must contact the NCI Referral Office at least SIX weeks prior to the Application Due Date if the requested budget will be 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**.

**Request For Applications (RFA) announcements for P01s may prescribe different Letter of Intent, receipt, and review dates.

B. General instructions for submission of an NCI P01 Grant Application are described in the PHS 398 (Part I Section 3). Applicants are strongly encouraged to include a cover letter with the original application. The letter is only for internal agency use and will not be shared with peer reviewers. Place the cover letter at the beginning of the original application; do not copy it. The cover letter should include:

- Application title
- Funding Opportunity Announcement (FOA) number and title.
- Request of an assignment (referral) to the National Cancer Institute and review by an NCI Special Emphasis Panel.
- The research disciplines involved, if the program is multidisciplinary
- A statement indicating that NCI has approved submission of the application, if the requested budget is $500,000 or more in any year, citing the NCI referral office and the name of the NCI program officer who approved the submission.
- For late applications, a justification for why the application should be accepted after the stated receipt date. (See NOT-OD_06-086, NIH Policy on Late Submission of Grant Applications, and NOT-OD-07-026, NIH Policy on Late Submission of Grant Applications – Clarification for Multiple PI Applications and New Submission/Receipt Dates)

The cover letter may also include a SHORT list of individuals that you think could not be

objective in reviewing the application, along with compelling reasons why each should be excluded. The SRO will evaluate the request and make final decisions about reviewer recruitment.

C. Packing and submission of the application and copies.

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

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

Or

Bethesda, MD 20817 (for Express/Courier/Non-USPS delivery)

Send **two** identical, single-sided copies of the original signed application and all CDs with Appendix materials under separate cover to:

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

IX. REVIEW PROCEDURES

A. Policies

The NCI Scientific Review Officer (SRO) serves as the Designated Federal Official (DFO) with legal responsibility for managing the review and ensuring that the review is conducted according to relevant laws, regulations, policies, and established NIH and NCI policies and procedures. The SRO provides guidance and direction with respect to review policies, procedures and criteria; the functions of the NCI staff; conflict of interest policies; implications of the Privacy Act; the need for confidentiality of the proceedings; the necessity of addressing gender, minority, and children representation in clinical study populations; and other policy and logistical matters. During the review, the NCI program director serves as a resource, as needed, concerning the history and development of the P01 program, changes in program direction for resubmitted and renewal applications, and other relevant programmatic matters.

- The NCI is committed to the conduct of impartial, high-quality peer review of grant applications submitted by the scientific community and to the maintenance of an objective review process.
- The Research Programs Review Branch, Division of Extramural Activities, NCI, which is responsible for managing the peer review of NCI 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 of NCI P01 applications shall be in all particulars consistent with, and subject to, NIH and PHS peer review practices and policies.
- NCI review staff members are responsible for managing the scientific and technical review of 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, all contacts should be made through the SRO. Following the peer review, program staff members again become the contact for communications with the applicant.
- Efforts are made to avoid both real and apparent conflict of interest in review of 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 focus of the peer review process on scientific merit and potential impact of the proposed research, current pay lines and funding policies are not discussed during the review.

B. Application Receipt and Referral

Program Project applications, like all other PHS grant applications, are received and processed initially by the Division of Receipt and Referral in the NIH Center for Scientific Review (CSR). Following current referral guidelines, the application is assigned to NCI. The NCI Referral Office subsequently assigns the application to an NCI program area. Applications that do not meet the referral guidelines for NCI programs are referred to another NIH institute. Finally, RPRB review staff group the P01 applications for review based on science and the number of applications received, and recruit appropriate reviewers for each Special Emphasis Panel (SEP).

C. Application Administrative Review

Upon receipt, the SRO reviews the application for conformance to NIH policies and NCI Guidelines. Incomplete applications will be returned without review. The applicant may submit a complete application for a later receipt date.

D. Review Format

All NCI P01 applications are reviewed by SEPs. The SEP members evaluate and score projects, shared resource cores, and program integration, and assign an overall impact/priority score to each application.

Applications are grouped for review based on broad scientific research areas and general technical approaches. New, competing renewal, resubmitted/amended and revision/supplemental applications are reviewed together. There will typically be 8 – 10 applications per SEP. There may be 3 to 5 SEPs per review round, depending on the number of applications received and the diversity of the science proposed.

The SEP membership will include senior investigators who can view the proposed science from a global perspective and specialists for specific scientific areas. Key members of the previous review panel will be included for continuity of review of resubmission (amended) and revision (supplement) applications. In organizing the review panel membership, real and apparent conflicts of interest will be managed according to NIH policy (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-120.html). In general, all Key Personnel and Other Significant Contributors for the overall application who are listed on page 2 in all of the P01 of the applications submitted for the same review cycle are considered in conflict for that review cycle, since they are competing for the same pool of funds.

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

The SEP will usually convene in a face-to-face meeting in the Washington, DC, metropolitan area or elsewhere at the convenience of the reviewers. The SRO will provide an introductory orientation on NIH and NCI review policies and procedures and administrative and logistic matters relating to the review. Then, the applications will be evaluated by the reviewers. Reviewers will discuss and rate each project and shared resource core component and program integration, and then discuss the overall program. The review panel will then assign the final overall impact/priority score to the application. Applications that fall in the bottom half of P01 applications normally seen for review by NCI will receive an expedited discussion or be not discussed.

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

E. Communications with the Principal Investigator

The SRO will contact the Principal Investigator to obtain names of investigators collaborating with the members of the applicant group and who may therefore be in conflict with the application. (For applications with multiple PIs, the SRO will contact the contact PI.)

Reviewer recruitment and assignment rest with the SRO responsible for the review. Applicants may suggest types of expertise that are required to review the application properly. **However, neither the SRO nor the NCI program director assigned to the application may accept names of specific potential reviewers from any member of the applicant group either directly or indirectly. In addition, although the cover letter submitted with the application may include a SHORT list of individuals that the Principal Investigator thinks may not be able to be objective in the review, all reviewer recruitment rests with the SRO and no guarantees are made that any of the persons named will not be included in the review.**

The SRO will provide a deadline for submission of allowable post-submission materials (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-091.html). Only certain types of materials, mostly resulting from unforeseen administrative changes in the program, such as loss of an investigator and natural disasters, are allowable. News of articles accepted for publication and news of FDA approval of INDs for clinical trials will also be accepted. Supplemental data, late breaking research findings and new letters of support or collaboration not resulting from changes in personnel due to loss of an investigator will NOT be accepted.

F. Communications with NCI Staff

Shortly after receipt of the applications, the SRO contacts appropriate NCI program staff to discuss programmatic issues related to the review of submitted applications and for recommendations for prospective reviewers, where appropriate. However, The SRO will select all reviewers and all review-related communications with actual or potential reviewers must be with the SRO.

G. Selection of Reviewers

The SRO will determine the size and composition of each SEP review panel based on the particular details of the applications to be reviewed. The SRO may consult with other NCI review staff and NCI program staff, as appropriate. The review panel members are recruited based on the scientific areas, methods and approaches proposed in the applications grouped for review each review cycle. The SEPs convened for P01 review therefore change every review cycle.

The roster for each SEP will reflect the broad areas of expertise required to review all applications to be reviewed by that SEP. For applications including clinical or population-based studies, one or more patient advocates/consumers 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.

In identifying prospective qualified reviewers, the SRO takes full advantage of many available resources, including existing databases of experienced reviewers, lists of grantees and contractors, and consultation with recognized authorities in the scientific community. The SRO, as well as program staff, will identify investigators 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 to SROs and NCI program staff.** However, applicants may suggest expertise areas appropriate for inclusion on the review panel. Resubmitted/amended applications will have some of the previous reviewers, 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. The Chairperson has responsibility for ensuring that each application receives a fair discussion and that the reviewers adhere to the review criteria and the NCI P01 scoring guidelines for each component of the application as well as for the overall impact/priority score for the program as a whole. Each application will have an assigned Discussion Leader who will briefly introduce the application by summarizing the research scope, goals and objective of the proposed program and providing a brief description of each proposed project and shared resource core for the review panel. The Discussion Leader will also draft a summary of the committee discussion of the overall program.

X. REVIEW CRITERIA

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. The mission of the NCI is to conduct and support research, training, health information dissemination, and other programs with respect to the cause, diagnosis,

prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

Peer review of NCI P01 applications emphasizes a synthesis of two major aspects of the P01 application: (1) review of the potential impact of each individual research project and the quality of each shared resource core (If proposed), 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 Significance, Investigators, Approach, Innovation, and Environment (NIH Guide Notice **NOT-OD-09-025,** December 2, 2008 – see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-025.html). Program as an Integrated Effort is also a review criterion for the overall program. The sections below give more detail about how these review criteria are applied to the overall program and to the individual projects. The review criteria for shared resource cores are also listed below.

A. Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood that the program as a whole will exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria listed in section X.E below (as applicable). An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a program that by its nature is not innovative may be essential to advance a field.

- **Significance:** Does the program as a whole address an important problem or a critical barrier to progress in the field? If the aims of the program are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the program change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- **Investigators/Overall Program Leadership:** Are the PD/PIs, collaborators, and other researchers well suited to the program? If the program is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership plan, governance and organizational structure appropriate for the program? Are the qualifications of the PD(s)/PI(s) and other senior scientists appropriate to coordinate all P01 activities? Do they provide effective scientific and administrative leadership, as demonstrated by selection of individual projects for scientific excellence and thematic relatedness? Is the commitment (percent effort) of the PD(s)/PI(s) and other senior investigators adequate?
- **Innovation:** Does the overall program challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- **Approach:** Is the overall design of the P01, including strategies, methodologies and analyses, well-reasoned and appropriate to accomplish the specific aims of the program? What is the overall quality and potential influence of the component projects on the field(s) involved, and are the services provided by the shared resource cores (if proposed) adequate to support the program.

If the program involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

- **Environment:** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the program adequate for the project proposed? Will the program benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Is there evidence of sufficient institutional support for the Program Project?

- **Integration:** Is there evidence of scientific and administrative integration of the proposed Program? Is there evidence of coordination, interrelationships, and synergy among the individual research projects and shared resource cores? Are there clear advantages or value added by conducting the proposed research as a Program Project rather than through separate research efforts? For competing renewal applications, is there evidence of productive collaborations during the current funding period?

B. Review Criteria for Individual Research Projects

Before the review meeting, each reviewer and discussant assigned to a project will give a separate score for each of five core review criteria (Significance, Investigator(s), Innovation, Approach, and Environment). For all applications, even those not discussed by the full committee, the scores of the assigned reviewers and discussant(s) for these criteria will be reported in the summary statement.

For each proposed project, reviewers will provide an impact/priority score that will reflect their assessment of the likelihood of the project to exert a sustained, powerful influence on the research field(s) involved.

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. The impact/priority score for each project will take into consideration these scored review criteria and any applicable Additional Review Criteria listed in Section X.D below. A project does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

- **Significance:** Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- **Investigators:** Are the Project Leaders, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
- **Innovation:** Does the project challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies,

instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

- **Approach:** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

  If the project involves clinical research, are the plans for (1) protection of human subjects from research risks and (2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

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

C. Review Criteria for Shared Resource Core(s) (If applicable)

Each Shared Resource Core must provide essential functions or services for at least **two** projects. The merit of each shared resource core will be assessed based on the following criteria:

- Is the proposed Shared Resource Core well matched to the needs of the overall program? Does it provide essential facilities or services for two or more scored research projects?

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

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

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

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

D. Additional Review Criteria

As applicable for the overall program, each research project and each shared resource core proposed, reviewers will consider the following additional items in the determination of scientific and technical merit and in providing an overall impact/priority score, **but will not give separate scores for these items**.

Protections for Human Subjects. For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed

protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

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

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

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

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

Renewal Applications. When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.

- Has adequate progress been made in both projects and shared resource cores since the previous competitive review?
- Were the previous specific aims accomplished, and are the proposed research goals logical extensions of work during the current funding period?
- Has scientific synergy occurred, as indicated by joint publications and new collaborative aims and/or projects?
- Is there adequate justification for adding new projects and/or deleting previous components?

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

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

E. Additional Review Considerations

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

Applications from Foreign Organizations. Although applications from Foreign Organizations will not be accepted, application from Domestic institutions may have foreign components as part of the proposed projects or shared resource cores. If this is the case, reviewers will assess whether the foreign component special opportunities for furthering the research program through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

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

Resource Sharing Plans. Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable:
1) Data Sharing Plan (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm);
2) Sharing Model Organisms (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html); and
3) Genome Wide Association Studies (GWAS) (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html).

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

F. Scoring

Projects which have significant and substantial merit receive an impact score using the standard NIH 1 (exceptional) – 9 (poor) scoring scale. Each assigned reviewer for projects will also provide scores for each of the five scored review criteria (Significance, Investigators, Innovation, Approach and Environment).

If a Project is of such poor quality that it lacks significant and substantial merit, or if it presents serious ethical problems in the protection of human subjects from research risks; or presents serious ethical problems in the use of vertebrate animals, biohazards, and/or select agents, it may be Not Recommended for Further Consideration (NRFC). In this case, the Chairperson calls for a motion and a second to the motion to “not consider the Project further.” The recommendation requires concurrence of a majority of the review panel members. A brief minority report is required if there are two or more panel members in opposition to the majority. **Note** that according to NIH policy, if any component of a P01 application is Not Recommended for Further Consideration, the entire application will also be Not Recommended for Further Consideration. Applications designated as NRFC do not proceed to the second level of peer review (National Cancer Advisory Board) because they cannot be funded.

Shared Resource Cores are rated Superior, Satisfactory, Minimally Satisfactory, or

Unsatisfactory. Program as an Integrated Effort is rated Highly Integrated, Integrated, or Not integrated.

For each discussed application, a final numeric impact/priority score from 1 (exceptional) to 9 (poor) will be given by each eligible committee member (those without conflicts of interest). Each member's overall impact/priority score will reflect his/her evaluation of the level of impact that the program as a whole is likely to have on the research field(s) involved, rather than a simple average of the reviewer's scores for the projects and the ratings for the shared resource cores. Inclusion of components of poor quality or which are unrelated to the main theme of the P01 are likely to be considered evidence of poor judgment by the Principal Investigator(s) and the program senior leadership, which may negatively influence the overall impact score.

If an application has many moderate to major weaknesses and therefore is likely to have low impact relative to all P01 applications normally received by the NCI, the review panel may chose to expedite the discussion or to not discuss the application.

XI. SUMMARY STATEMENT

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

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

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

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

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

XII. AWARD

The award and administration of 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:

Caron A. Lyman, Ph.D.
Acting Chief, Research Programs Review Branch
Division of Extramural Activities
National Cancer Institute
6116 Executive Boulevard, Room 8119, MSC 8328
Bethesda, MD 20892-8328
(use Rockville, MD 20852 for Express Mail)
Telephone: (301) 451-4761
FAX: (301) 496-6497
E-mail: lymanc@mail.nih.gov

APPENDIX A

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Program Overview
- Introduction to the Overall Application
- Overall Program Goals and Specific Aims
- Overall Research Strategy
- Program Related Publications
- Literature Citations

Program Integration and Management

Overall Program Environment

Letters of Support

Multiple PD/PI Leadership Plan (Required if proposing Multiple PDs/PIs)

Individual Research Project 1
- Title Page (Title, Project Leader Name, Degree)
- Description, Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells
- Detailed Budget for Initial Budget Period
- Budget for Entire Proposed Period of Support
- Resources
- Detailed Budget for First 12-Month Period for Any Included Consortium/Subcontract Arrangement
- Budget Estimate for Each Year of Any Included Consortium/Subcontract Arrangement
- Resources for Consortium/Subcontract Arrangement
- Research Plan
  - Introduction to Resubmission or Revision Application (if applicable)
  - Specific Aims
  - Research Strategy
- Progress Report Publication List (for Renewal and Revision Applications)
- References/Literature Cited
- Human Subjects
  - Inclusion Enrollment Report (Renewal or Revision Applications Only)

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

Core Component A

- Title Page (Title, Core Director Name, 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
- Resources
- Shared Resource Core Services Plan
  - Introduction to Resubmission or Revision Application (if applicable)
  - Specific Aims
  - Core Services Strategy
- Progress Report Publication List and Bibliography (for Renewal and Revision Applications)
- References/Literature Cited
- Human Subjects
  - Inclusion Enrollment Report (Renewal or Revision Applications Only)
  - Protection of Human Subjects
  - Inclusion of Women and Minorities
  - Targeted/Planned Enrollment Table
  - Inclusion of Children
- Vertebrate Animals
- Select Agent Research
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plan(s)

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

APPENDIX B

(SAMPLE TABLE)
DISTRIBUTION OF PROFESSIONAL EFFORT (%) IN THE P01

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 SHARED RESOURCE CORE EFFORT TO PROJECTS

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