Guidelines for

PROGRAM PROJECT GRANTS

National Institute of Biomedical Imaging and Bioengineering

National Institutes of Health

Department of Health and Human Services

CONTENTS

CHAPTER 1

OVERVIEW

I. INTRODUCTION

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) Program Project Grant (P01) supports research in the broad areas of biomedical imaging and bioengineering, enabled by the physical and life sciences as well as mathematics and engineering. A P01 award is for the support of a broadly based multidisciplinary or multifaceted research program, which has a well-defined major objective or central theme. It is directed toward a range of scientific questions having a central research focus in contrast to the more narrow thrust of the traditional research project (R01). The program project involves the organized efforts of groups whose members are conducting research designed to elucidate the various aspects or components of the central theme. The leader of the overall P01 is called the principal investigator (PI); the leaders of the subprojects in a P01 are subproject leaders. A P01 requires a minimum of three research subprojects, which receive funding, led by three separate subproject leaders one of whom must be the PI. Each research subproject is usually under the leadership of a different experienced investigator and should contribute to the common theme of the total research effort. Collectively, these subprojects should demonstrate essential elements of unity and interdependence and result in a greater contribution to program goals than would occur if each subproject were pursued individually. It is expected that most of the collaborating scientists will be independent investigators. Thus, support of one senior investigator and several postdoctoral or research associate-level scientists as subproject leaders is not appropriate. The P01 grant is not intended to be a vehicle for departmental research support. In most cases, several departments should be represented.

The NIBIB accepts investigator-initiated P01 applications with the caveat that NIBIB prior approval by the Institute is necessary for the acceptance of the application and for any budget that exceeds $500,000 in direct costs in any year.

Individual subprojects of the P01 can be submitted as R01 applications. If a subproject submitted as an R01 application and as part of a P01 application receives independently derived priority scores/percentile rankings, which merit funding of both applications, funding of the P01 will take precedence over the R01, and the latter will be inactivated administratively.

In addition to the support of research subprojects, the P01 may provide funds for support of common resources and facilities (cores) that would be available for use by the individual subprojects comprising the program. Cores should furnish a group of investigators with some service, technique, determination, or instrumentation that will enhance the research endeavors, consolidate manpower effort, and contribute to cost effectiveness and quality. Core support may include personnel, equipment, supplies, services, and facilities required for the integration of the subprojects toward their central research focus. A core must provide essential functions or services for at least two subprojects, which merit funding.

The size of a P01 is an important consideration. A P01 must have at least three approved subprojects. P01s that are too large may suffer from lack of communication and interaction among collaborators. On the other hand, smaller research endeavors may suffer from lack of a "critical mass" of investigators and would best be funded using the R01 mechanism.

II.   PRE-SUBMISSION

Four to six months prior to the submission of a new P01, the applicant is **encouraged** to meet with NIBIB staff (program and review; grants management, if requested by the PI) to discuss their planned application. This meeting is not necessary for revised applications or competing-continuation applications. In advance of that meeting, the applicant should send to NIBIB the NIH biographical sketches of the PI, the subproject leaders and core leaders, an estimated budget, a brief overview of the program (1 page or less), and a brief overview of the subprojects and cores (1 page or less for each subproject or core). Ideally this meeting would be in-person with the NIBIB staff. However, a teleconference is also possible. The purpose of the meeting is to engage in detailed discussions with the proposed PI and offer advice and suggestions. NIBIB staff, however, will not provide comments on the merit of the science proposed. Following this meeting, the PI should submit a revised description of the P01 including the same information as requested above.

At least three months prior to the submission of a new, renewal or revised P01, the PI should send a letter of intent. This letter should be sent to:

David T. George, Ph.D.
Director, Office of Scientific Review
Office of Research Administration
National Institute of Biomedical Imaging and Bioengineering
6707 Democracy Boulevard, Suite 920, MSC 5469
Bethesda, MD 20892-5469 (20817 for FedEx, UPS, and other courier services)
Phone: (301) 496-8633
Fax: (301) 480-0675
Email: GeorgeD@nih.gov

The letter of intent need include only:

1. Names of the principal investigator and the subproject leaders;
2. Descriptive title of the potential application;
3. Identification of the organization(s) involved; and
4. Announcement (if any) to which the application is responsive.

If the P01 budget requests $500,000 or more in direct costs in any year, the applicant **must** contact NIBIB staff at least 6 weeks prior to any receipt date as per the NIH policy (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html). In return, the applicant will receive written confirmation that NIBIB will accept the application for consideration for award.

Applications submitted without prior consultation with staff, that are not prepared according to the NIBIB P01 guidelines, or do not meet the criteria for a P01 grant application will be returned to the applicant without review.

III.   CHARACTERISTICS OF A PROGRAM PROJECT

A P01 application should include:

A.   A clearly defined, unifying, central theme to which each component subproject relates and to which each research investigator contributes.

- In keeping with the tradition of investigator-initiated research, the NIBIB expects the applicants to define the integrating theme and to develop multidisciplinary approaches used to accomplish the objectives of the proposed research.
- The central theme should be clearly developed in the introduction with a rationale to indicate why the P01 is the appropriate mechanism to conduct the proposed multidisciplinary research.
- The target goals anticipated on completion of the 5-year program should be outlined carefully in the introduction with special reference to contributions expected from the multidisciplinary team.
- Examples of previous collaborations that may have led to the goals and proposed work of the program should be presented.

B.   Component research subprojects that contribute scientifically to the central theme of the program.

- The relationship of the goals of each component subproject to the central theme should be described.
- Each component subproject requires a well-described research plan, preliminary data, and a timetable for conducting the proposed investigations.
- Subprojects may be technology development or hypothesis-driven basic or clinical research, or a combination of technology development and hypothesis-driven research. A P01 grant may not be used to support clinical trials. All research involving human subjects must conform to the NIH policies for inclusion of women, minorities, and children.
- If core facilities are included, the technical/scientific and fiscal relationship of each component subproject to each core should be described.
- A P01 requires a minimum of three submitted and funded component subprojects. Separate and independent investigators should direct each subproject.
- There is no requirement that the component subprojects be located at a single institution. However, it is incumbent upon the applicant to make clear how component subprojects and cores would function across institutions.

C.   A PI who is an established research scientist with the ability to ensure quality control and who has the experience to effectively administer and integrate all components of the program.

- The PI must devote a minimum of 25 percent effort to the grant.
- The PI must be the subproject leader of one of the submitted and funded component subprojects. If the subproject submitted by the PI is judged by peer review to be of low scientific merit, this will markedly reduce the overall scientific merit ranking assigned to the entire application by the review committee.
- The PI should be fully established at the applicant institution.

D. Subproject leaders who provide expertise from several disciplines.

- Expertise will be evaluated based on contributions to the scientific literature and potential to contribute to the overall theme of the P01. The P01 grant is not intended to be a vehicle for departmental research support. In most cases, several departments should be represented.
- Subproject leaders should devote a minimum of 20 percent effort to each subproject for which they serve as subproject leader.
- Investigators with excellent research training, though their total research experience is not yet optimal, may participate; however, it is expected that most of the subproject leaders will be investigators with significant research experience.
- Project leaders should be fully established at their institution.
- A P01 grant requires at least three independent subproject leaders, one of whom must be the PI. At least three subprojects must be submitted and recommended for support for the P01 grant to be peer reviewed and considered for funding.

E. A section titled "Synergy and Interactions among Subprojects and Subproject Leaders." The section includes:

- An administrative structure should be organized to foster interactions among investigators and accelerate the pace of research.
- Collaborative aspects of the research and the role of each subproject in the central theme of the application.
- Multi-authored publications that demonstrate collaboration among investigators has taken place.
- A description of inter-project utilization of resources and research findings.
- A proposed schedule of seminar series, monthly group meetings, and semi-annual retreats.
- Any other activities intended to promote close communication and collaboration.
- Plans for internal and external advisory committees to evaluate progress and the level of interaction among participants. The external advisory board should consist of two to five advisers committed to the evaluation of the program by written documentation. New P01 grant applications should not constitute their external advisory board prior to or during the review of their application because individuals either invited or named to this group would not be able to serve as peer reviewers of the application. The internal advisory board should consist of three to five members outside of the program but within the same institution (or within neighboring institutions) who are able to assist in ongoing reviews on a more regular basis.

Applications must be complete at the time of submission, as neither site visits nor reverse site visits will be utilized in the review process.

CHAPTER 2

GUIDELINES FOR THE PREPARATION
OF A PROGRAM PROJECT GRANT APPLICATION

This chapter supplements instructions in PHS Form 398
(http://grants1.nih.gov/grants/funding/phs398/phs398.html), but with sections modified and
expanded to provide the additional information needed for the P01 application.

I.   GENERAL INFORMATION

With the exceptions and additions noted below there are no major changes from the
general requirements provided in the instructions for PHS Form 398. Page limitations
specified for individual (R01) grant applications (25 pages) in PHS Form 398 apply to
each subproject and core unit.

II.   SPECIFIC INSTRUCTIONS

A.   Face Page (page 1 of application): Type "Program Project" on line 2. The title of
the grant application must not exceed 81 characters. Complete all items on the
face page of the application. This is page 1 of the application; number ALL
succeeding pages accordingly.

B.   Description, Performance Sites and Key Personnel (see PHS Form 398
Instructions)

- In the block requesting key personnel, add the position title, department, and
institution for each individual.

C.   Table of Contents (**Figure 1**)

- Prepare a detailed table of contents that will enable the readers to find specific
information readily. List each subproject, the budget for each subproject, each
core unit, and the budget for each core unit, and supply the page number for
each item. Identify each subproject by title, assign each subproject a number
that reflects the order in which the subprojects are presented in the
application, and provide the name of the subproject leader. (In the case of
competing continuation applications, identify each subproject with the same
number as used in the previous application, or, if subprojects have been
dropped or added, arrange the numbers in sequence and correlate the
subproject being renewed with its former number.)

D.   Detailed Budget for Initial Budget Period (**Table 1**)

i.   For all P01 applications

- A detailed budget will be required for EACH SUBPROJECT AND EACH CORE UNIT in their respective sections of the application. (See below under Research Plan)
- To aid in the review of your application, it is suggested that you incorporate a detailed budget for all requested support during the first year (See Sample Table 1). For each category, such as "Personnel," "Equipment," "Supplies," "Travel," and "Other Expenses," give the amount requested for EACH SUBPROJECT AND CORE UNIT with subtotals. If contractual arrangements or "purchased services" involving other institutions or organizations are anticipated (as in subproject 5 in Sample Table 1), include total (direct and indirect) costs associated with such third party participation in the "Consortium/Contractual Costs." In addition, a complete budget for a consortium subproject is to be developed and identified as such.

 ii. New P01 Applications

- New applications may request up to $1.4 million direct costs, (not including indirect costs for collaborating institutions) in each year.
- Equipment is included in this budget ceiling.
- Requests for expensive items of equipment that cause an application to exceed these limits may be permitted on a case-by-case basis following staff consultation. However, applicants should make every attempt to include all equipment in the ceiling amount. They must discuss the equipment request with NIBIB early in the planning phase and must receive written permission from the Institute to include these costs in their budget request. All requests for such equipment that may cause the application to exceed the limits will require in-depth justification. Final decisions will depend on the nature of the justification and the Institute's fiscal situation.

 iii. Renewal P01 Applications

- Renewal applications may request up to $1.4 million direct cost or a 10 percent increase over the recommended amount shown on the award statement for the last non-competing year, whichever is less (not including indirect costs for collaborating institutions and non-recurring costs, such as equipment).
- The same policy regarding expensive items of equipment that is stated above under "New Applications" applies to competing renewals.

E. Budgets for Entire Proposed Period of Support.

- Prepare a budget by category that provides totals for each year of requested support. Requests for any increases in succeeding years must be clearly stated

and the changes in percent effort and funds justified in the individual subproject and core unit budgets.

F.   Biographical Sketch (see PHS Form 398 Instructions)

G.   Other Support (see PHS Form 398 Instructions)

- As indicated in the PHS 398 instructions, the description of other support should be included as part of the biographical sketch (Research Support) and should not exceed four pages.

H.   Resources (see below under Research Plan)

I.   Research Plan: **The following sections should precede the subprojects:**

    i.   <u>Program Overview and Statement of Objectives</u>

- A P01 application should be viewed as a group of interrelated research subprojects, each of which is not only individually meritorious technically or scientifically but is also complementary to the other subprojects in the program and contributes to the central theme.
- The theme of the proposed P01 should be established in the first few sentences of the general introduction.
- Describe the rationale for the overall program. Explain the strategy for achieving the objectives of the overall program and how each subproject and core unit relates to that strategy.
- The general introduction of the overall program description is the appropriate place to indicate any prior collaborative arrangements between investigators in the group, to emphasize the events that have led to the current application, to predict the anticipated unique advantages that would be gained by the research being conducted within the proposed P01, to describe how the subprojects are synergistic and mutually reinforcing (a diagram may be appropriate), and to explain how the subprojects collectively would enhance the stated objective of the proposed research.

    ii.   <u>Institutional Environment(s) and Resources</u>

- Briefly describe the features of the institutional environment that are relevant to the effective implementation of the overall program. As appropriate, describe available resources such as clinical and laboratory facilities, participating and affiliated units, patient populations, geographic distribution of space and personnel, and consolidated resources. The information requested here supplants the "Resources" page in the PHS Form 398 grant application, which is NOT to be used.

iii. <u>Organizational and Administrative Structure of the P01</u>

- CHAIN OF RESPONSIBILITY. Describe in detail, and by diagram if appropriate, the chain of responsibility for decision making and administration, beginning at the level of a principal investigator and including investigators responsible for the direction of the research subprojects and core units. Indicate where, in the chain of responsibility, advisory groups (internal and external consultants) would be used, and describe the function of these consultants in ensuring quality control in the research efforts.

- EXTERNAL AND INTERNAL ADVISORY BOARDS. Every P01 must have plans for both an external advisory board and an internal advisory board. The external advisory board should consist of two to five advisers committed to the evaluation of the program by written documentation. New P01 grant applications should not constitute their external advisory board prior to or during the review of their application because individuals either invited or named to this group would not be able to serve as peer reviewers of the application. The internal advisory board should consist of three to five members outside of the program but within the same institution (or within neighboring institutions) who are able to assist in ongoing reviews on a more regular basis.

- SPECIFIC MANAGERIAL RESPONSIBILITIES: Indicate who would be responsible for assisting the principal investigator with the day-to-day administrative details, program coordination, and the planning and evaluation of the program.

- RELATION OF THE P01 ORGANIZATION TO THE ADMINISTRATION OF THE APPLICANT INSTITUTION: Describe the relation between the proposed P01 and other existing research, academic, and administrative units of the applicant institution such as schools, centers, institutions, departments, and central administration.

- CONSORTIUM ARRANGEMENTS: If a grant application includes activities that involve institutions other than the sponsoring organization, the program is considered a consortium effort. Such activities may be included in a P01 grant application, but it is imperative that a consortium application be prepared so that the programmatic, fiscal, and administrative considerations are explained fully. As stated under Chapter 1, B., there is no requirement that all component subprojects be located at a single institution. However, it is incumbent upon the applicant to make clear and demonstrate how component subprojects and cores would function across institutions. The published policy governing consortia is available in the business offices of institutions that are eligible to receive Federal grants-in-aid. Consult the latest published policy governing consortia before developing the application. If clarification of the policy is

needed, contact the Director, Office of Grants Management, Office of Research Administration, NIBIB, at 301-451-4789. Principal Investigators of P01s should exercise great diligence in preserving the interactions of the participants and the integration of the consortium subprojects with those of the parent institution, because synergy and cohesiveness could be diminished when subprojects are located outside the parent institution.

- DESIGNATION OF REPLACEMENT FOR PRINCIPAL INVESTIGATOR: Describe the procedure for appointing a replacement for the Principal Investigator, should the need arise. The NIBIB must approve the replacement of the Principal Investigator.

iv.   Summary Report of Progress

Renewal applications must include a progress report that highlights achievements under the P01 since the last competitive review. A progress report is required for each subproject and core unit in other sections of the application. This composite summary/progress report must include the following information:

- A brief summary of major accomplishments that can be attributed to the project grant and a brief explanation of how these accomplishments have contributed to furthering the stated objectives of the program.

- A list of all publications and *in press* and submitted (not "in preparation") manuscripts that have resulted from the P01 grant. It is expected that these publications will acknowledge NIBIB P01 funding.

- A list of changes, if any, in the professional staffing since the last competitive review.

- A list of subprojects and core units, in tabular form, that have been discontinued, modified, or completed since the last competitive review, identified by number and title, with a brief explanation of the actions taken.

- A list of subprojects and core units in the current program, with the amount of current funding for each and the requested funding for the first budget period of each subproject and core unit that would be continued in the P01. Identify each as a "new" or "continuing" component.

J.   Subprojects

1.   General Guidance

- EACH SUBPROJECT SHOULD FOLLOW THE FORMAT OF THE PHS FORM 398 and provide supplementary information when necessary for each section as indicated below. Describe each subproject and each core unit in the same detail required for an individual R01 grant application, so that the scientific merit can be judged on the basis of the written proposal. Keep in mind that experts who can judge, collectively, all areas represented in the application but who may not be cognizant, individually, with each area of research proposed, will review the application. Therefore, the description of a subproject should be concise yet explicit enough to enable experts in related areas to understand the main thrust of each subproject.
- The research plan for each subproject is limited to 25 pages. Additional information concerning collaboration and integration between subprojects and cores and the contribution of each component to the program's specific goals should be succinct and must be included within the 25 pages. Unnecessarily long, wordy, or confusing presentations are usually perceived as indicative of premature or poorly planned research. The bibliography is not counted toward the 25-page limitation per subproject. Applications exceeding the page limitation or using inappropriate fonts or margins will be returned without review. Measure the printed page for font compliance before submission.
- Appendices: Prepare appendices for each subproject and core according to the NIH policy for research project grant applications.
  http://grants.nih.gov/grants/funding/phs398/phs398.doc

2. <u>Specific Guidance</u>

a) Title and number each subproject so that it can be readily distinguished from any other subproject in the program. An individual DESCRIPTION (ABSTRACT) should be prepared for each subproject in the P01 as would be required for an R01. The title must NOT exceed 81 typewriter characters/spaces. DO NOT provide a face page (i.e., PHS Form 398 face page) for subprojects. Provide the name and academic title of the subproject leader and each participating investigator.

b) The budget for each subproject must be presented according to the instructions indicated for PHS Form 398. A detailed budget is required for the first year and a budget for the entire proposed period of support. Include detailed budget justifications for all years.

c) Resources: Describe in detail the facilities to be used. This is to be accomplished as described under "Resources."

d) Research Plan: State the overall objective of the proposed research and explain the relationship of the subprojects to the central theme of the P01, their inter-relationship, and their relationship to the core units in the program.
   i) Specific Aims
      - List the specific aims of the research subproject for the total period of requested support. Indicate the general priority of each aim in the overall research plan.
   ii) Background and Significance
      - Review the most significant previous work and describe the current status of research in this field: document with complete references.

- Indicate the relevance of the research subproject to the theme of the P01. In addition, specify the overall biomedical significance of the work proposed.

iii) Preliminary Studies/Progress Report
- Refer to PHS form 398 Instructions for Preliminary Studies.
- See under Summary Report of Progress.

iv) Research Design and Methods
- Give details of the research plan, including the description of the experiments or other work proposed; present the methods and techniques to be used; note the limitations, if any, of the procedures proposed. In so far as possible, describe the technology development and/or experiments in the sequence in which they would be conducted. (A time line might be useful.)
- Discuss the kinds of results expected from the procedures, and explain how results will be analyzed and interpreted.
- Discuss the extent to which anticipated results will satisfy the original aims and how those results will be important for planning the next steps in the proposed work.

v) Human Subjects (see PHS Form 398 Instructions)
- The NIH policies concerning research on human subjects will apply. PHS Form 398 should be followed for human subjects information.
- The NIH policy is that applicants proposing clinical research in grants and cooperative agreements include minorities, women and children in study populations. If women or minorities or children are excluded or inadequately represented in clinical research a clear and compelling rationale should be provided.
- NIH-defined clinical research is acceptable providing it is presented as one of several subprojects in the program and has objectives that can be completed in a 5-year project period. A P01 grant may not be used to support clinical trials.
- The composition of the proposed study population must be described in terms of gender and racial/ethnic groups. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included on PHS Form 398 in Section 1, C. 9 A-D of the Research Plan AND summarized in Section 1, C. 9E, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.
- If the required information is not contained within the application, the application will not be peer reviewed.

vi) Vertebrate Animals (see PHS Form 398 Instructions.)
- If animals are involved, indicate what kinds are to be used and whether nonhuman primates are to be used, listing the special justifications for their use, and indicate all details for the care, use, treatment, and dispatch of all animals.

vii) Literature Cited
- Include a full and complete citation for each reference in the text. Titles of reference publications including names and initials of **ALL** authors should be included.

viii) Consortium/Contractual Arrangements

- Consortium/Contractual Arrangements and/or Collaborative Arrangements (See PHS Form 398 Instructions)
- Describe the collaboration of investigators within the P01. Describe in detail any other collaborative arrangements anticipated, either within the applicant institution or between institutions.
- Consultants (See PHS Form 398 Instructions)

3).   Format of a Core Unit

A core unit is defined as a resource for the P01 that provides centralized services to two or more of the subprojects.

a. Title of core unit

Title and assign a LETTER designation to each core so that it can be readily distinguished from any other core unit. Do NOT exceed 81 typewriter characters/spaces for its title.

b. Names and titles of investigators

Provide the name and academic title of the core unit leader and each participating investigator.

c. Budget for core unit

Present the budget for each core unit according to the instructions indicated for Form 398. A detailed budget (direct costs only) is required for the first year and a budget for the entire proposed period of support. Include detailed budget justifications for all years. If a consortium is involved, include the indirect costs of the consortium as part of the overall direct costs.

d. Resources

Describe in detail the facilities to be used by EACH core unit. This is to be accomplished by completing the "Resource" page included in the PHS Form 398 grant application packet.

e. Description of core unit

Describe the function of the core unit as a resource to the P01. This section must present clearly the facilities, techniques, and professional skills that the core unit would provide. As justification for the core unit, briefly indicate the specific research subprojects that would use the resources of the core unit. A core unit is principally designed as a service of a resource component; it would be unusual to include research in a core unit (a possible exception would be methodology development). Please contact the Institute staff if you require guidance on this issue.

f. Relation of core units to research subprojects

Include in tabular form information concerning the research subprojects that each core unit would serve and the proportion of the cost of the core unit associated with each research subproject involved **(Table 2)**.

CHAPTER 3

SUBMISSION AND REVIEW OF APPLICATIONS

The NIBIB will accept all new, resubmission, and revision program project applications on standard receipt dates for P series grant applications.

http://grants.nih.gov/grants/funding/submissionschedule.htm

The NIBIB **encourages** pre-submission discussions of new P01 grant applications with staff to ensure that each application meets the policies and guidelines for P01 grant applications and to encourage more complete and well-prepared documents. P01 grant applicants must receive written consent from the NIBIB to submit an application. In addition, submission of any application requesting a budget of $500,000 or greater in direct costs in any year must receive the consent of the NIBIB (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html).

I. APPLICATION AND REVIEW PROCESS

The following phases will normally comprise the process of submission and review of a P01 application:

A. PRE-SUBMISSION
   1. For all P01 applications (new, renewal and revised), investigators are encouraged to discuss their intent to submit the application with NIBIB staff well in advance (4-6 months) of the receipt date. Such discussion is *encouraged* for all new P01 grant applications.
   2. To plan the review schedule, not less than 3 months before submission of the application, a letter of intent should be sent to:

   David T. George, Ph.D.
   Director, Office of Scientific Review
   Office of Research Administration
   National Institute of Biomedical Imaging and Bioengineering
   6707 Democracy Boulevard, Suite 920, MSC 5469
   Bethesda, MD 20892-5469 (20817 for FedEx, UPS, and other courier services)
   Voice: (301) 496-8633
   Fax: (301) 480-0675
   Email: georged@nih.gov

   The letter should contain the overall program title and that for each of their component subprojects, together with the names and the institutions of the PI, the subproject leaders and key personnel.

3.   To enable the Institute staff to advise whether the application meets the scientific and programmatic requirements for a P01 and is prepared according to the technical guidelines, it is recommended that a draft application be sent to the appropriate Program Director early in its preparation. It is the policy of the NIBIB that all applications requesting $500,000 or greater in direct costs in any year will not be accepted without written Institute approval.

4.   Questions concerning budgets and/or grants policy should be addressed to the Director, Office of Grants Management of the NIBIB.

B. SUBMISSION

1.   At the same time that the original and three copies of the grant applications are submitted to the Center for Scientific Review, at:

Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive MSC 7710
Bethesda, MD 20892-7710

TWO ADDITIONAL COPIES OF THE GRANT APPLICATION AND THE APPENDIX CD ARE REQUESTED TO BE SUBMITTED TO NIBIB BY A SEPARATE MAILING to:

David T. George, Ph.D.
Director, Office of Scientific Review
Office of Research Administration
National Institute of Biomedical Imaging and Bioengineering
6707 Democracy Boulevard, Suite 920, MSC 5469
Bethesda, MD 20892-5469 (20817 for FedEx, UPS, and other courier services)
Voice: (301) 496-8633
Fax: (301) 480-0675
Email: GeorgeD@nih.gov

2.   A copy of the letter indicating the willingness of the NIBIB to accept the application and a copy of the letter indicating that NIBIB will accept the application with a budget of $500,000 or more in direct costs in any year should be included with any P01 grant application.

C. SCIENTIFIC REVIEW

1.   New, competing renewal, and revised P01 applications will be reviewed by a Special Emphasis Panel (SEP) composed of scientific peers convened to review one or more P01 applications with similar content.

2. Following receipt of an application, a Scientific Review Officer (SRO) will be assigned responsibility for review. The PI will be notified of the SRO's name and contact information through eRA Commons.
3. For all reviews, the SRO will:
   a. Inform the applicant whether submission of supplemental material after the receipt date would be permitted. If permissible, the time frame and details will be transmitted to the applicant.
   b. Transmit questions from reviewers to the applicant in preparation for the review, if the SRO believes they are critical to the review.
4. Review Criteria:
   a. Subproject: Each subproject will receive a priority score based on its intrinsic stand-alone merit. This scoring process and review criteria will be comparable to that for a R01 grant application as follows:

   The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, and weighted as appropriate for each subproject.

   - Significance
   - Approach
   - Innovation
   - Investigator
   - Environment
   - Additional Review Criteria

   Note that a subproject does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

   Significance: Does this study address an important scientific health problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

   Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? For applications designating multiple PDs/PIs, does the Multiple PD/PI Leadership Plan ensure that there will be sufficient coordination and communication among the PDs/PIs? Are the governance and organizational structure of the research project, including communication plans, process for making decisions

on scientific direction, allocation of resources, publications, intellectual property issues, and procedures for resolving conflicts, adequate? Are roles and administrative, technical, and scientific responsibilities for the project or program delineated for the PDs/PIs, including responsibilities for human subjects or animal studies, appropriate?

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

Investigators: Are the PD/PI(s) and key personnel appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI(s) and other researchers? Do the PD/PI(s) and investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

Additional Review Criteria: In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed.

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

Care and Use of Vertebrate Animals in Research: The adequacy of the plans for care and use of vertebrate animals to be used in the project will be assessed.

Biohazards: If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

Applications from Foreign Organizations: Applications from foreign institutions or international organizations will be evaluated and scored during the initial review process using the standard review criteria. In addition, the following will be assessed as part of the review process and award decision

Whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources.

Budget and Period of Support: The reasonableness of the proposed budget and the appropriateness of the requested period of support in relation to the proposed research may be assessed by the reviewers. Is the number of person months listed for the effort of the PD/PI(s) appropriate for the work proposed? Is each budget category realistic and justified in terms of the aims and methods?

Resource Sharing Plan(s)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. If the final data/resources are not amenable to sharing, this must be explained in the Resource Sharing section of the application (see http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm.)

(a) *Data Sharing Plan*: Regardless of the amount requested, investigators are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Applicants are encouraged to discuss data-sharing plans with their NIH program contact (see Data-Sharing Policy or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.)

(b) *Sharing Model Organisms*: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms and related resources or state appropriate reasons why such sharing is restricted or not possible (see Sharing Model Organisms Policy, and NOT-OD-04-042.)

(c) *Genome-Wide Association Studies (GWAS):* Regardless of the amount requested, applicants seeking funding for a genome-*w*ide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. A genome-wide association study is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (e.g., blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (go to NOT-OD-07-088, and http://grants.nih.gov/grants/gwas/.)

b.   Core: Each Core Unit will be rated as "Recommended" or "Not Recommended" based upon the below review criteria:

Assess the quality of services and facilities provided, their cost-effectiveness, their utility to the program, the extent to which they benefit two or more of the research components, and the quality of the principal investigators.

c.   The SEP will vote an overall score for the P01 grant application.
d.   It is possible that one or more of the components will have scientific merit but fit poorly, or not at all, within the P01. Inclusion of subprojects that are unrelated to the theme of the P01 may reflect negatively on the PI's leadership and adversely affect the P01's overall score.
e.   The SEP will provide written comments on the overall program, as well as the synergy of the subprojects. The importance and contribution of each subproject to the overall program will be described in each subproject's critique.

D. COUNCIL REVIEW
The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) will assess the recommendations of the SEP. They will take into account the scientific merit of the component subprojects, the overall merit of the program, programmatic considerations relevant to each application, and the total recommended budget.

E. FUNDING
1.   The NIBIB and NACBIB are committed to the P01 as an important support mechanism to accomplish various research goals and opportunities.
2.   The NIH Plan for Managing the Costs of Biomedical Research has placed an increased emphasis on the total cost of an application as a factor in the funding decision. This will have an impact on P01 grant applications and other grant applications having a high total cost.
3.   The priority scores given to the component subprojects will be used as only one key factor in making funding decisions of P01s components.
4.   P01 grants must consist of a minimum of three fundable component subprojects directed by at least three separate, independent subproject leaders and the PI's subproject must be fundable.

F. POST-AWARD ISSUES
1.   If a component subproject group leader moves to another institution, the subproject is not automatically allowed to continue under a consortia relationship with the new institution. Therefore, in such a situation, the principal investigator should plan to justify to NIBIB staff the continuation of the component subproject based on its role in the overall P01.
2.   The P01 grant may normally not be transferred administratively to another institution. An application from the new institution must be submitted for competitive review as described in this chapter.

3.   The NIBIB will *consider* reinstatement into a P01 any subproject initially deleted from the P01 by the NIBIB if **all** of the following conditions have been met.

> a.   The subproject has been submitted as an R01, but not in response to an RFA.
>
> b.   Reinstatement is requested by the PI of the P01 grant, the PI of the R01, and the applicant institution.
>
> c.   The P01 is in the first or second year of the project period.
>
> d.   The scientific objectives of the R01 remain consistent with the major theme of the P01.
>
> e.   The R01 funds requested and approved are the same as, or lower than, those submitted in the P01, including subproject and associated core costs so that the total P01 budget cap would not be exceeded.
>
> f.   The percentile is equal to or better than that used for the official pay line at the Council for the competing investigator-initiated grants.

If all of these conditions are met, the NIBIB will consider reinstatement of the subproject (and associated core costs) for funding for the same period of time that remains in the parent P01.

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APPENDIX

FIGURE 1

Table of Contents

* See PHS 398 Application Kit
** For Continuation, Supplemental and Revised Applications See NIBIB
   Program Project Administrative Guidelines for additional instructions

TABLE 1

Detailed Budget for the First 12-Month Period
Direct Costs only

Principal Investigator/Program Director (Last, first, middle):_____							
DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY				FROM		THROUGH	
PERSONNEL (Applicant organization only)				DOLLAR AMOUNT REQUESTED (omit cents)			
NAME	ROLE ON PROJECT	TYPE APPT. (months)	% EFFORT ON PROJ.	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Project 1					30,000	3,000	33,000
Project 2					20,000	2,000	22,000
Project 3					25,000	2,500	27,500
Project 4					15,000	1,500	16,500
Core Unit A					22,000	2,200	24,200
Core Unit B					10,000	1,000	11,000
				SUBTOTALS	122,000	12,200	134,200
CONSULTANT COSTS							
Project 2 ($1,000)							
Core Unit A ($2,000)							3,000
EQUIPMENT (Itemize)							
Project 1 25,000							
Project 2 19,500							
Project 3 15,000							
Core Unit A 20,400							79,900
SUPPLIES (Itemize by category)							
Project 1 3,500							
Project 2 8,000							
Project 3 0							
Project 4 10,000							
Core Unit A 2,400							
Core Unit B 6,600							30,500
TRAVEL $1,250 each for Projects 1-4							5,000
PATIENT CARE COSTS	INPATIENT						
	OUTPATIENT						
ALTERATIONS AND RENOVATIONS (Itemize by category)							
Core Unit A - Cold Room Installation							50,000
OTHER EXPENSES (Itemize by category)							
Project 1 ($1,000)							
Project 2 ($1,500)							
Project 3 ($3,000)	Core Unit A ($1,500)						
Project 4 ($2,500)	Core Unit B ($1,000)						10,500
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD							$313,100
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS PROJECT 5						53,000
	INDIRECT COSTS PROJECT 5						17,000
							$383,100
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page)							
PHS 398 (Rev. 5/01)							

TABLE 2

Relation of Core Units to Research Projects

Projects	Core Unit A	Core Unit B
Project 1	$ 0	$ 6,900
Project 2	13,100	6,000
Project 3	14,500	10,000
Project 4	10,000	0
Project 5	20,000	0
TOTAL	$57,600	$22,900