FOREWORD

It is a pleasure to provide the research community served by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) the revised Administrative and Review Guidelines for the Program Project Grant Application of the NIDDK. These Guidelines supersede the October, 1998 guidelines, and they include changes in PHS Form 398 (Rev. 4/98) and in procedures. The Guidelines are written to serve applicants, members of peer review groups, and NIDDK staff.

I would like to point out a change in the allowable budget for program project grants which takes effect on January 4, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-DK-01-004.html). The maximum dollar request for new NIDDK program project applications is subject to a limit of $5 million in direct costs over 5 years. Policy concerning budget caps is presented in further detail in this document. Furthermore, effective February 22, 2001, both new competing (Type 1) and competing continuation (Type 2) P01 grant applications will be restricted to two receipt dates per year: June 1 and October 1. Amended P01 applications will continue to be accepted three times per year: on February 1, as well as on the June 1 and October 1 dates (http://grants.nih.gov/grants/guide/notice-files/NOT-DK-01-005.html).

Allen Spiegel, M.D.
Director, NIDDK

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I. DESCRIPTION OF THE PROGRAM PROJECT GRANT

A research program project (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. Each research project is usually under the leadership of a different experienced investigator and should contribute to the common theme of the total research effort. Collectively, these projects should demonstrate essential elements of unity and interdependence and result in a greater contribution to program goals than would occur if each project 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 project leaders is not appropriate. The program project grant is not intended to be a vehicle for departmental research support. In most cases, several departments should be represented.

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

In addition to the support of research projects, the program project may provide funds for support of common resources and facilities (cores) which would be available for use by the individual projects 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 projects toward their central research focus. By definition, a core must provide essential functions or services for at least two priority-scored individual research projects.

The size of a program project is an important consideration. Program projects 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. In attempting to deal with these issues, NIDDK has adopted the following policies:

1. New (Type 1) program project applications cannot request more than $5 million (direct cost) over 5 years.

2. Competing continuation (Type 2) applications may request direct cost budgets up to 20 percent more than the previous year's direct cost portion of the commitment level shown on the Notice of Grant Award.

   Competing continuation (Type 2) program projects have an absolute cap of $6.25 million in direct costs requested for 5 years. This ceiling can be attained only through the stepwise increments described above.

3. Exceptions to the caps will apply to program project applications that include subcontracts. In such cases, the indirect costs related to the subcontracts will be excluded from the requested direct cost levels prior to application of the cap.

4. Noncompeting years will be held to a 3 percent increase over the preceding year, adjusted for expansions or contractions of effort or scope as recommended by peer review.

5. Competing supplements will be accepted only for the continuation of projects that were originally funded for a time period shorter than the overall program project. The supplemental request may be up to 3 percent above the previous year's support for that project(s).

The basic criteria for classification as a program project are:

1. A clearly defined, unifying central theme to which each project relates and to which each investigator contributes;
2. A minimum of three component research projects that extend for the duration of the program and that are judged to have significant scientific merit, as well as being complementary or contributory to the central theme of the program project;
3. The participation of experts in several disciplines or in several areas of one discipline. All investigators must contribute to, and share in, the responsibilities of fulfilling the program objective;
4. A principal investigator/program director who is an established research scientist and who has the experience, ability, and time commitment to ensure quality control and to effectively administer and integrate all components of the program. The administrative structure should be individualized to meet the needs of the program project. However, the use of an internal advisory committee selected from the participating investigators and/or an external advisory committee of outside consultants is encouraged; and
5. The interrelationship of projects and collaboration of investigators which will yield synergy and results beyond those achievable, were each project pursued independently.

II. PRE-APPLICATION PROCEDURES

A. Assignment

Applications submitted to the National Institutes of Health (NIH) are assigned to individual Institutes (e.g., NIDDK) after careful consideration of the overall scientific goals of the applications in relation to the missions of the Institutes. In general, the NIDDK accepts program project applications in all scientific areas relevant to its mission. In addition, the Center for Scientific Review (CSR; formerly the Division of Research Grants), in consultation with Institute staff, makes the decision as to whether or not a given application fits the criteria of a program project. If the budget of any application exceeds **$500 thousand per year**, that application will be returned, unless the Institute program staff have been contacted and agree to its submission.

It is strongly encouraged that potential applicants submit a letter of intent, so that it can be determined whether the proposed program project fits the mission of the NIDDK. The letter should be sent at least three months prior to the application receipt date to allow NIDDK staff to identify potential opportunities and problems early in the development of the application.

Letters of intent should be sent to:

CHIEF, REVIEW BRANCH
DIVISION OF EXTRAMURAL ACTIVITIES
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE
AND KIDNEY DISEASES
6707 DEMOCRACY BLVD., RM. 752 MSC 5452
BETHESDA, MD 20892-5452
(for express/courier services: Bethesda, MD 20817)
Telephone: (301) 594-8885
FAX: (301) 480-3505

The letter of intent need include only: 1) names of the principal investigator/program director and principal collaborators; 2) descriptive title of the potential application; 3) identification of the organization(s) involved; and 4) announcement (if any) to which the potential application is responsive.

B. Communication with NIDDK Staff

The purpose of the letter of intent is only to establish communication between the potential applicant group and NIDDK staff. It is not part of the peer review material. Upon receipt of the letter, the appropriate NIDDK program director will contact the prospective principal investigator to assist in the following areas:

1. **Scientific Content and Objectives**: It is important for the applicant to appreciate what areas of science are appropriate for NIDDK sponsorship. It is to the applicant's advantage to discuss scientific content and objectives of an application with the appropriate NIDDK staff member. For new applications, a pre-application meeting with NIDDK staff is encouraged. However, advice given by staff must not be interpreted as a commitment to make an award. The staff will not evaluate or discuss the merit of the scientific aspects of the application.

2. **Focus**: The size of the proposed program is an important item for discussion.

3. **Organization**: The NIDDK staff may assist the potential applicant by suggesting revisions in the organization of the proposed application to reflect better the program project concept. For example, appropriate use of core components and consultants may strengthen an application. Weaknesses in the organization and integration of the written application reflect poorly on both leadership and collaborative arrangements. It is essential to have a clear understanding of why the program project mechanism of support is more appropriate than a collection of individual research applications.

4. **Clarifications**: Often problems are created when an application reflects a misunderstanding or misinterpretation of the program project guidelines. Therefore, clarifications should be obtained early in the process from NIDDK staff. It is, however, the

applicant's responsibility to read and to follow carefully the directions for application submission as set forth in the PHS Form 398. An incomplete application may result in deferral of the application to a subsequent review cycle, or in the withdrawal of the application from review and return to the applicant.

III. PREPARATION OF P01 GRANT APPLICATION

A. Form

PHS Form 398 is available at most grantee institutions and must be used for submitting a program project application. The original and three copies of the completed application should be mailed to the Center for Scientific Research; an addressed label is included in PHS Form 398 application kits. In addition, two copies of the application and all appendices should be sent under separate cover to the Chief, Review Branch, NIDDK (same address as for the Letter of Intent, above). If the forms are not available, they may be obtained from the Office of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910; telephone: (301) 435-0714; email: grantsinfo@nih.gov.

B. Instructions

The instructions provided below modify and expand appropriate sections of PHS Form 398 to make it applicable for a new or competing continuation program project request. These instructions are meant to be used with the PHS Form 398 instructions. It is important to follow the PHS Form 398 instructions closely. For supplemental applications, reference should be made to additional instructions below in these P01 guidelines. For applications submitted in response to a Request for Applications (RFA), other instructions and requirements may apply.

1. **Face Page, Page 1**: Type "Program Project" on line 2 of the face page next to "Title." Complete all items on the face page as directed. Items 4 and 5 must have current approval dates (see Section F, Assurance and Certifications, of PHS Form 398 instructions).

2. **Program Project Description, Performance Sites and Key Personnel**, **Page 2**: Describe the proposed research program, indicating the major thrust of the component projects. List performance sites and complete the key professional personnel section.

3. **Table of Contents**: The various sections of the Table of Contents for a program project grant application are described in Illustration 1 of this document.

4. **Composite Budget**: New budget guidelines (January 4, 2001 can be found at (http://grants.nih.gov/grants/guide/notice-files/NOT-DK-01-004.html). New(Type 1)

program project applications cannot request more than $5 million (direct costs) over 5 years. An exception to the cap will apply to program project applications that include subcontracts. In such cases, the indirect costs related to the subcontracts will be excluded from the requested direct cost levels prior to application of the cap. Competing continuation (Type 2) applications may request budgets only up to 20 percent more than the previous year's direct cost portion of the commitment level shown on the Notice of Grant Award. Non-competing years will be held to a 3 percent increase. The absolute cap of $6.25 million in direct costs requested for 5 years will be maintained. This ceiling can be attained only through the stepwise increments described above. As noted above, CSR will return any application requesting more than $500 thousand per year, unless the appropriate program staff have been contacted in advance and the Institute has agreed to the application's submission. A series of composite budgets (Illustrations appended) are to be prepared as follows:

a. A first-year budget for the program project using the page of PHS Form 398 entitled "Detailed Budget for First 12-Month Budget Period" (Illustration 2).

b. The "Budget for Entire Proposed Period of Support" using the appropriate budget page of PHS Form 398. The first year of support will reflect the category totals from "Illustration 2" budget. Omit budget justifications on this page, but include them with the individual project budgets.

c. A breakdown of the composite budget for each requested year as indicated in Illustration 3.

d. A requested personnel table, listing all professional and non-professional participants in the program, including those for whom no salary is requested, according to the format in Illustration 4. Similarly, present the detailed information for the remaining categories as specified in the instruction sheets for PHS Form 398.

C. Biographical Sketches

Updated biographical sketches are required for all professional personnel. These should be prepared in accordance with the directions for PHS Form 398, arranged in alphabetical order, and placed at the end of the budget section of the application.

D. Current Sources of Support

Provide a detailed list of the sources of awarded and pending research support including fellowships and contracts for all participating investigators. Key funding (as described in PHS Form 398), including those from federal, private, and institutional sources, must be identified. Follow the instructions of PHS Form 398 which requires that each item give: (a) identifying number, title, and source of support; (b) the major goals of the project; (c) dates of entire project period; (d) annual direct costs; (e) percent effort on the project; (f) indication whether the item overlaps, duplicates, or is being replaced or supplemented by the present application; delineation and justification of the nature and extent of any scientific and/or budgetary overlaps or boundaries; and (g) any modifications that will be made should the present application be funded. See PHS Form 398 for format.

E. Overall Research Plan

Using continuation pages, substitute the following for the Research Plan instructions of PHS Form 398:

1. **Program Introduction and Statement of Objectives:** Describe the rationale for the proposed research program. Explain the strategy for achieving the objective of the overall program, how each project and core unit relate to the strategy, and how the projects and cores relate to one another.

   It is important to indicate 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 within the proposed program project, to describe how the projects are mutually reinforcing, and to explain how the projects collectively would achieve the stated objective of the proposed research.

2. **Institutional Environment and Resources:** Briefly describe the features of the institutional environment that are or would be relevant to the effective implementation of the proposed 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 consultative resources.

3. **Organizational and Administrative Structure of the Program Project:** Describe in detail, and by diagram if appropriate, the chain of responsibility for decision-making and administration. Describe to whom the principal investigator/program director reports and the administrative structure as it relates to the individual project/core principal investigators.

   If advisory groups are included, indicate where in the chain of responsibility they fit, and describe the specific functions of these consultants in the overall program.

4. **Specific Managerial Responsibilities:** Indicate who would be responsible for assisting the principal investigator/program director with the day-to-day administrative details, program coordination, and planning and evaluation of the program, and who would be in charge in the absence of the director.

5. **Designation of Replacement for Principal Investigator:** Describe procedures for appointing a replacement for the principal investigator if the need should arise.

6. **Relation of the Program Project Organization and Administration to the Applicant Institution:** Describe the relationships among the proposed program project and other existing research, academic, and administrative units of the applicant institution, such as centers, institutes, departments, and central administration. Indicate if any of the proposed cores will utilize or expand cores already existing at the institution.

F. Research Projects

Use a separate PHS Form 398 (minus the standard face page) for each project, and title and number each project sequentially so that it can be readily distinguished from other projects in the program. Each research project should be identified clearly by the same title as that provided in the Table of Contents.

Each project should begin with a face page consisting of the project number, title, and name of the project leader. This should be followed by the abstract, budget pages, and information requested in Sections A through I of the instructions for PHS Form 398. Describe each in the same detail and format as required for a regular research grant application so that the scientific merit can be judged on the basis of the written application. For each project, adhere to the restrictions on number of pages and type size indicated in the instructions for PHS Form 398. The total number of pages for Sections A-D must not exceed 25 pages. Applications exceeding this page limitation will be returned to the applicant. As described under "General Review Considerations," priority scores will be assigned to individual research projects as well as to the program project as a whole. Thus, the description of each project should be explicit enough to enable experts in related areas to understand the main thrust of each project without resorting to appendix materials to provide detailed procedures or critical data. If human subjects or vertebrate animals will be used, the necessary information must be supplied in Sections E and F, and the issue of inclusion of gender and minority must be addressed for each project, as outlined in PHS Form 398.

The budget for each research project should adhere to the instructions from PHS Form 398. A detailed budget is required for the first year; budget estimates are required for all subsequent years of support. Explicit and detailed budget justifications must be included for all years. For example, all personnel positions, regardless of whether dollars are requested, must be clearly justified. All listed individuals must have a specified time commitment.

G. Core Units

Use a separate PHS Form 398, and name and assign a letter designation to each unit. Provide a detailed budget for each core in the same way as for each project. Describe the core unit and the various services it would provide, as well as the personnel, facilities, management, and any special arrangements such as cooperation with other established cores. The core description should include a clear delineation of procedures, techniques, and quality control, and how core usage would be prioritized. If applicable, describe in detail statistical analyses and data management. Provide necessary information of usage of human subjects and vertebrate animals and inclusion of gender and minorities in human research, as appropriate.

Within each core, indicate which core services each project would utilize. In addition, prepare a table that indicates the research projects each core unit would serve and the proportion of the cost of the core unit associated with each research project
(see Illustration 5).

H. Checklist

See Sample Checklist Form in PHS Form 398.

I. Appendix

List all appendix material to accompany the application (see page 19 of PHS Form 398). Note: Send all appendices to Chief, Review Branch, NIDDK, with the two copies of application (see below). Original glossy photographs or color images that do not reproduce well should be included in the appendix. The appendices should be collated to form complete sets and labeled as to the specific projects and cores to which they relate.

IV. ADDITIONAL INSTRUCTIONS FOR COMPETING CONTINUATION APPLICATIONS

A. Budget Caps

In general, the size of funded program project grants will be limited by caps on the amounts that can be requested and by restricting the scientific scope of the grant.

1. Competing continuation (Type 2) applications may request budgets only up to 20 percent more than the previous year's award.

2. As a general rule, the Institute's goal will be to hold increases in competing continuation awards to an average of no more than the Biomedical Research and Development Price Index (BRDPI).

3. The absolute cap of $6.25 million direct cost requested for 5 years will be maintained, including any requested escalation in future years. This ceiling can be reached only through the stepwise increments described above.

4. Noncompeting years will be held to a 3 percent increase over the preceding year, adjusted for expansions or contractions of effort or scope as recommended by peer review.

5. Beyond the allowable 20 percent expansion, once a program project is funded, expanding its scientific scope--by expanding the number of scientific goals and objectives in a competing continuation application--will not be possible. This applies to all program project grants, including those below the absolute cap of $6.25 million direct cost. Support for such expansions must be sought through separate grants.

B. Application

Preparation of a competing continuation (renewal) application should follow the instructions provided in the section of this document entitled "PREPARATION OF P01 GRANT APPLICATION." Retain the number and letter designations for projects and cores in the present grant. In addition, include a general progress report that highlights achievements under the program project since the last competitive review. A more detailed progress report will be required for each individual project and core unit in other sections of the application. The general progress report must include the following information:

1. A brief summary of major accomplishments that can be attributed to the program project grant, a brief explanation of how these accomplishments have contributed to the achievement of the stated objectives of the grant, and a demonstration that synergy has occurred;

2. Evidence that the previous specific aims have been accomplished and that the new research goals are logical extensions of those aims;

3. The previous performance of the core(s);

4. A list of projects and core units that have been discontinued, modified, or completed since the last competitive review, identified by number, title, and investigator with a brief rationale for the actions taken;

5. The justification for adding new projects or cores;

6. A list of all publications and "in press" (not "in preparation") manuscripts that have resulted from the program project grant, with credits to respective components (see Illustration 5). Do not list publications at the end of each component. The applicant must state clearly when publications have resulted from support through more than one funding

source. The reviewers must evaluate the progress and achievements specific to the grant application under review. If this information is unclear, it can affect the review of the application;

7. A list of changes, if any, in professional staffing and how these changes have affected the overall program since the last competitive review; and

8. A list of projects and core units in the current program, the amount of current funding for each, and the requested funding for the first budget period of each component that is requested for continuation in this program project renewal.

C. Progress Report

The progress report for each component should relate specifically to the research supported by this grant and include the following information:

1. Period--the beginning and ending dates for the period covered by the report.

2. Detailed report--a description of the progress relative to the research objectives for period covered by the report, whether or not the work has been published. Adjustment of aims, such as those required due to programmatic adjustments to awards, should be discussed.

V. ADDITIONAL INSTRUCTIONS FOR COMPETING SUPPLEMENT APPLICATIONS

Competing supplements will be funded only for the continuation of projects that were originally funded for a time period shorter than the overall program project. Once a program project is funded, expanding its scientific size through submission of competing supplement applications will not be possible. A supplemental request may be up to 3 percent above the previous year's support for that project(s).

Strong justification must be provided for a program project competing supplement application. It should contain sufficient detail to permit an adequate evaluation of the requested extension of time of projects/cores without having to refer to the parent application.

A letter of intent or direct consultation with NIDDK staff by the principal investigator of the original application may precede the submission of a competing supplement. The named principal investigator of the competing supplement application must be the principal investigator of the parent program project.

In addition to the instructions given in the "PREPARATION OF APPLICATION" section, the following points should be noted for supplemental applications:

A. A competing supplement application will not be accepted before the original application receives an award.

B. The format as described previously for new applications is to be followed for the competing supplement application. Thus, the budgets (Illustrations 2 and 3) described earlier are to be provided, as well as active and pending support. In addition, the funding relationship between the parent grant and the supplemental request is to be shown in table form (Illustration 7). "Current support" is defined as the first budget period of the parent grant to which the supplement would be added.

C. Program Introduction and Statement of Objectives must be included. In addition to the information requested, the reasons for the urgent need for supplemental support must be described.

D. A summary report of progress made in the overall program since the previous competitive review must be discussed. List any publications relevant to the supplemental request using the format in Illustration 5.

E. In the request for extension of ongoing projects and/or cores which were reviewed in the original application, a detailed description of each component for which supplemental funds are requested should be presented in the format previously described for new/renewal applications. Retain the number and letter designations from the current grant. The progress report for each project should include information describing events which led to the need for supplemental support. For extension of ongoing cores, summarize the utilization and value of the core unit during the preceding project period.

VI. ADDITIONAL INSTRUCTIONS FOR REVISED APPLICATIONS

Preparation of a revised (amended) application should follow the instructions provided in the section of this document entitled "PREPARATION OF P01 GRANT APPLICATION." A revised application will be returned if substantive changes are not clearly apparent and identified. Simple deletion of components or aims does not constitute substantive revision. Discussion with NIDDK program staff is encouraged prior to submission. Receipt of a revised application automatically withdraws the prior application.

The following additional guidelines should be followed in the preparation of a revised application:

A. Preceding the Research Plan for the overall program project, provide an Introduction which summarizes the additions, deletions, and changes that have been made.

B. Preceding the Research Plan for each component, provide an Introduction which responds to the criticisms of the previous summary statement and which summarizes changes made in the research plan.

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

D. In all parts of the application, revised portions or passages must be clearly identified to facilitate the review of the revised aspects of the application. The preferred method is to use a vertical line in the margin to mark each revised area of the application.

VII. RECEIPT DATES AND COPY REQUIREMENTS

The receipt dates for both new competing (Type 1) and competing continuation (Type 2) program project grant applications is restricted to two receipt dates per year: June 1 and October 1. Amended and supplemental applications will continue to be accepted three times per year: February 1, June 1 and October 1.

P01 APPLICATIONS: RECEIPT, REVIEW, AND AWARD

Letter of Intent*	Receipt Date for Applications	Initial Review	Council Review	Earliest Possible Start Date
Minimum of 3 months prior to application receipt date	FEB 1	MAY-AUG	SEP	DEC 1
	JUN 1	SEP-DEC	FEB	APR 1
	OCT 1	JAN-APR	MAY	JUL I

*Letter of intent is highly encouraged but is not mandatory.

To maximize the likelihood of the continuity of funding, grantees are encouraged to submit competing continuation applications at least one year prior to termination of the current project period. The original and three copies of the application should be sent or delivered to the following address:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710

BETHESDA, MD 20817 (for express/courier service)

Do not send appendices to the above address.

Two additional copies of the application along with all appendices should be sent to:

CHIEF, REVIEW BRANCH
DIVISION OF EXTRAMURAL ACTIVITIES
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE
AND KIDNEY DISEASES
6707 DEMOCRACY BLVD, ROOM 752
BETHESDA, MD 20892-5452
(for express/courier services: Bethesda, MD 20817)
Telephone: (301) 594-8885

VIII. REPORTING REQUIREMENTS AND ANNUAL EVALUATION

Annual progress reports, submitted as part of the annual non-competing continuation application, are used by the NIDDK and advisory committees to review the program project and its progress. These reports serve to verify in detail the achievement of the objectives outlined in the initial application and award. The NIDDK staff may, as necessary, assemble consultants to review the progress of the program project or to discuss major changes in the program that may require budget adjustments and/or review by the National Advisory Council.

The progress report should describe the progress during the past budget year as indicated under the instructions for competing continuation applications on page 8. This expanded progress report does not replace other management reports required by PHS policy.

IX. REVIEW GUIDELINES

A. General Review Considerations

For a program project application to be assigned a priority score, at least three component projects must be judged to have sufficient scientific merit to receive priority scores. At least three projects must extend for the duration of the program project. The NIDDK is interested in supporting only the best research; individual research projects which are relatively lower in merit may not be funded under the "umbrella" of the program project mechanism. It is primarily for this reason that each project will be assigned a separate priority score, taking into consideration only its merit as an individual research project. It is important that each project fits and contributes to the theme of the overall program project, but this factor should be judged separately and have no bearing on a project's individual priority score. Instead, these considerations will be addressed later with respect to the merit of the overall program project.

It is expected that individual components, in order to receive funding, will not represent significantly poorer research than is being funded by the R01 mechanism. The NIDDK may identify a priority score cut-off for the funding of individual components in a program project. A project whose score is somewhat poorer than currently funded R01s may benefit greatly from inclusion in the overall program project, whereby synergism with other components and use of core facilities significantly enhance its value. Conversely, such a project might provide certain elements which greatly enhance other projects in the overall program project. Such considerations would be expected to have impact on the overall priority score assigned by the reviewers to the program project.

Requested core budgets may need to be adjusted downward if it is recommended that some of the individual projects utilizing their services are reduced in scope or if they are recommended for no further consideration. Therefore, it is important for both the applicant and the reviewer to address the contribution of the core to each project in both scientific and budget terms. Projects may be deleted during second level review (staff and Advisory Council) when they have priority scores significantly lower than those of the other projects within the program project or significantly lower than those of fundable individual research applications of the NIDDK.

All applications except supplements must request and be reviewed for five years of project period support. While one or more projects may be recommended for less than five years, only in very unusual circumstances may the entire program project be recommended for less than five years.

B. Preliminary Scientific Peer Review of Program Project Grant Applications

NIDDK will conduct a preliminary scientific peer review to eliminate those applications that are not competitive. Those applications will be withdrawn from further review without receiving a priority score, and a summary statement including the reviewers' comments will be sent directly to the applicant.

Any questions regarding these procedures may be directed to:

CHIEF, REVIEW BRANCH
DIVISION OF EXTRAMURAL ACTIVITIES
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE
AND KIDNEY DISEASES
6707 DEMOCRACY BLVD, ROOM 752
BETHESDA, MD 20892-5452
(for express/courier services: Bethesda, MD 20817)
Telephone: (301) 594-8886

C. Review of Individual Projects

For each research component judged to have sufficient scientific merit, a priority score is assigned, based on the criteria for the review of individual research projects.

The review criteria for individual research projects are given below:

1. Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

2. Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

4. Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

5. Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

6. Availability of resources necessary for the research;

7. Appropriateness of the timetable in relation to the scope of the proposed research;

8. Adequacy of the proposed means for protecting against or minimizing potential adverse effects upon humans, animals, or the environment; and

9. Adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research.

D. Review of Individual Cores

The review criteria for the individual cores are given below (cores receive merit descriptors rather than numeric scores):

1. Utility of the core to the program project; each core must provide essential facilities or service for two or more projects judged to have substantial scientific merit;

2. Quality of the facilities or services provided by this core (including procedures, techniques, and quality control) and criteria for prioritization of usage;

3. Qualifications, experience, and commitment of the personnel involved in the core; and

4. Appropriateness of the timetable in relation to the scope of the proposed research support.

In the case of the review of a competing continuation (renewal) application, the progress made during the past period of funding is also an important consideration in the review of projects and cores.

E. Review of Overall Program Project

The relationship and contributions of each research component and core (excluding those recommended for no further consideration) to the overall theme of the program project are discussed and evaluated; these points must be clearly and specifically outlined in the summary statement. This should be a separate consideration which is not determined exclusively by the priority scores of the individual projects. Although projects that are not scored are removed from consideration as part of the overall program project, the inclusion of such projects will reflect on the leadership capabilities of the principal investigator/program director.

The overall program project application is evaluated considering the priority-scored projects, supporting cores, and the administrative structure. For a program project to receive a priority score, it must consist of at least three priority-scored individual projects for the duration of the project period. Each core must provide essential functions or services for at least two of these projects.

1. Specific factors to be evaluated in the consideration of the overall program project are as follows:

  a. Scientific merit of the program as a whole, as well as that of individual projects, and its potential impact on the field;
  b. The evaluation of the overall program in terms of significance, approach, innovation, investigators, and environment;
  c. Scientific gain of combining the component parts into a program project (beyond that achievable if each project were to be pursued separately);
  d. Cohesiveness and multidisciplinary scope of the program and the coordination and interrelationship of all individual research projects and cores to the common theme;
  e. Leadership and scientific ability of the principal investigator/program director and his or her commitment and ability to develop a well-defined central research focus and to devote adequate time and effort to the program; and
  f. Past accomplishments of the program or a demonstrated ability in mounting similar programs.

2. Additional criteria for competing continuation (renewal) applications include:
  a. Progress and achievements specific to this program project since the previous competitive review and the evidence through publications, conferences, etc., that collaboration has occurred;
  b. Evidence that the previous specific aims have been accomplished and that the new research goals are logical extensions of ongoing work;
  c. Previous performance and estimated use of the core(s); and
  d. Justification for adding new projects or cores or for deleting components previously supported.

3. Additional criteria for supplemental applications include:
  a. Carefully conceived and explained rationale for extension of currently funded projects; and
  b. Progress made through the program to warrant the extension.

F. Administrative Considerations

For all program project applications (new, competing continuation, and supplemental), in addition to evaluating the scientific components, the review also will assess:

1. Academic environment and resources in which the research will be conducted, including availability of space, equipment, human subjects, animals, or other resources as required, and the potential for interaction with scientists from other departments;

2. Institutional commitment to the requirements of the program, including fiscal responsibility and management capability of the institution to assist the principal investigator/program director and his or her staff in following DHHS, PHS, and NIH policy;

3. Administrative planning and leadership capability to provide for internal quality control of ongoing research, allocation of funds, enhancement of internal communication and cooperation among the investigators involved in the program, and replacement of the principal investigator/program director if required on an interim or permanent basis;

4. Appropriateness of the budget in relation to the proposed program; and

5. Human subjects protection, animal welfare, and biohazard issues.

G. Final Recommendation

If the overall program project is judged to have sufficient merit, a priority score will be assigned based on the application's merit as a program project. This score is not the average of the priority scores assigned to the individual components. If a component project lacks sufficient scientific merit, it will receive neither a priority score nor a budget recommendation, and it will not be considered in the assignment of an overall priority score.

It is possible that one or more of the components will have excellent scientific merit but fit poorly, or not at all, within the program project. Such projects may be deleted from the program project and thus would be omitted from consideration when assigning the final priority score to the overall program project. Conversely, components with relatively poorer scientific merit may contain parts that would strengthen or bridge other proposed projects. Therefore, the review committee specifically should address the value of each project to the overall program project and the resultant synergy.

ILLUSTRATION 1

NIDDK PROGRAM PROJECT GRANT APPLICATION

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3. Breakdown of composite budget (Illust.-3)
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G. Overall Research Plan***
    Introduction to Revised Application
    Introduction to Supplemental Application
1. Program introduction and statement of objectives
2. Institutional environment and resources
3. Organizational & administrative structure of Program Project
4. Specific managerial responsibilities
5. Designation of replacement for Program Director
6. Relation of the Program Project organization and administration to the applicant institution
7. Summary report of progress (Renewal Applications)
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H. Research Projects
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        Project Director
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    Core #. Title of Core
        Project Director
        Budget
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J. Checklist (398-II)
K. Appendix (Five collated sets - No page numbering necessary)

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

Check if Appendix is included ☐

Illustration 2

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) Project 4 ($2,500)	Core Unit A ($1,500) 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
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page)		$383,100
PHS 398 (Rev. 1/99)		

Composite Budget
For Budget Period ___________*

ILLUSTRATION 3

Projects and Core Units	Personnel	Consultant	Equipment	Supplies	Travel	
					Domestic	Foreign
Project 1	33,000	0	25,000	3,500	1,250	0
Project 2	22,000	1,000	19,500	8,000	1,250	0
Project 3	27,500	0	15,000	0	1,250	0
Project 4	16,500	0	0	10,000	1,250	0
Project 5**	0	0	0	0	0	0
Core Unit A	24,200	2,000	20,400	2,400	0	0
Core Unit B	11,000	0	0	6,600	0	0
TOTAL	134,200	3,000	79,900	30,500	5,000	0

Projects & Core Units	Patient Care Costs Inpatient	Patient Care Costs Outpatient	Alterations and Renovations	Other Expenses	Consortium Costs	
Project 1	0	0	0	1,000	0	63,750
Project 2	0	0	0	1,500	0	53,250
Project 3	0	0	0	3,000	0	46,750
Project 4	0	0	0	2,500	0	30,250
Project 5**	0	0	0	0	70,000	70,000
Core Unit A	0	0	50,000	1,500	0	100,500
Core Unit B	0	0	0	1,000	0	18,600
TOTAL	0	0	50,000	10,500	70,000	383,100

** Project 5 is a Consortium agreement

Illustration 4

JJ Principal Investigator/Program Director (Last, first, middle): ______________________________

REQUESTED PERSONNEL (1st year only)

All Personnel for the Initial Budget Period

Name	Degree(s)	Project/Core #	Role on Project (e.g. PI, Res. Assoc.)	Annual % Effort
G. Shultz	Ph.D.	Project 1	Project Leader	15%
		Project 2	Co-investigator	10%
		Core A	Core Leader	10%
P. Pennington	M.D.	Project 2	Principal Investigator	20%
		Project 3	Co-investigator	5%
		Core B	Core Leader	15%
N. Rogers	Ph.D.	Project 3	Project Leader	25%
		Project 4	Co-investigator	5%
Y. Chui	Ph.D.	Project 4	Project Leader	15%
S. Hansen-Bahr	M.D., Ph.D.	Project 5	Project Leader	25%
J. Gonzales	M.S.	Core A	Technician	35%

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ILLUSTRATION 5

Publications Citing Support from this Program Project Grant

Contributing Projects/Cores

Project Number and P.I. Name	Publications	Project 1	Project 2	Project 3	Core A	Core B
1. Brown	Brown, A.C; Jones R.C.; Smith, A.J. The control of gluconeogenesis. Diabetes, 1995	P		S	S	
	Brown, A.C.; Cheng, A.G.; Anderson, J.C. Futile cycling in noninsulin-diabetes mellitus. Endocrinology, 1994	P	S		S	
	Smith, A.J.; Brown, A.C. Regulation of fatty acid metabolism in diabetic animals. Diabetologia, 1993	P		S		S
2. Cheng, A.C.	Cheng, A.C.; Meyer, G.C. Relationship between hyperglycemia and hepatic glucose production. Diabetes, 1995.	S	P		S	
	Smith, F.G.; Cheng, A.C.; Role of insulin in tissue metabolite transport. Endocrinology, 1994		P	S		S

*List each publication only once under the project number most significantly contributing to the work. The project most significantly contributing to the work should be signified by a P (primary). All other contributing projects and cores are designated by an S (secondary).

ILLUSTRATION 6

DISTRIBUTION OF CORE UNIT COSTS AMONG RESEARCH PROJECTS

Projects	Core Unit A	Core Unit B	Core Unit C	Core Unit D
Project 1	$ 3,000		$1,500	
Project 2	$ 4,000	$ 6,000	$1,500	
Project 3	$ 3,000		$2,500	$5,500
Project 4	$10,000	$ 6,000	$1,500	$2,500
TOTALS	$20,000	$12,000	$7,000	$8,000

ILLUSTRATION 7

RELATIONSHIP BETWEEN PARENT GRANT AND SUPPLEMENTAL REQUEST

(For Project Year -04: 1/1/95 to 12/31/96)

Title and Number of Project and Core Unit	Current Support*	Supplemental Funds Requested for Extension of Project(s)	Total (Direct Costs Only)
Project 1 Synthesis of Peptides	37,500		37,500
Project 2 Receptor Sites	-0-	49,460	49,460
Project 3 Biosynthesis	39,825		39,800
Project 4 Clinical Pharmacology	16,635		16,365
Project 5 Animal Models	36,000		36,000
Project 6 Pathological Lesions	22,000		22,000
Core Unit A Administration	29,320		29,320
Core Unit B Electron Microscopy	15,000		15,000
Totals	196,280	49,460	245,740

* □Current Support□ is the first budget period of the parent grant to which the supplement would be added. In this case, it would be the upcoming -04 budget year (1/1/95 to 12/31/96) for which funds for Project 2 were not awarded.