

Administrative and Review Guidelines for Program Project Grant Applications

These guidelines supplement the Program Announcement [PAR-11-043](#) and serve applicants, members of peer review groups, and NIDDK staff. The NIDDK appreciates the time and effort that goes into preparing and reviewing a Program Project application. Early communication with NIDDK program and review staff is essential for a successful application and project. The goal of these guidelines is to clearly communicate NIH and NIDDK policies to facilitate the application and review processes in order to best support high priority science.

Contents

| | |
|---|----------|
| I. Description of the Program Project Grant | 2 |
| II. Pre-Application Procedures | 3 |
| A. <i>Communication with NIDDK Staff</i> | 3 |
| B. <i>Approval Process in Order to Submit a P01 Application</i> | 3 |
| III. Preparation of P01 Grant Application | 4 |
| A. <i>Form</i> | 4 |
| B. <i>Instructions</i> | 4 |
| 1. <i>Face Page</i> | 4 |
| 2. <i>Table of Contents</i> | 5 |
| 3. <i>Composite Budget</i> | 5 |
| 4. <i>Biosketches</i> | 5 |
| 5. <i>Overall Research Plan</i> | 5 |
| 6. <i>Research Projects</i> | 6 |
| 7. <i>Cores</i> | 7 |
| 8. <i>Appendix</i> | 7 |
| IV. Additional Instructions for Renewal Applications | 7 |
| V. Additional Instructions for Resubmission (Amended) Applications | 8 |
| VI. Receipt Dates and Copy Requirements | 8 |
| VII. Reporting Requirements and Annual Evaluation | 9 |
| VIII. Review Guidelines | 9 |
| A. <i>General Review Considerations</i> | 9 |
| B. <i>Review Criteria for Individual Research Projects</i> | 9 |
| C. <i>Review of Individual Cores</i> | 12 |
| D. <i>Review of Overall Program Project</i> | 12 |

| | |
|---------------------|----|
| Illustration 1..... | 15 |
| Illustration 2..... | 16 |
| Illustration 3..... | 17 |
| Illustration 4..... | 18 |
| Illustration 5..... | 19 |

I. Description of the Program Project Grant

The basic criteria for a program project are:

1. A clearly defined, unifying **central theme** to which each project relates and to which each investigator contributes. The program project 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). A program project also differs from a Collaborative Interdisciplinary Team R24 grant where the research addresses a single question. More information on grant mechanisms supported by NIDDK can be found at [Types of Grants Funded by the NIDDK](#).
2. The interrelationships of projects and collaborations among investigators will yield **synergy** and results beyond those achievable if each project were to be pursued independently.
3. A **principal investigator**/program director who is an established research scientist and who has the experience, ability, and time commitment to ensure quality control, effective administration and integration of all components of the program project. If multiple PD/PIs are proposed, investigators should be aware that any New Investigator named as PD/PI will lose his or her New Investigator status.
4. Leadership of each research project by an **experienced investigator** with an established record of productivity and independent funding. The participation of experts in several disciplines or in several areas of one discipline should greatly enhance the goals of the program project. All investigators must contribute to, and share in, the responsibilities of fulfilling the program objectives.
5. A minimum of **three projects** that are judged to have significant scientific merit, as well as being complementary and contributory to the central theme of the program project. Investigators are allowed to submit a project as an R01 application and as part of the program project for review in the same review cycle. If such a project were to receive impact/priority scores that merit funding of both the R01 and P01 applications, funding of the project in the program project will take precedence, and the R01 application will be inactivated administratively.
6. One or more research **core facilities** that provide services to at least two research projects. Administrative cores, except in special, well-justified circumstances, will not be allowed.

The NIDDK has adopted the following policies to balance the needs of individual program projects with the overall priorities of the Institute.

1. New (Type 1) and renewal (Type 2) program project applications have an absolute cap of \$6.25 million in direct costs requested for 5 years. The indirect costs related to subcontracts will be excluded from the requested direct cost levels prior to application of the cap.
2. The NIDDK envisions that only rarely, if ever, will applications request less than \$500,000 in direct costs per year for all years. Therefore, most, if not all, applications must obtain agreement before submission of a new, renewal or resubmission application. Potential applicants are strongly recommended to contact NIDDK while they are still in the process of developing conceptual plans for an application and at least 3 months before the receipt date.
3. Minimum recommended levels of effort for the overall P01 application are three person months for a single PD/PI or an aggregate of three months with multiple PD/Pis and 1.2 person months for individual project leaders.
4. Any P01 grant receiving a competing award in FY 2011 or later will be limited to one subsequent renewal. For example, if a P01 grant in its 20th year is successfully renewed in 2012, only one additional competing renewal will be allowed. New P01 grants are allowed one competing renewal for a maximum project duration of 10 years.

II. Pre-Application Procedures

A. Communication with NIDDK Staff

Early communication between the potential applicant group and a NIDDK program director is critical for the development of a successful P01 application and is required for the NIDDK to accept a P01 application. These discussions should start a minimum of six months and ideally at least **nine months** before submitting the application and may include the choice of funding mechanism for the proposed science; relevance of the topic to the NIDDK mission; the scope and approach of the project and cores; and the organization of the application. [Scientific areas within the NIDDK mission and program staff contact information](#).

B. Approval Process in Order to Submit a P01 Application

NIH requires that all applications (both new and competing renewal) requesting more than \$500,000 in direct costs in any year obtain approval from the appropriate Institute before the application can be accepted for review. Given the large budgetary commitment to a program project, the NIDDK reviews these requests based on their relevance to high priority areas within the Institute.

A written “request for preapproval” is due at least **3 months** prior to the [application receipt date](#). The request can be sent as a single attachment to an email or by regular mail to the Program Director who is the point of contact for the application.

The “request for preapproval” should contain:

- a. A project description (abstract).
- b. Summary of the overall project that includes the unifying scientific theme, background, rationale and significance of the application and an overview of the scientific design. A statement on how the synergy and interrelatedness among the projects and cores will move the field forward should be included. If the application is a renewal, the summary should provide specific examples of accomplishments of the projects (5 pages).
- c. Specific aim page for each individual project and core (1 page each).
- d. Biosketches (including other research support) of all the project and core leaders..
- e. A complete budget on a PHS 398 form ([Illustration 2](#)).
- f. For renewals, a list of publications that derived from the P01 grant.

The following criteria will be used in the administrative staff review of these requests:

- a. Relevance to the NIDDK: Importance of the unifying central theme to the NIDDK mission.
- b. Programmatic priority: Will the proposed research significantly advance the mission of NIDDK?
- c. Programmatic balance: How does the proposed research relate to currently funded research in the NIDDK and by the investigative team?
- d. Grant Mechanism: Are there at least three discrete projects and a core that serves at least two projects? Is the proposed work appropriate for the P01 grant mechanism?”

If the NIDDK agrees to accept an application, a cover letter should be included with the application that identifies the NIDDK program staff who agreed to accept assignment of the application to the NIDDK. The NIDDK will also notify the NIH Receipt and Referral office of the willingness to accept the application.

III. Preparation of P01 Grant Application

A. Form

The [PHS Form 398](#) is available online and must be used for submitting a program project application.

B. Instructions

The instructions modify and expand sections of the [PHS Form 398](#) that are specific to NIDDK program project applications. These instructions are meant to be used with the PHS Form 398 instructions and the [program announcement](#) for NIDDK P01 grants.

1. **Face Page, Page 1:** For Box 2, check Yes and include the Number, PAR-11-043 and Title, NIDDK Program Project Applications (P01).

2. **Table of Contents:** Use the format as described in [Illustration 1](#).
3. **Composite Budget:** New (Type 1) and renewal (Type 2) program project applications cannot request more than \$6.25 million in direct costs over 5 years. The indirect costs related to the subcontracts will be excluded from the requested direct cost levels prior to application of the cap.

Composite budgets 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 the Detailed Budget for First 12-Month Budget Period. Omit budget justifications on this page, but include them with the individual project budgets.
 - c. A requested personnel table, listing all key personnel including those for whom no salary is requested ([Illustration 3](#))
4. **Biosketches:** The biosketch for the PD/PI is placed first and then all the biosketches for key personnel are placed in alphabetical order. Biosketches should only be placed here and not with the individual projects.
 5. **Overall Research Plan:** Using continuation pages, substitute the following for the Research Strategy instructions of PHS Form 398. For new applications, the overall research plan consists of the overall research strategy that covers points a-d below (12 page limit). For resubmission applications, the overall research plan consists of an introduction (one page limit) and the overall research strategy. For renewal applications, the overall research plan consists of the overall research strategy and includes a table with publications cited by the program project during its previous funding period ([Illustration 5](#)) (no page limits).

The overall research strategy includes:

- a. **Program Introduction and Statement of Objectives:** Present the background, rationale and hypothesis of the central scientific theme and the specific objectives that address questions based on this central theme. Explain the strategy for achieving the objectives of the overall program.
- b. **Organization and Synergy of the Program Project:** Describe the relationships among the project and cores and their contribution to the overall strategy. Describe the unique advantages that would be gained by the proposed program project, the synergy among the projects and the means by which the projects collectively will achieve the stated objectives of the proposed research. For new (Type 1)

applications, this section should indicate prior collaborative arrangements among investigators in the group. For renewal (Type 2) applications, [additional items](#) should be included.

- c. **Institutional Environment and Resources:** Briefly describe the features of the institutional environment that would facilitate effective implementation of the program project. 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. If the projects are not at the same location, describe the plans for communication and sharing of biologic material.
 - d. **Relation of the Program Project Organization to the Applicant Institution:** Describe the relationships among the proposed program project and other existing research units at the applicant institution. List any NIDDK-supported center or program project at the applicant institution and their relationship with the proposed program project. Indicate if any of the proposed cores will utilize or expand cores already existing at the institution.
6. **Research Projects:** Use a separate PHS Form 398 for each project and follow the instructions, as modified below. Each project should begin with a cover page consisting of the project number, title, and name of the project leader and key personnel. This should be followed by all the sections of the PHS 398 form with the exception that biosketches are omitted. Describe each project in the same detail and format as required for a regular research grant (R01) application so that the scientific merit can be judged on the basis of the written application. The page limits of an R01 application apply to the research projects. As described under "General Review Considerations," impact 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 peer reviewers to understand and evaluate each project independently.

If human subjects or vertebrate animals will be used in a project, the necessary information must be supplied with that project description.

Each project is required to comply with resource sharing plans ([Data Sharing Plan](#); [Sharing Model Organisms](#); and [Genome Wide Association Studies \(GWAS\)](#)), as applicable. These resource sharing plans can be included with the individual projects or with the overall research plan, if the resource sharing is the same across the projects.

Program project grant applications do not utilize modular budgets. A detailed budget is required for the first year; and total budget numbers 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.

7. **Cores:** Use a separate PHS Form 398 and follow the [instructions](#) except as noted here. The cover page should include the core number, title, and names of the project leader and key personnel. Provide a detailed budget for each core in the same way as for each project. Include the distribution of core unit costs among the projects as shown in [Illustration 4](#). Cores should provide services to at least two research projects.

In the core research strategy, describe the core 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 research strategy should also 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.

The core description and specific aims are limited to one page each and the core research strategy to six pages.

Administrative cores, except in special, well-justified circumstances, will not be allowed.

8. **Appendix:** List all appendix material to accompany the application on the Table of Contents and follow the instructions for the PHS 398 form. Up to three publications per project or core of the types listed in the PHS 398 instructions are allowed.

Send all appendices (five CDs) to [Chief, Review Branch, NIDDK](#), with two copies of the application.

IV. Additional Instructions for Renewal Applications

The PHS 398 instructions should be followed with the following clarifications. The **overall research strategy** within its 12 page limit should include a progress report that includes:

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. The rationale for adding new projects or cores, deleting a project or core, or changing the key personnel.

After the overall research strategy include a table of publications that directly resulted from the program project since it was last reviewed using the format of [Illustration 5](#).

The **individual projects** should include a progress report in the research strategy section and the Progress Report Publication List as described in the [PHS 398 Form instructions](#).

V. Additional Instructions for Resubmission (Amended) Applications

Preparation of a resubmission application should follow the [PHS 398 instructions](#) with the following additional guidelines:

1. The Overall Research Strategy should include a one-page introduction that summarizes the changes that have been made from the previous submission.
2. Preceding the Research Strategy for each project or core, provide a one-page Introduction that responds to the criticisms raised in the previous review and summarizes changes made in the research plan.
3. Substantial scientific changes must be marked in the text of the application by bracketing, indenting, or changing typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction.

VI. Receipt Dates and Copy Requirements

The standard [receipt dates](#) for program project applications are used. The continuous submission process does not apply to P01 applications.

The original and three copies of the completed application should be mailed to the Center for Scientific Review; an address label is included in the PHS Form 398 application information. In addition, two paper copies of the application and five CD copies of the appendices should be sent directly to the Chief, Review Branch, NIDDK.

**Chief, Review Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Two Democracy Plaza, Room 752
6707 Democracy Boulevard, MSC 5452
Bethesda, MD 20892-5452. For courier/express delivery, please use 20817 Zip code
Phone: (301) 594-8897**

Fax: (301) 480-3505 or (301) 480-4126

VII. Reporting Requirements and Annual Evaluation

A non-competing continuation application should be submitted on the [PHS 2590 form](#). Each project should submit a complete PHS 2590 and the forms from all projects submitted as a single packet.

Annual progress reports, submitted as part of the annual, noncompeting, renewal application, are used by the NIDDK to review the progress of the program project. These reports serve to verify, in detail, the achievements of the objectives outlined in the initial application. 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 NIDDK Advisory Council.

VIII. Review Guidelines

A. General Review Considerations

For a program project application to be assigned an overall impact score, at least three component projects that extend for the duration of the program project must have been judged to have sufficient scientific merit and received impact scores. The NIDDK is interested in supporting only the best research; individual research projects that are relatively lower in merit may not be funded under the "umbrella" of the program project mechanism. Therefore, each project will be assigned a separate impact score, taking into consideration only its merit as an individual research project. Each project must fit and contribute to the theme of the overall program project, but these factors are judged separately and have no bearing on a project's individual impact 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, should in general receive impact scores similar to those for funded R01 grants. However, a project whose score is somewhat poorer than currently funded R01 grants may contribute significantly to the overall program project, whereby synergism with other components and use of core facilities significantly enhance its own value and the value of the other projects. Such considerations would be expected to have an impact on the overall impact score assigned by the reviewers to the program project.

Both the applicant and the reviewers should address the contribution of requested cores to each project in both scientific and budget terms.

Questions on the review process for program projects should be addressed to the [Chief of the NIDDK Review Branch](#).

B. Review Criteria for Individual Research Projects

Reviewers will provide an overall impact score for each project to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

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

Significance

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

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

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

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

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of

the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria. As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

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

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

Inclusion of Women, Minorities, and Children. When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

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

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

Resubmissions. For Resubmissions, the reviewers will evaluate the projects as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made.

Renewals. For Renewals, the committee will consider the progress made in the last funding period.

Additional Review Considerations. As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in arriving the overall impact score.

Applications from Foreign Organizations. Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

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

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

C. Review of Individual Cores

The review criteria for the individual cores are given below (cores receive merit descriptors rather than numeric scores, and individual criterion scores are not provided):

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.
5. For renewals, the reviewers will consider the progress made in the last funding period.
6. If human subjects, vertebrate animals, or biohazards are to be used in the core, the adequacy of these sections must be assessed and will be considered in determining the score of the individual core.

D. Review of Overall Program Project

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the program project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the

project proposed).

The relationship and contributions of each research component and core to the overall theme of the program project will be discussed and evaluated. These points must be clearly and specifically outlined in the critique of the overall program project. This should be a separate consideration which is not determined exclusively by the impact scores of the individual projects and cores.

1. Specific factors to be evaluated in the consideration of the overall program project are:
 - 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, innovation, investigators, approach, 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 (request of support for sufficient effort to provide effective oversight and administration of the program should be considered); and
 - f. Past accomplishments of the program or a demonstrated ability in mounting similar programs.
2. Additional criteria for renewal (competing continuation) applications include:
 - a. Progress and achievements specific to this program project since the previous 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 Review Considerations –Reviewers will consider the Resource Sharing

Plans, but will not give a score for it and should not consider it in providing an overall impact score. They will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) [Data Sharing Plan](#); 2) [Sharing Model Organisms](#); and 3) [Genome Wide Association Studies \(GWAS\)](#).

Illustration 1

NIDDK PROGRAM PROJECT GRANT APPLICATION

TABLE OF CONTENTS

| | Page Numbers |
|---|--------------|
| A. Face Page (398-Form Page 1) | 1 |
| B. Description, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells..... | 2 |
| C. Table of Contents (Illustration 1) | |
| D. Composite Budget | |
| 1. Detailed Budget for Initial Budget Period (Illustration 2; 398 Form Page 4) | |
| 2. Budget for entire proposed project period (398-Form Page 5)..... | |
| 3. Requested effort for Key Personnel for the first year (Illustration 3)..... | |
| E. Biographical Sketches (PD/PI first, then key personnel in alphabetical order; only include in this section) | |
| F. Overall Research Plan | |
| Introduction to a Resubmission Application (one page limit) | |
| Overall Research Strategy (twelve page limit) | |
| 1. Program introduction and statement of objectives..... | |
| 2. Organization of the program project | |
| 3. Institutional environment and resources | |
| 4. Relation of the program project organization to the applicant institution | |
| Table of publications citing the program project, (for renewal applications, Illustration 5) | |
| G. Research Projects | |
| Introduction to a Resubmission Application (one page limit) | |
| Cover Page (include project number, project leader and key personnel) | |
| Project Description (one page limit) | |
| Budget | |
| Specific Aims (one page limit) | |
| Research Strategy (twelve page limit) | |
| References | |
| H. Core Facilities | |
| Introduction to a Resubmission Application (one page limit) | |
| Cover Page (include core number, project leader and key personnel) | |
| Budget | |
| Distribution of Core Unit Costs Per-Project Table (Illustration 4) | |
| Core Description (one page limit)..... | |
| Core Specific Aims (one page limit) | |
| Core Research Strategy (six page limit) | |
| References | |
| I. Checklist (398-II)..... | |
| J. Appendix (Five CDs) | |

Check if Appendix is included

Delete any headings not applicable

Illustration 2

| Principal Investigator/Program Director (Last, first, middle): _____ | | | | | | | | | |
|--|-------------------------------|---------------------------|-------------|--------------|--------------------------------------|------------------|-----------------|------------------|---------|
| DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY | | | | | FROM | THROUGH | | | |
| PERSONNEL (Applicant organization only) | | Months Devoted to Project | | | DOLLAR AMOUNT REQUESTED (omit cents) | | | | |
| NAME | ROLE ON PROJECT | Cal. Mnths | Acad. Mnths | Summer Mnths | INST.BASE SALARY | SALARY REQUESTED | FRINGE BENEFITS | TOTALS | |
| Project 1 | | | | | | 60,000 | 6,000 | 66,000 | |
| Project 2 | | | | | | 25,000 | 2,500 | 27,500 | |
| Project 3 | | | | | | 30,000 | 3,000 | 33,000 | |
| Project 4 | | | | | | 20,000 | 2,000 | 22,000 | |
| Core Unit A | | | | | | 42,000 | 4200 | 46,200 | |
| Core Unit B | | | | | | 15,000 | 1,500 | 16,500 | |
| SUBTOTALS | | | | | | 192,000 | 19,200 | 211,200 | |
| CONSULTANT COSTS | | | | | | | | | |
| Project 2 | (\$5,000) | | | | | | | | |
| Core Unit A | (\$3,000) | | | | | | | | 8,000 |
| 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 | 5,500 | | | | | | | | |
| Project 2 | 8,000 | | | | | | | | |
| Project 3 | 1,000 | | | | | | | | |
| Project 4 | 10,000 | | | | | | | | |
| Core Unit A | 7,400 | | | | | | | | |
| Core Unit B | 6,600 | | | | | | | | 38,500 |
| TRAVEL | \$1,250 each for Projects 1-4 | | | | | | | | 5,000 |
| PATIENT CARE COSTS | | INPATIENT | | | | | | | 50,000 |
| | | OUTPATIENT | | | | | | | 10,000 |
| ALTERATIONS AND RENOVATIONS (Itemize by category) | | | | | | | | | |
| OTHER EXPENSES (Itemize by category) | | | | | | | | | |
| Project 1 | (\$2,000) | | | | | | | | |
| Project 2 | (\$1,500) | | | | | | | | |
| Project 3 | (\$3,500) | | | Core Unit A | (\$1,500) | | | | |
| Project 4 | (\$2,500) | | | Core Unit B | (\$1,000) | | | 12,000 | |
| SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Cover Page) | | | | | | | | \$414,600 | |
| CONSORTIUM/CONTRACTUAL COSTS | | DIRECT COSTS | | | PROJECT 4 | | | | 106,000 |
| | | INDIRECT COSTS | | | PROJECT 4 | | | | 34,000 |
| TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD | | | | | | | | \$554,600 | |

Illustration 3

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. PD/PI, Res. Assoc.) | Annual Effort (Person Months) |
| G. Shultz | Ph.D. | Project 1 | Project Leader | 1.8 |
| | | Project 2 | Co-investigator | 1.2 |
| | | Core A | Core Leader | 1.2 |
| P. Pennington | M.D. | Project 2 | Principal Investigator | 2.4 |
| | | Project 3 | Co-investigator | 0.6 |
| | | Core B | Core Leader | 1.8 |
| N. Rogers | Ph.D. | Project 3 | Project Leader | 3.0 |
| | | Project 4 | Co-investigator | .06 |
| Y. Chui | Ph.D. | Project 4 | Project Leader | 1.8 |
| | | | | 4 |

Page _____

Illustration 4

Distribution of Core Unit Costs among Research Projects

Core A – (Title of Core)

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|------------------|---------------|---------------|---------------|---------------|---------------|
| Project 1 | \$30,000 | \$33,000 | | \$20,000 | \$32,000 |
| Project 2 | \$35,000 | \$50,000 | \$46,000 | \$20,000 | \$15,000 |
| Project 3 | | \$20,000 | \$30,000 | \$29,000 | \$15,000 |
| Project 4 | \$35,000 | | \$30,000 | \$40,000 | \$50,000 |
| TOTALS | \$100,000 | \$103,000 | \$106,000 | \$109,000 | \$112,000 |

Illustration 5

**Publications Citing Support from this Program Project Grant
During the Project Period From (Month/year) to (Month/year)**

Contributing Projects/Cores

| Project Number and P.I. Name | Publications | Project 1 | Project 2 | Project 3 | Core A | Core B | Other funding (note type) |
|-------------------------------------|---|------------------|------------------|------------------|---------------|---------------|----------------------------------|
| 1. Brown | Brown, A.C.; Jones R.C.; Smith, A.J. The control of gluconeogenesis. Diabetes, 2008 | P | | S | S | | S (R01 DK12345) |
| | Brown, A.C.; Cheng, A.G.; Anderson, J.C. Futile cycling in noninsulin-diabetes mellitus. Endocrinology, 2009 | P | S | | S | | |
| | Smith, A.J.; Brown, A.C. Regulation of fatty acid metabolism in diabetic animals. Diabetologia, 2009 | P | | S | | S | |
| 2. Cheng, A.C. | Cheng, A.C.; Meyer, G.C. Relationship between hyperglycemia and hepatic glucose production. Diabetes, 2007 | S | P | | S | | S (JDRF grant) |
| | Smith, F.G.; Cheng, A.C.; Role of insulin in tissue metabolite transport. Endocrinology, 2008 | | P | S | | S | |

***List each publication only once under the project number most significantly contributing to the work and mark with a "P" for primary. All other contributing projects and cores are designated by an "S" for secondary.**