DIABETES ENDOCRINOLOGY RESEARCH CENTERS

DIABETES RESEARCH AND TRAINING CENTERS

ADMINISTRATIVE GUIDELINES

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

January 2009

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I. DESCRIPTION

Background

The NIDDK-supported Diabetes Endocrinology Research Centers (DERCs) and Diabetes Research and Training Centers (DRTCs) are part of an integrated program of diabetes and related endocrinology and metabolism research. Centers provide increased, cost effective, collaboration among multidisciplinary groups of investigators at institutions with an established, comprehensive research base in diabetes and related areas of endocrinology and metabolism. DERCs and DRTCs are intended to improve the quality and multidisciplinary nature of research on diabetes by providing shared access to specialized technical resources and expertise.

General Description

Both DERCs and DRTCs are intended to facilitate progress in research with the goal of developing new methods to treat, prevent and ultimately cure diabetes mellitus and its complications. Both DERCs and DTRCs support research cores that provide shared resources to enhance the efficiency of biomedical research and foster collaborations within and among institutions with established, comprehensive bases of research relevant to diabetes mellitus. Both types of Center also support a Pilot and Feasibility Program and an Enrichment Program. DRTCs differ from DERCs in that they provide additional support for cores and pilot and feasibility projects directed at prevention and control of diabetes. These should focus on translation of research advances into clinical practice.

The objectives of the Centers are to bring together investigators from relevant disciplines in a manner that will enhance and extend the effectiveness of their research. In addition to collaborations between scientists within an institution, core centers can foster interaction and collaborations between investigators at multiple institutions to promote a multifaceted approach to a common goal. A core center must be an identifiable unit within a single university medical center or a consortium of cooperative institutions, including an affiliated university. An outstanding existing program of biomedical research in the area of diabetes is required. This research should be in the form of NIH-funded research projects (R01), program projects (P01), or other peer-reviewed research, such as that supported by the American Diabetes Association and the Juvenile Diabetes Research Foundation. This established research program must be in existence at the time of submission of a Center application. Research programs outside the primary institution where the Center is based may utilize the core resources. The base of research projects to be served by the cores must be clearly defined and justified in the application. The research base for the Center must consist of at least $3,000,000 of peer-reviewed research projects. Efficient management of resources and close cooperation, communication, and collaboration among involved personnel in multiple professional disciplines are ultimate objectives of core centers.

Basic Requirements for a P30 Core Center

To be eligible for a Core Center grant, the potential applicant institution must already have a substantial base of ongoing, independently-supported, high-quality research in diabetes and related areas of endocrinology and metabolism. The research base for a core center is made up of investigators with individually-funded research projects who can benefit from shared resources. Core center funding will provide core facilities (shared resources), pilot and feasibility studies (new initiatives), and program enrichment activities. Except for pilot and feasibility studies, core center funds are not intended to support individual biomedical research projects other than through core usage. The major source of support for biomedical research projects associated with the Center should be derived from separately-funded projects of the participating investigators. Similarly, professional trainee stipends are not to be supported through core center funding.

A Core Center may serve a single institution or a consortium of institutions engaged in a collaborative approach to research on diabetes. Cores may be based solely at the applicant institution or at multiple institutions through subcontracts. If subcontracts are to be utilized the applicant must clearly demonstrate how a cohesive and integrated operation will be ensured and describe the advantages of this approach to the performance of Core functions. The Core Center may also provide resources for funded projects at collaborating institutions without a subcontractual arrangement with the parent institution. If such projects are to be included in the research base, the applicant must clearly describe and justify the reasons why it is appropriate for these projects to be included in the research base and the advantages to be derived from the collective utilization of the Core Center.

At the time of initial submission, the applicant institution or consortium of institutions must have an active program of excellence in basic and clinical biomedical research in the area of diabetes and related areas of endocrinology and metabolism. **The biomedical research base will be given primary consideration in the peer review process**. There should be a focus on diabetes, however, related endocrinology and metabolism research relevant to diabetes may also be supported and included in the research base. Focus, relevance, interrelationships, quality, and to some extent quantity, are all considerations in judging the adequacy of the research base.

Basic Requirements for a P60 Core Center

All the elements (see above) required for a P30 Core Center are also required for a P60 Core Center. The following additional requirements for DRTCs should be noted. The research base of the DRTC must include a substantial focus on research directed at translation of research advances in the area of diabetes into clinical practice. DRTCs must request substantial support for cores and pilot and feasibility projects directed at prevention and control of diabetes. The cores and pilot and feasibility projects directed at prevention and control of diabetes should focus on translation of research advances into clinical practice. This includes the identification of barriers to widespread adoption of

new science and the development and testing of interventions to overcome these barriers under real world conditions. Applicants are encouraged to focus on underserved populations disproportionately affected by diabetes in the cores and pilot and feasibility projects directed at prevention and control of diabetes.

II. ADMINISTRATIVE CORE COMPONENT

Description

The DERC or DRTC must be an identifiable organizational unit within a university medical center or a consortium of cooperating institutions including the university-affiliated Center. Such a Center will involve the interaction of broad and diverse elements; thus, lines of authority and approval by the appropriate institutional officials must be clearly specified. The administrative core plays a key role in the coordination and functioning of the center.

Requirements

Each applicant institution specifies a Core Center Director to be responsible for the scientific and administrative leadership of the Center. The Director should be an experienced and respected scientist with a proven track record for obtaining NIH funding. He/she must be able to coordinate, integrate, and provide guidance in the establishment of new programs in diabetes and related research. The Core Center Director should provide at least 10% effort on the Administrative Core and a total of 20% effort distributed among the Administrative and other components of the Center. One or more Associate Directors should be named who will be involved in the administrative, scientific, or training efforts of the center and will serve as Acting Center Director in the absence of the Director. A process must be in place that would be used to recommend a successor to the Director, if needed. An administrative assistant may also be proposed.

It is expected that the organization of the Administrative core should encompass a supportive structure sufficient to ensure accomplishment of the following: coordinating and integrating the Center components and activities; overseeing the solicitation, review and selection of pilot and feasibility studies; reviewing the utilization and quality of core resources; interacting with the scientific and lay communities and the NIDDK in order to develop relevant goals for the Center; and interacting with the administrative and scientific leadership at the applicant institution(s) to enhance the visibility and effectiveness of the center as a focus for diabetes research.

The final administrative structure of the Center will be left largely to the discretion of the applicant institution (subject to review by NIH peer review mechanisms). However, NIH's experience has demonstrated that the effective development of the Center programs require close interaction between the Center director, the principal investigators, appropriate institutional administrative personnel, the staff of the awarding agency, and the members of the community in which the Center is located. Therefore, each Center applicant should establish an administrative structure that will permit the

development of such interaction. Within this structure, each applicant institution must also establish a mechanism to oversee the use of funds for the proposed pilot and feasibility program. This mechanism must include the use of appropriate consultants for review from the scientific community outside the Center institution. Consultants who will serve on advisory committees should not be specifically identified in the application but the process by which they will be selected should be described. These same consultants may be utilized, if desired, for review of other activities of the Center. The mechanism for reviewing the use of the pilot and feasibility funds will be considered by the initial review groups in the evaluation of the Center applications. Further details regarding this mechanism will be found below in the discussion of the pilot and feasibility program. The projects selected to receive these funds will be described by the Centers in their annual reports and will be given special attention by the NIDDK in its annual evaluation of the Center program. The Center grant may also include limited funds for program enrichment (i.e., seminars, etc.) that should be included in this core.

The initial base of research projects to be served by the cores must be clearly defined in the application. The process by which additional projects will be selected to utilize the core resources and by which selected projects will be prioritized must be delineated. There should be well-defined criteria for designating an investigator as a Center participant. Each Center, however, is expected to formulate these definitions based on its own situation.

Although facilities available should be described for each element of the application, a more general description of overall facilities and a statement regarding institutional commitment to the Center should also be included here.

III. BIOMEDICAL RESEARCH COMPONENT

Research Base

The Core Center Grant provides a mechanism for fostering interdisciplinary cooperation within a group of established investigators conducting high quality research on diabetes and related areas of endocrinology and metabolism. Therefore, existence of a strong research base in this area is a fundamental requirement for, and the most important aspect of, the establishment of a Core Center.

Applicants should include an overview of current research in diabetes and related areas being conducted at their institution in sufficient detail to allow reviewers to judge its extent and the interrelationship of ongoing research. There should be a substantial body of ongoing research in diabetes and/or its complications. The relevance to diabetes of all research included in the research base should be described. Projects at other institutions may also be included if collaborations exist with scientists at the applicant institutions. Applicants should indicate how the establishment of a Center will provide added dimensions, such as greater focus and increased cooperation, communication and collaboration.

Presentation of the research base in the application should be done in two ways: (1) by completing a Table like the one shown in Illustration III, and (2) by a full description of the diabetes and related research activities at the applicant institution and any collaborating institutions. This presentation should be organized into several areas of emphasis that demonstrate the research focus of the Center. The research of each Center participant should be discussed and interrelationships of research being conducted by Center participants should be highlighted. Since most, if not all, of the research base will have undergone separate peer review, the quality of the individual funded projects is already established. The more important aspects are: (1) interactions and interrelationships of the research efforts; (2) uses and benefits of core services; and (3) plans to develop productive collaborations among Center investigators.

For renewal applications, consideration will be given to progress and accomplishments in the research base, to development of multidisciplinary, collaborative, and cooperative interrelationships, and to alteration in the original Center design in order to meet the evolving needs of the research base. This should be described in a narrative fashion accompanied by a Table like the one shown in Illustration IV that documents the contribution of individual cores to the publications by the research base. Since one of the objectives of the Center is to extend research relevant to diabetes, new areas of research and acquisition of new funding should be highlighted.

There is obviously insufficient space in the application for a detailed presentation of the research base. It is recommended that Center applicants subdivide the research base into areas of research emphasis for clearer presentation. Appropriate presentation of the research base is very important since its assessment is a primary criterion in the evaluation of an application.

Biomedical Research Cores

***Definition*:** A biomedical research core is a shared facility that provides a needed service to Center investigators enabling them to conduct their funded individual research projects more efficiently and/or more effectively. Cores should be designed to furnish a group of investigators with materials, techniques, determinations, instrumentations, and/or quality control to enhance research and contribute to cost effectiveness. A recharge mechanism is acceptable to help defray costs to the Center. If such a cost recovery system is developed, a detailed charge justification must be presented. Participating Center members must also be informed to include such costs with their full budget justifications in their applications for individual grant support. Cores may be proposed to support any research activity of the Center, but usually fall into one of five categories: (1) provision of a technology that lends itself to automation or preparation in large batches; (2) complex instrumentation; (3) animal preparation, care and characterization; (4) clinical resources; and (5) service and training. Limited developmental research is also an appropriate function of a core facility. Such activities, however, must be directly related to enhancing the function or utility of the core.

Justification for proposing a core: The establishment and continued support of biomedical research cores within a Center is justified on the basis of use by independently-funded Center investigators. The minimum requirement for establishing a core is significant usage by two or more investigators with independently-funded, peer-reviewed projects. While investigators holding awards from the Center pilot and feasibility program are appropriate users of the core facilities, their use does not contribute to justification for establishment or continued support of a core. Additionally, the minimum of two independently funded users does not in itself provide sufficient justification and will receive close scrutiny in peer review.

Personnel: A director must be named for each core. Core directors may be acknowledged experts with independently-funded research programs that will use the core services. In such cases, the person months on the grant is usually relatively low. The minimum effort for a core director is 5%. A core director with requisite expertise may devote a greater effort to the core and with justification could devote up to 12 person months. Where appropriate, an established expert in the core activities could also be included as a consultant to the core. Technicians, etc. are allowable in accordance with the volume and type of work in the core.

Facilities, space, and special arrangements: Particularly in initial applications, the description of the physical arrangements and instrumentation for the cores should be given special attention. Arrangements for sufficient space for core activities or for access to appropriate established facilities must be made. Centers are strongly encouraged to enter into cooperative arrangements with cores already established within their institution, or with other Centers in close proximity, when the existing cores offer the services needed. These arrangements are important whenever greater efficiency or cost savings can be realized by such an agreement. However, it should be clear that DERC or DRTC cores can function independently. It may be advantageous for a Diabetes Center to provide support for appropriate personnel to work specifically for Diabetes Center members in an existing facility/core (e.g. transgenic animal core) at the institution. In this case, the designated Diabetes Center core Director must work closely with the parent facility core Director to coordinate services, unless the same individual assumes both roles.

In renewal applications, any changes should be carefully documented. Cores are encouraged, whenever possible, to enter into cooperative arrangements with established cores in other Centers or resources offering a similar type of service.

Recharge System

A recharge system may be developed to allow investigators to utilize any core. Recharge fees are allowable budgetary items in the investigators' individual research project grants. A system of payment management/accounting must be established such that it is clear to the individual users, the institutional business office, and the NIDDK what the recharge system covers and how funds recovered are being used. This will enable center

investigators to appropriately adjust the budgets on their own grants and ensure accountability.

When a Center is first established, individual investigator-initiated research project grants may include funds for services that will ultimately be available through the cores. At the time of their next competitive or noncompetitive continuation application, investigators should remove from their individual research project grant budgets all costs associated with services received from the cores for which they are not charged. The elapsed time before this adjustment is made generally constitutes a very minor overlap, if any, since it is usually several months before a core is fully functional. Recharge fees to the Center should be included in the budget of the research project grant once the cores are running since these are a necessary expense and are justified by cost savings. Some mechanism should be proposed in the Center application to monitor these budgetary adjustments and to ensure that Center core users describe their relation to the Center in their individual grants.

Management of the core and operational plan: The organization and proposed mode of operation of each core should be presented. Included should be a plan for prioritizing investigator use of the core as well as a definition of qualified users. If use by investigators outside the parent institution is proposed, the mechanism by which such investigators will apply and be evaluated and selected should be detailed. The definition of qualified users should not be too narrow. Some minor core use could serve to entice established investigators in other scientific disciplines into the field of diabetes research. Any proposed, ongoing or completed developmental efforts should be described. If the core is used to train investigators in special techniques, the mechanism for this training should be included.

Renewal applications: Information relative to cores in renewal applications should generally cover all of the same points as initial applications. In addition, past performance and accomplishments should be described. The effect of the service provided by a core on investigator productivity and cost effectiveness should also be addressed.

Pilot and Feasibility Program

Research projects associated with a Core Center will, in general, be funded from other resources, such as R01 or P01 grants from NIH, similar project funding from other Federal agencies, or nonfederal sources. There is one exception--pilot and feasibility studies.

Definition: The Pilot and Feasibility Program provides modest research support for a limited time (usually one to two years) to enable eligible investigators to explore the feasibility of a concept related to the mission of the Center and generate sufficient data to pursue it through other funding mechanisms. The pilot and feasibility studies are intended to: (1) provide initial support for new investigators; (2) allow exploration of possible innovative new leads or new directions for established investigators in diabetes and (3)

stimulate investigators from other areas to lend their expertise to research in this area. Pilot and feasibility study support is not intended for large projects by established investigators that would otherwise be submitted as separate research grant applications. Pilot and feasibility funds are also not intended to support or supplement ongoing funded research of an investigator.

Requirements: Each Center must propose a minimum of 2 pilot and feasibility studies to be supported from NIDDK funds.

Eligibility and related guidelines: Investigators eligible for pilot and feasibility funding generally fall into three categories: (1) new investigators without current or past NIH research support as a principal investigator (current or past support from other sources should have been modest); (2) established investigators with no previous work in diabetes who wish to apply their expertise to a problem in this area; and (3) established investigators in diabetes who propose testing innovative ideas that represent clear departure from ongoing research interests. It is expected that the majority of the investigators will fall into the first category. All eligible investigators, however, must have faculty appointments and be independent investigators. Postdoctoral fellows or their equivalent are not eligible. Each pilot and feasibility study proposal should state clearly the justification for eligibility of the investigator under one of the above three criteria.

A proposed pilot and feasibility study should present a testable hypothesis and clearly delineate the question being asked, detail the procedures to be followed, and discuss how the data will be analyzed. It must be on a topic related to the objectives of the Core Center. Projects should be focused, since funding for these studies is modest (typically $50,000 or less in direct costs per year per project) and is usually limited to two years or less. Any one investigator is eligible only once for this support, unless the additional proposed pilot and feasibility study constitutes a real departure from his/her ongoing research.

For new Center applications only, applicants should provide an abstract for each proposed pilot and feasibility project, followed by the biographical sketch of the investigator of the proposed pilot and feasibility project.

The application should clearly describe and justify the pool from which potential pilot and feasibility applications will be selected. This can be limited to investigators at the parent institution or expanded to include investigators at institutions with a well defined affiliation with the Core Center. Such an affiliation can occur either through a subcontractual relationship for support of core resources or through inclusion of funded projects at a collaborating institution in the research base utilizing the shared resources of the Core Center. The mechanisms by which information on the availability of pilot and feasibility awards will be disseminated and by which applicants will apply and be selected for these awards must be described and will be an important element in the review of the pilot and feasibility component of the Core Center.

Initial review and management of the pilot and feasibility program: By the very nature of this program, a significant responsibility for its management will be left to the Center administration during the project periods. For new Center grant applications, the pilot and feasibility proposals are reviewed for scientific merit and eligibility by the initial review group. These initial pilot and feasibility studies must have been reviewed by the Center in the manner proposed for review of future studies so that only those considered to be the highest quality are included in the grant application. The amount of pilot and feasibility funds provided for the first year will be based on the review of the proposed studies. The budget for future years is recommended by the initial review group based on the quality of the proposed pilot and feasibility studies, and the proposed method for management and review (as evidenced by this set of projects). Also considered will be the review group's evaluation of the future justification for continued pilot and feasibility support.

Since pilot and feasibility studies can be awarded for varying periods of time, these studies may end at various times. In addition, the studies may also be terminated by the Center administration before their approved time limit for various reasons: e.g., (1) the investigator may receive outside funding for the project; (2) the project was found not to be feasible; (3) the investigator may leave the Center institution; etc. When this occurs, the Center may make new awards for pilot and feasibility studies with the remaining funds.

While a Center's administrative framework for management of the pilot and feasibility program is basically left up to each Center (subject to NIH peer review), certain minimal requirements must be met. The program must have a director who is an established investigator in diabetes. There must also be a committee representing all the aspects of the Center to assist the director in the management of the program. The major responsibilities of the director and the committee will be to:

(1) Maintain oversight and review of ongoing pilot and feasibility studies;

(2) Make recommendations regarding termination or other actions to the Center Executive Committee (or equivalent);

(3) Prepare and ensure appropriate distribution of announcements of the availability of pilot and feasibility funding;

(4) Arrange and preside over the scientific merit review of proposals. At least one reviewer from outside the parent institution must be used for each proposal. All reviewers should assign priority scores in accordance with the NIH system. Copies of all of the proposals with written documentation of their reviews, priority scores, and final action must be retained by the Center. These records must be made available to reviewers if requested at the time of a renewal application;

(5) Maintain, insofar as is possible, a record of subsequent career events of each pilot and feasibility study recipient. This record must also be made available to reviewers at the time of the renewal application;

(6) Make recommendations to the Center Executive Committee (or equivalent) for final decisions. A record of actions by this committee must be documented and be available if requested by the initial review group.

All applicants should describe how these requirements will be met and have been met in the case of renewal applications. Also included should be an assessment of the relevancy of the proposed individual pilot and feasibility studies and of the program as a whole to research on diabetes and related areas of research and to the specific goals and objectives of the individual Center and of the Center program generally.

Review of the pilot and feasibility program in renewal applications: After the initial review of pilot and feasibility proposals as described above, all responsibility for review and funding during the remainder of the project period will reside within the Center itself. This approach provides each Center with the needed flexibility for effective and efficient management of the program. In competing renewal applications, the review of this program will be based on the past track record, the management of the program, and an assessment of overall potential needs and opportunities.

In general, a competing renewal application will include: (1) an historical overview; (2) a description of Center management of the program; (3) a description of the method for solicitation for pilot and feasibility projects and the number of respondents received for each solicitation; (4) a listing of all previous, ongoing and approved proposed pilot and feasibility studies with reports on those which were supported by the Center during the last project period; and (5) a statement of the benefits of the program to the Center as well as the contribution of the uniqueness of the Center environment to the program. These points are detailed in the following paragraphs.

The historical overview will cover the pilot and feasibility program since the inception of the Center. This should include, in summary format, all pilot and feasibility projects ever awarded. For each project listed, the following should be included: (1) publications as a result of the studies; (2) peer-reviewed funding as a result of the studies; and (3) whether the recipient is still active in the area of diabetes. The pilot and feasibility program director may wish to highlight certain studies or certain aspects of the past studies. Collaborations which resulted in lasting relationships, acquisition of new skills by the study recipient, or other significant outcomes should be identified. The relationship of the scope of the various studies to that of the Center should be emphasized. Details such as back-up documentation (described earlier in relation to the arrangement of the pilot and feasibility program) should not be included, but should be available for examination by the reviewers if requested.

The description of center management of the program will present in detail the current system used to manage the pilot and feasibility program, including its integration with and relationship to the rest of the administrative structure. The use of outside consultants for review should be included in the discussion. Important features of the solicitation process should be provided including the distribution and the number of respondents.

The historical review of all pilot and feasibility studies ever awarded should include a report on each pilot and feasibility study conducted during the last project period. These reports should be brief (1-2 pages) and contain (1) the name of the investigator, degree(s), professional career status at the time awarded, and current professional career status (if known); (2) an overview of the project including its significance and salient results; (3) a list of resulting publications; and (4) peer-reviewed subsequent funding in the same or related area. The proposals should be available, if requested by the reviewers.

The recommendation of the initial review group will be based on the overall performance of the center's pilot and feasibility program as documented in the application. This recommendation will be based on: (1) the extent to which awarded funds were fully utilized during the previous project period; (2) awards were made to investigators who fully met the eligibility criteria for pilot and feasibility support as outlined above; (3) Center-relatedness; and (4) success of previously supported pilot and feasibility studies (e.g., publications, subsequent independent R01 or other peer-reviewed support, and/or attraction of new investigator into Center related research).

Enrichment Program

The Diabetes Center enrichment program should be designed to advance translational research in diabetes, endocrinology and metabolism and promote scientific exchange among investigators with research interests in these topic areas, and to enhance interactions between diabetes researchers and investigators from other fields with relevant expertise. The enrichment program can support activities such as seminars, guest speakers, visiting scientists, consultants, and workshops. Applicants should describe any training opportunities afforded by the Diabetes Center for Center participants, and document ways the Center may facilitate, enhance or foster the institutional training environment. Specifically, Center applicants should provide information on related NIDDK T32 programs at the Center institution(s), and describe how the Diabetes Center will help to integrate, facilitate and enhance activities of T32-supported trainees. A letter from the PI of any related NIDDK-funded T32 at the Center institution should be included that acknowledges and details how the PI of the T32 intends to promote cohesive interactions between the two programs.

Training postdoctoral fellows to conduct research in diabetes is an associated activity of a Center. While stipends for fellows cannot be funded from the Center, the establishment of a Center should provide an enhanced environment for research training. Just as in the case of funding for individual research projects, funding for fellowships should be sought from NIH NRSA institutional training grants (e.g. T32, T35) and individual fellowships

(e.g. F30, F32), and other sources such as private foundations, and commercial companies.

IV. PRE-APPLICATION PROCESS

It is the policy of the NIDDK that new and competing continuation Center applications are only accepted in response to a Request for Applications (RFA) announced in the NIH Guide for Grants and Contracts. It is strongly encouraged that potential applicants for a Center submit a letter of intent. The letter should be sent at least one month prior to submission to allow NIDDK staff to identify potential opportunities and problems early in the development of the application. The letter of intent needs to include only: (1) names of the principal investigators and principal collaborators, (2) identification of the organization(s) involved; and (3) announcement to which the potential application is responsive. The purpose of the letter of intent is 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 contacts the prospective principal investigator to assist in a number of areas that include scientific content and objectives, organization, and clarifications. However, applicants should not construe advice given by the NIDDK staff as assurance of favorable review. The staff will not evaluate or discuss the merit of the scientific aspects of the application.

V. PREPARATION OF APPLICATION

Description

Applications must be submitted using PHS Form 398 (Rev. 11/2007).

Submit the signed original application, including the Checklist, plus three signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Suite 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or Regular mail)
Bethesda, MD 20817 (Express/Courier Non-USPS Service)

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

Chief, Review Branch
Division of Extramural Activities, NIDDK
6707 Democracy Boulevard, Rm. 752, MSC 5452
Bethesda, MD 20892-5452
(for express/courier service: Bethesda, MD 20817)

The arrangement of materials should follow both the instructions in the PHS Form 398 application kit and the more specific guidance detailed below. Applications not in accordance with Center guidelines will be returned to the applicant.

Applicants should keep in mind that the written application is the basis for the merit review. Particular attention should be given to the format of the application. Awards for Center grants are for five-year project periods. Basic information useful for preparing the application follows. Applicants may also consult with NIDDK staff concerning the technical aspects of preparing the application.

Content Order for Applications

SECTION 1: INTRODUCTION AND OVERVIEW

- Face Page: Center applications are only accepted in response to a Request for Applications (RFA). The RFA number and title must be typed on line 2 and the 'yes' box must be marked.

- Description, Project/Performance Sites, Senior/Key Personnel, and Other Significant Contributors

- Table of Contents

- Budgets
    1. Detailed Budget for Initial Budget Period (PHS 398 Form Page 4)
    2. Budget for Entire Proposed Project Period (PHS 398 Form Page 5)

- General description of the proposed or established Center
  For Renewals: Changes from the original Center design should be highlighted

SECTION 2: ADMINISTRATIVE COMPONENT

- Description (PHS 398 Form Page 2)

- Key Personnel (PHS 398 Form Page 2 – continued)

- Budget with comprehensive budgetary justifications (PHS 398 Form Page 4)

- Biographical Sketches: Director and Associate Director

- Presentation of the administrative structure

- Relationship and lines of authority and sanction by appropriate institutional officials

- Committee structure (include external and internal advisory boards and the pilot and feasibility program oversight committee)

- Description of plans for website development, maintenance and curation

- General overall description of facilities and institutional commitment

- Other Considerations (include listing of other relevant Centers and cores at the institution, and plans to integrate, harmonize and reduce redundancies in activities)

SECTION 3: BIOMEDICAL RESEARCH COMPONENT

- Overview of ongoing research and impact of Center on this research. Description of Research Base - Grouped into areas of emphasis for the Center

- For Renewals: Progress Report including description of significant findings, new participants and new funding. Publications Citing Support from this Core Center (such as the chart shown in Illustration IV)

- Biomedical research cores (present each core separately)

    1. Description (PHS 398 Form Page 2)
    2. Key Personnel (PHS 398 Form Page 2- continued)
    3. Budget with justifications (PHS 398 Form Page 4)
    4. Biographical sketches: Core Director and key personnel
    5. Objectives of the core
    6. Core function, including quality control
    7. Benefits from the core
    8. Proposed developmental research or training
    9. Funded investigators who will use the core and proposed extent of use (see Guidelines Illustration V) For Renewals: Core Use during the last grant period (see Guidelines Illustration V)
    10. Core progress and productivity (include literature citations, grant awards, and 2-3 key advances supported by core activity)
    11. Future directions and plans to ensure continuing evolution and relevance of the core

- Prevention and Control core

1. Description (PHS 398 Form Page 2)
2. Key Personnel (PHS 398 Form Page 2- continued)
3. Budget with justifications (PHS 398 Form Page 4)
4. Biographical sketches: Core Director and key personnel
5. Objectives of the core
6. Core function, including quality control
7. Benefits from the core
8. Proposed developmental research or training
9. Funded investigators who will use the core and proposed extent of use (see Guidelines Illustration V) For Renewals: Core Use during the last grant period (see Guidelines Illustration V)
10. Core progress and productivity (include literature citations, grant awards, and 2-3 key advances supported by core activity)
11. Future directions and plans to ensure continuing evolution and relevance of the core

- Pilot and Feasibility Program

1. Description (PHS 398 Form Page 2)
2. Key Personnel (PHS 398 Form Page 2- continued)
3. Composite budget with justifications; include justifications for any changes in future years (PHS398 Form Page 4)
4. Biographical sketches: Program Director and Committee
5. Management of the pilot and feasibility program
6. Program progress and productivity (include publications, grant awards, and 2-3 key advances supported by the pilot and feasibility program)
7. Future directions and plans

In new applications include: eligibility requirements, selection process, abstracts of proposed pilot and feasibility awards in the initial budget period, and justification for core usage by pilot and feasibility awards.

For competing renewal applications include: total number and titles of all pilot and feasibility submissions received during the prior project period, selection process and funding success rate, single paragraph synopses of pilot and feasibility studies awarded during the last project period and productivity associated with each (e.g. publications, presentations, grant awards)

- Enrichment Program

1. Description (PHS 398 Form Page 2)
2. Key Personnel (PHS 398 Form Page 2- continued)
3. Budget with justifications (PHS 398 Form Page 4)

4. Biographical Sketches: Program director and key personnel
5. Future directions and plans to ensure continuing evolution and relevance of the enrichment program
6. Other considerations (include plans to enhance interactions with relevant NIDDK supported T32 training programs; letters of acknowledgement and support from T32 Principal Investigators should be provided)

SECTION 4: CENTER-RELATED INFORMATION

- Biographical Sketches for all other Center participants (Non-Key Personnel) in alphabetical order (PHS 398- Form Pages)

- Distribution of Professional Effort for Key Personnel (see Guidelines Illustration II)

- Summary of total current and pending support of all Center participants including person months. List support related to diabetes first, followed by non-Center related research support (see Guidelines Illustration III)

- Checklist (PHS 398 Form Page)

- Appendix (Follow PHS 398 instructions)

VI. BUDGET CONSIDERATIONS

Unless otherwise indicated in the Notice of Grant Award, allowable costs and policies governing the research grant program of the NIH will prevail. The anticipated award will be for five years. The maximum dollar request in any budget period is limited to $1,250,000 in direct costs for DRTC (P60) and $1,000,000 in direct costs for DERC (P30) applications with the following exceptions. Not included in these direct cost limits are: 1) requests for equipment in the first year of a competitive award; 2) direct costs on subcontracts to historically black colleges and universities (HBCU's), health departments, community health centers or other agencies that focus on underserved populations for the purpose of establishing collaborations and providing access to the research infrastructure to investigators at these institutions to foster research to reduce or eliminate health disparities in populations disproportionately affected by diabetes; and 3) Facilities and Administrative (F&A) Costs associated with any subcontract.

Generally, at least 20-25% of the direct costs requested in P30 and P60 applications, exclusive of equipment, should be for support of a Pilot and Feasibility program. Each pilot/feasibility study is limited to $50,000 per year and a two-year duration of support However, a limited number of proposals may be selected for support as enhanced pilot

and feasibility awards with prior NIDDK approval. Enhanced pilot and feasibility awards will be selected from worthy proposals in the following three project categories: clinical and translational research awards, clinical and basic research innovative partnership awards, or technology research and development awards. These enhanced awards may be funded at up to $100,000 direct costs per year and for up to 3 years. Efforts to increase the number of pilot and feasibility awards and availability of funds for the program through the use of program income or alternative funding sources are particularly encouraged. Future budget period escalations may not exceed a 3 percent increase over the previous budget period.

Budget Categories

Professional Personnel: This category may include support for salaries of key personnel within the Center who contribute to allowable activities of the Center. The salaries derived from the Center grant will depend on the effort provided and institutional salary as well as existing NIH policies; however, current NIDDK practice limits annual increments to 3 percent. The Center Director is expected to devote at least 20% of his/her efforts to the Center. The Center application should include salaries for individual principal investigators only to the extent that they provide an essential Center function. No overlap of time or effort between the Center and separately-funded projects is permitted.

Salaries of professional personnel engaged in research activities supported by pilot and feasibility funds of the Center are an allowable cost item as are salaries of professional personnel in core facilities.

Technical and Support Personnel: This may include salaries for identified positions to be filled in the Center. No overlap of time or effort between the Center and separately funded projects is permitted.

Equipment: Requests for large equipment costs must include documentation of similar equipment already available at the institution and provide a clear justification in terms of core need and service to Center investigators. General purpose equipment needs should be included only after surveying the availability of such items within the institution.

Supplies: Consumable supplies related to the operation of the Center are allowed and include office materials, as well as scientific supplies, but should not be supplements to separately funded projects. The supply budgets of individual projects must be reduced to reflect cost savings through core usage.

Research Patient Care Costs: Research patient care costs (both in-patient and out-patient expenses) will be considered in the context of other existing institutional clinical resources. Attempts should be made by the applicant institution to utilize existing clinical facilities, such as General Clinical Research Centers and individually supported beds. Costs relating to the clinical research efforts of Center investigators may be funded through the Center, provided there is no overlap of funding. Costs already budgeted in

individual projects should be appropriately reduced if such costs are to be transferred to the Center budget. The Center is not intended to be a facility for health care delivery; thus, only those patient costs directly related to research activities may be charged to the Center.

Alteration and Renovation: Funds for alteration and renovation of an existing structure to provide suitable core facilities for the Center may be made available from the grant under current PHS guidelines.

Travel: Domestic and foreign travel of project personnel directly related to the core activities of the Center is allowable. Travel of Center participants for attendance at annual Center directors meetings is also allowable.

Consultants: Consultants and any associated costs (consultant fees, per diem, travel) may be included when their services are required within the Center.

VII. REVIEW PROCESS AND CRITERIA

Upon receipt, applications will be initially reviewed by the Center for Scientific Review (CSR) for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation of responsiveness to the program requirements and criteria stated in the RFA is an NIDDK staff function.

Applications that are complete and responsive will be evaluated in national competition in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the NIDDK. It is essential that the written application be in a form to be reviewed on its own merit, since no site-visit is anticipated.

As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed, assigned an impact/ priority score, and receive a second level review by the National Diabetes and Digestive and Kidney Diseases Advisory Council.

Review Criteria

The goals of the DRTCs and DERCs are to advance our understanding of biological systems relevant to diabetes and its complications, and to facilitate development of new methods to treat, prevent and ultimately cure diabetes and its complications. DRTCs have the additional goal of improving the control and prevention of diabetes and its complications and enhancing health by facilitating translational research, particularly in underserved populations and populations disproportionately affected by diabetes. In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed

and considered in assigning the overall score, and weighed as appropriate for each application. The most important component of DRTCs and DERCs is the quality (strengths, breadth and depth) of its established, independently supported, ongoing base of diabetes research at the institution(s) to be served by the Center. For the DRTC this research base must include translational research in addition to the biomedical research base required for DERCs.

NIDDK-specific review criteria for Diabetes Center applications are:

o Scientific excellence of the Center's research base that must have a broad and central focus in diabetes and may extend to related research in metabolism and endocrinology. The relevance of the separately funded research to the Center objectives (see above) and the likelihood for meaningful collaboration among Center investigators must be demonstrated.

o Potential of the cores for contribution to ongoing research, including their appropriateness, impact, relevance, uniqueness, modes of operation, and suitability of facilities. Renewal applications must document the use, impact, quality control, and cost effectiveness of each core, and demonstrate progress of any developmental research in the cores. Progress will be judged in part by the publications supported by the cores. While a minimum of two users (exclusive of Pilot and Feasibility projects) are required to establish a core, a greater number of users will be considered to be more cost effective.

o Scientific and administrative abilities of the Center Director and Associate Director and their commitment and ability to devote adequate time to the effective management of the Diabetes Research Center.

o The qualifications, experience, accomplishments, and commitment of the Center investigators and their inter-relatedness and collaborations.

o For new applications, the pilot and feasibility program is judged on the basis of: (1) scientific merit of the studies as submitted and (2) the merit of the administrative process for selecting subsequent studies. The scientific merit of the submitted pilot and feasibility studies will be evaluated for:

Standard review criteria are:

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact. Reviewers will provide an overall impact/priority score 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 five core review criteria, and additional review criteria (as applicable for the project proposed).

Core Review Criteria. Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. 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, 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?

NIH considers the following in evaluating Center grant applications:

- The scientific and technical merit of the proposed program;
- The qualifications and experience of the center director and other key personnel;
- The statutory and program purposes to be accomplished;
- The extent to which the various components of the proposed program would be coordinated into one multi-disciplinary effort within the center;
- The extent to which the center's activities would be coordinated with similar efforts by other organizations;
- The administrative and managerial capability of the applicant; and
- Other factors which the awarding IC considers appropriate in light of its particular statutory mission.

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.

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

Vertebrate Animals. The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of

euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

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

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

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.

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 providing an overall impact score.

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.

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

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

In competing renewal applications, emphasis is placed on the pilot and feasibility program as a whole, including past track record and management of the program.

o The Administrative organization proposed, including: coordination of ongoing research; establishment and maintenance of internal communication and cooperation among DRTC investigators; mechanisms for prioritizing usage of shared resources; mechanisms of selecting and replacing essential personnel within the Center; mechanisms

for reviewing the use of and administering funds for the pilot and feasibility program, and management capabilities.

o The appropriateness of the DRTC budgets for the proposed and approved work to be done in core facilities, for pilot and feasibility studies, and for enrichment in relation to the total Center program.

o Institutional commitment to the program, including lines of accountability regarding management of the DRTC grant and a commitment to establish new positions as necessary.

o Although the DRTCs do not specifically support research training, demonstration of accomplishments and future plans related to the training of investigators necessary to conduct research in diabetes and related metabolic and endocrine disorders will be considered in assessing the potential to meet Center objectives. The integration of these efforts into the overall Center, including core facilities is of particular importance. Efficient and effective use and/or planned use of the limited enrichment funds, including the contribution of these activities in enhancing the objectives of the Center will also be considered.

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

o Adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

o The reasonableness of the proposed budget and duration to the proposed research.

o The adequacy of the proposed protection of humans, animals, or the environment, to the extent that they may be adversely affected by the project proposed in the application.

o The adequacy of the proposed plan to share data.

Funding decisions will be based on the quality of the proposed Center as determined by peer review, overall balance in the Diabetes Research Centers program, and the availability of funds.

VIII. EVALUATION AND REPORTING REQUIREMENTS

The annual Non-Competing Continuation Progress Report (PHS 2590), which is due two months before the anniversary date of the award, should be submitted as described in the application instructions.. The following order for presentation of information in the Non-Competing Continuation Progress Report is suggested:

(1) Cumulative Budget

(2) Budget for each Core

(3) List new Key personnel followed by their biographical sketches

(4) Other support for all Key personnel

(5) Listing of current Center Investigators, with member's name, department, and area of interest; indicate those who are new to the Center in past year and those who are collaborative (outside Center) members

(6) Administrative Core: Highlight significant accomplishments, evaluation activities, and enrichment activities (e.g. seminars and symposia; regional and national presentations; collaborations with other Diabetes Centers, institutions and centers; website developments)

(7) Biomedical and Translational Research Cores: Highlight significant changes from previous report (e.g. new personnel; new services, or changes in existing services); Describe services provided and number of users; and List publications citing support from the Center which used this core

(8) Pilot and Feasibility Projects: Describe new projects and progress on ongoing progress and projects that terminated during the previous funding period; List publications and new peer-reviewed research support emanating from the pilot and feasibility projects.

IX. SPECIAL CONSIDERATIONS

Each Center will be expected to develop its own program in accordance with local talents, interests, and resources. Each Center must also be responsive to national needs to develop new approaches to the prevention, treatment and cure of diabetes and its complications and must be willing to work with the NIDDK and other organizations in furthering the overall goals of the Centers Program. In this regard, the Center Director and selected other Center participants may be invited to meet periodically with NIDDK staff and its consultants to review progress, identify emerging needs and opportunities, and plan approached for future investigations.

Within the context of these guidelines, potential applicants for Center grants are encouraged to exercise the flexibility necessary to utilize the strengths of their particular institutions in preparing a plan which will eventually cover the spectrum of required activities. While types of activities that should be included are indicated in the guidelines, specific approaches for their accomplishment are left to the individual applicant.

Because of resource limitations and in light of the size of the Center grants, it is unlikely that NIDDK will be in a position to provide hardship allowances in the event that an application for renewal of Center support is not funded.

ILLUSTRATION I

CONSOLIDATED BUDGET FOR 1st YEAR OF REQUESTED SUPPORT

Budget Category	Core A	Core B	Core C	P&F Projects	Totals
Personnel					
Consultant Costs					
Equipment					
Supplies					
Domestic Travel					
Foreign Travel					
Patient Care Costs					
Alterations and Renovations					
Other Expenses					
Contractual Costs					
Total					

ILLUSTRATION II

DISTRIBUTION OF PROFESSIONAL EFFORT (in calendar months) ON THIS APPLICATION

Participating Investigators*	Core A	Core B	Core C	Core D	P&F (Project #)	Application Total	Other Support
Dr. A.	*1.4			1		2.4	6
Dr. B.		1			*1 (3)	2	5
Dr. C.	2					2	
Dr. D.			1.5	*1.5		3	6
Etc.							

*Star the calendar months (see Core A) when that individual is the core director or the principal investigator on a pilot and feasibility study.
Minimum effort for a Core Director is 0.6 calendar months. Minimum total effort for a Center Director is 2.4 calendar months.

ILLUSTRATION III

SUMMARY OF TOTAL CURRENT AND PENDING SUPPORT OF ALL CENTER PARTICIPANTS

DIABETES RESEARCH BASE: Current Support

Principal Investigator (Co-Investigator*)	Supporting Organization and Grant Number	Title	Project Period	Total Costs for Entire Project Period	Annual Direct Costs	Effort (in calendar months)
Example: Doe, Joe	P01 DK-00000	Immunopathogenesis of Diabetes	4/1/05-3/31/10	$8,100,000	$750,261	4.8
Jones, Sam	R21 DK-00000	Cellular Therapy for Diabetes	6/1/07-5/31/09	$370,000	$125,000	6.0
Lane, Andrea (G. Under)	R01 DK-00000	Genes for Type 2 Diabetes	7/1/07-6/30/12	$1,462,518	$ 200,000	1.8

DIABETES RESEARCH BASE: Pending Support

Principal Investigator Co-Investigator*	Supporting Organization and Grant Number	Title	Project Period Requested	Total Amount Requested	First Year Support Requested	Effort Requested

NON-CENTER-RELATED RESEARCH: Current Support
(as above)

NON-CENTER-RELATED RESEARCH: Pending Support
(as above)

* If co-investigator's name is used, put principal investigator's name in parentheses below.

ILLUSTRATION IV--FOR COMPETING RENEWALS ONLY

PUBLICATIONS CITING SUPPORT FROM THIS CORE CENTER GRANT

Core or P&F/P.I. Name	Publications	Core A	Core B
Core A/ Brown	Brown, A.C; Jones R.C.; Smith, A.J. Metformin reduces hepatic glucose output. Diabetes, 2008 volume; page # PMCID#	P	
	Brown, A.C.; Cheng, A.G.; Anderson, J.C. Results of Islet Transplantation. Diabetes, 2008, volume: page# PMCID#	P	S
Core B/ Cheng,	Cheng, A.C.; Meyer, G.C. Linkage Studies in Animal Models for Diabetes Nature Genetics, 2008, volume: page#, PMCID#.	S	P
	*Smith, F.G.; Cheng, A.C.; Tissue Specific Knockout of Glut 4 PNAS, 2008, V: page#, PMCID#		P

Instructions: List each publication only once under the project number most significantly contributing to the work. Each publication listed should cite the Diabetes Center grant number. For any publications that received Center grant support but did not cite the Center grant number, use an asterisk (*) at the beginning of the publication listing (see example above). 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 V

USE OF CORE FACILITIES

CORE: NAME

Determination/Services Rendered

A.

B.

Users	Funded Projects with Identifying Number	Period of Performance	Determinations Services	Estimated Use and Comments
1.				
2.				
3.				

EXAMPLE

Core A: Molecular Biology

Determination/Services Rendered

A. Isolation of DNA and RNA

B. Analysis of gene expression using GeneChips and microarrays

C. DNA sequencing

D. Oligonucleotide synthesis

Users	Funded Projects with Identifying Number	Period of Performance	Determinations Services A B C D	Estimated Use and Comments*
1. J. F. Smith	R01 DK00000-00	3/7/04-3/7/09	X X	A. 5 per month C. 100 per month
2. S. R. Jones	K08 DK00000-00	1/4/06-1/4/11	X X	B. 40 per week D. 8 per month
3. R. G. Brown	R01 GM00000-00	9/1/01-9/1/06	X	A. 16 per week for 6 months

Core B: Morphology

Determination/Services Rendered

Same format

* In renewal applications, the last column should be entitled "Actual Usage."