DIABETES RESEARCH CENTERS

ADMINISTRATIVE GUIDELINES

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

August 2011

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I. DESCRIPTION

Background

The NIDDK-supported Diabetes Research Centers (DRCs), formerly known as 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. DRCs are intended to improve the quality and multidisciplinary nature of research on diabetes by providing shared access to specialized technical resources and expertise.

Description and Basic Requirements

Centers 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. DRCs 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. DRCs also support a Pilot and Feasibility Program and an Enrichment Program.

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.

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 emphasis 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.

II. ADMINISTRATIVE CORE COMPONENT

Description and Requirements

The DRC 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.

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. She/he 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 1.2 person months (calendar year) effort on the Administrative Core and a total of 2.4 person months (calendar year) 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 requires 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 interactions. 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 that would not likely occur without Center resources.

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 are 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 are usually relatively low. The minimum effort for a core director is 0.6 person months (5% of full-time professional effort). A core director with requisite expertise may devote a greater effort to the core and with very strong 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 the DRC 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 renewal 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, nor is it intended to provide bridging support. 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 and approaches 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 sub-contractual 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, impact 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 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 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.

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 narrative reports should be brief 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).

Named New Investigator [optional]

Each Diabetes Research Center may provide salary support for a P&F project recipient whom they designate a Named New Investigator. Support for this individual is generally for 2 years, and cannot exceed $90,000 per year, additional appropriate fringe benefits, and 9.0 to 12.0 calendar months effort. These funds are included in the Administrative Core budget, and the initial Named New Investigator should be clearly identified in the application. The individual selected should be an early stage investigator (ESI) who meets the P&F project eligibility criterion and is a permanent resident or U.S. citizen. Individuals are eligible only once for this support. Subsequent candidates for this position are nominated by the Center and reviewed by its External Advisory Board. Appointment of the Named New Investigator is contingent upon the concurrence of the External Advisory Board and the NIDDK program director.

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 PD/PI of any related NIDDK-funded T32 at the Center institution should be included that acknowledges and details how the PD/PI of the T32 intends to promote cohesive interactions between the two programs. Applicants should indicate if they plan to participate in the medical student summer research program that is currently organized through the Diabetes Research Centers program (http://medicalstudentdiabetesreseach.org/). For those Centers that have participated in this program in the past, a brief report should be provided in the application.

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.

Additional Features and Opportunities

Additional Opportunities for Resource Cores (opportunities to exceed the $1M direct costs cap, but not to exceed $1.25M in direct costs)

The principal goal of the opportunities listed below is to provide NIDDK Diabetes Center research core services (and pilot and feasibility grant opportunities) to diabetes researchers at institutions that are not currently served by an NIDDK Diabetes Research Center.

1) To broaden the scope and reach of current research core services, a Center may propose to serve a wider scientific community on a geographic or national level through the establishment of a Regional/National Shared Resource Core that is located at a different institution. Such a Regional/National Core may not be established with an affiliated hospital of the applicant organization; such an arrangement would be considered an institutional, rather than a regional/national, core for the purposes of this FOA. If the Center is primarily located at an affiliated hospital, core(s) based at another affiliated hospital of the same academic institution will not be considered Regional/National Shared Resource Cores. With a regional or national core located at a different institution, the Center will service a specific research base that is expanded beyond investigators at the academic institution and/or affiliated hospitals where the Center is primarily located. Support for the expansion of the Center P&F program to investigators at the institution where the Regional/National Shared Resource Core is located may also be requested (see below).

2) A Diabetes Research Center Core may serve a wider scientific community on a geographic or national level through the establishment of a Regional/National Shared Resource Core that is located at the applicant institution or an affiliated hospital. Such a Regional/National Shared Resource Core should provide a plan for expanding core services to investigators outside of the parent academic institution and its affiliated hospitals. Applicants should document that there is sufficient demand by the wider scientific community for the expansion (or establishment) of the proposed core services. The research base in diabetes at the institution(s) that would use the regional core(s) should also be documented. Plans for prioritization of research core services, as well as training to the broader research community, should be provided. Support for the

expansion of the Center P&F program to the partnering institution(s) may also be requested (see below).

3) To broaden the scope and reach of the Diabetes Research Center P&F program, a Center may propose to serve a wider scientific community by expanding the Diabetes Center P&F program to a different institution(s). Expansion of the P&F program to an affiliated institution/hospital is encouraged, but will not be considered a Regional/National program for purposes of expanding the allowable requested funds. In general, NIDDK currently expects Diabetes Research Centers to allow investigators at affiliated hospitals or institutions to participate in the Center P&F program. Applicants may request funds to expand their P&F program to researchers at non-Diabetes Research Center institutions, and the applicant should provide details on how F&A costs for P&F grants will be handled with the partnering institution(s).

Subcontracts to Support Underserved or Health Disparity Populations (**subcontracts for these funding opportunities have no direct costs cap**)

Diabetes Research Centers may propose partnerships that establish research cores and/or P&F programs at institutions of higher education [i.e., rural institutions, historically black colleges and universities (HBCUs), Tribally Controlled Colleges and Universities (TCCUs) and Hispanic-serving Institutions (HSIs) and Alaska Native and Native Hawaiian Serving Institutions, historically black colleges and universities (HBCUs)], or other agencies that focus on underserved or health disparity populations. The primary goal of such partnerships is to foster scientific collaborations and to provide access to the Diabetes Research Center infrastructure to investigators at these institutions or organizations in order to foster health disparities research in populations disproportionately affected by diabetes. All funds exceeding the cap proposed for this purpose must be awarded to the subcontracting institution that serves underserved or health disparity populations. Funding for activities supporting the collaboration at the Diabetes Center institution must be included with the Diabetes Research Center cap.

IV. LETTER OF INTENT

It is the policy of the NIDDK that new and renewal 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 six weeks prior to submission of an application to allow NIDDK staff to identify potential opportunities and problems early in the development of the application. The letter of intent needs to include the following: (1) descriptive title of application, (2) names, addresses, and telephone numbers of the principal investigator(s) and other key personnel, (3) identification of the organization(s) involved; and (4) funding opportunity 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 may contact 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; 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 the most recent PHS Form 398.

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: CENTER OVERVIEW

• Face Page, Descriptive Abstract, Key Personnel and Table of Contents should be prepared as per standard instructions.

• Budgets

1. Detailed Budget for Initial Budget Period (398- Form Page 4)
2. Budget for Entire Proposed Project Period (398- Form Page 5);
3. Consolidated budget for first year of requested support (See Guidelines Illustration I; budgets for each individual Core should immediately precede the narrative for each Core)
4. Distribution of Professional Effort (see Guidelines Illustration II)

• Biographical Sketches (in alphabetical order): for all Diabetes Research Center investigators (key personnel, research base investigators, consultants and collaborators (PHS 398- Form Pages)

Biographical sketches for principal investigators on proposed P&F projects should be included within the P&F program section.

• Summary of total current and pending support of all Center investigators. Some institutions may have more than one NIDDK-funded Center grant. In such cases, research grants of investigators who participate in more than one NIDDK-funded Center should be noted when the research grant listed in the research base of the Diabetes Research Center application is also included as part of the research base of another NIDDK Center (see Guidelines Illustration III).

• Resources Format Page (PHS 398 Form Page):

Facilities and Major Equipment: general overall description of research facilities (space, equipment, collaborations, etc.) and the major, shared pieces of equipment to be used by Center members should be provided.

Note: Specific core facilities, equipment, and special resources should also be listed in each proposed core component.

• Specific Aims (limited to 1 page): Provide the broad, long-range objectives and goals of the proposed Diabetes Research Center.

• Research Strategy (limited to 12 pages): This narrative section summarizes the overall plan for the proposed or established multi-component Center. The multi-component application should be viewed as a confederation of interrelated research resources that are complementary to one another. This is an important section for it provides the group of investigators an opportunity to give conceptual wholeness to the overall Center – by giving a statement of the general problem area and by laying out a broad strategy for attacking the problems. As the strategy develops, each individual research component/core should be cited briefly as to its place in the overall scheme. Provide a general overall description of the facilities and institutional commitment; summarize the special features in the environment and/or resources that make this application strong or unique. Other Considerations: include listing of other relevant Centers and cores at the institution and affiliated hospitals, and plans to integrate, harmonize and reduce redundancies in activities. For Renewals: the Center Overview section should also highlight past performance

and the major accomplishments from the prior funding period as described in the PHS 398 Instructions; 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 cont'd)
• Budget with comprehensive budgetary justifications (PHS 398- Form Page 4); funds requested for the P&F and enrichment programs should be included in the "other expenses" category of the budget for the Administrative Core.
• Biographical Sketches: Director and Associate Director(s) (PHS 398 Form page)
• Specific Aims (limited to 1 page): Describe the broad, long-range objectives and goals of the Administrative structure within the context of the proposed Center.
• Research Strategy (limited to 6 pages): Presentation of the administrative structure; Relationship and lines of authority and sanction by appropriate institutional officials; Description of the process that would be used to recommend a successor to the Director, if needed; 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.

SECTION 3: BIOMEDICAL RESEARCH COMPONENT

• Center Biomedical Research Base, Research Strategy (limited to 6 pages): Provide an overview of ongoing research and the impact of the Center on this research. Include an overview of the current research in diabetes, its complications, and in related endocrine and metabolic diseases at the institution(s). An appropriate and clear presentation of the ongoing research base is critical since it will show the research focus of the Diabetes Research Center and the interrelationships and potential for collaborations among investigators. Since the research base projects will already have been peer- reviewed, the quality of the individual funded projects will have been established and will not be re-evaluated. Provide sufficient detail to assist reviewers in judging the extent and the interrelatedness of ongoing research. Grouping the research base into areas of emphasis for the Center is advised.

New applications: Emphasize the anticipated impact of the establishment of a Diabetes Research Center on the research base. Include an indication of how the establishment of a Diabetes Research Center will provide added dimensions and new opportunities for diabetes and related research, along with increased cooperation, communication, and collaboration among investigators.

For Renewals: Progress including description of significant findings and new participants.

• Description of biomedical research base investigators: Organize the presentation of the research base to emphasize the focus of the research and the interrelationships of the Diabetes Research Center investigators. Provide a narrative description of no more than one page per research base investigator; try to limit each to less than one page. These narratives should include: (1) the grant number(s), title (s), and a few descriptive sentences, and (2) a list of the core(s) used with a brief

sentence indicating what aspect of the research justifies the use of each core. Include ONLY those grants awarded, or subcontracted, to investigators at the applicant institution or consortium, not to investigators at other locations, in the description of the research base. It is particularly important to provide a few sentences indicating the relatedness of a cited grant to research in diabetes, its complications, or related endocrine and metabolic diseases when this is not readily apparent from the title of the grant.

• Document collaborative efforts using a format such as Guidelines Illustration IV to aid in the review process.

• Biomedical Research Cores (present each core separately; Research Strategy limited to 12 pages per core)

1. Description (PHS 398- Form Page 2)
2. Key Personnel (PHS 398- Form Page 2-cont'd)
3. Budget with justifications (PHS 398- Form Page 4)
4. Biographical sketches: Core Director and key personnel (PHS 398- Form Page)
5. Specific Aims (limited to 1 page): List in priority order, the broad, long-range objectives and goals of the proposed core. In addition, state the core's relationship to the Center goals and how it relates to the other cores at the applicant institution and in the application.
6. Research Strategy, including: Objectives of the core; Core function, including quality control; Benefits from core; Proposed developmental research or training; Future directions and plans to ensure continuing evolution & relevance of the core; For renewals: Core progress and productivity (include 2-3 examples of literature citations, grant awards, and 2-3 key advances supported by core activity); to assist reviewers, for each core also refer to the page numbers of the individual core-specific research publications in Guidelines Illustration VII; if applicable, describe any recharge system that may be in place to allow investigators to utilize a core, including information on any proposed F&A charges to outside users of the core.
7. New applications: 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)

• Pilot and Feasibility Program

1. Description (PHS 398- Form Page 2)
2. Key Personnel (PHS 398- Form Page 2-cont'd)
3. Budget with justifications (to be included in the Administrative Component budget; justify any changes for future years)
4. Biographical sketches: Program Director and Committee (PHS 398- Form Page)
5. Specific Aims (limited to 1 page):
6. Research Strategy (limited to 12 pages): Management of the pilot and feasibility program; Program progress and productivity (include key publications supported by the P&F program, grant awards resulting directly from P&F awards, and 2-3 key advances supported by the P&F program); Future directions and plans; For initial applications

include: eligibility requirements, selection process, abstracts of proposed P&F awards, and justification for core usage by P&F awards; For renewal applications include: Total number of all P&F submissions received each year during the prior project period, selection process and funding success rates, single paragraph synopses of Pilot & Feasibility studies awarded during the last project period. Clearly indicate the Named New Investigator, if such a position is being requested, and how he/she was selected. Include salary support for this position in theAdministrative Core personnel section.
7. For Renewals: Pilot and Feasibility Project Outcomes (see Guidelines Illustration VI)

• Enrichment Program

1. Description (PHS 398- Form Page 2)
2. Key Personnel (PHS 398- Form Page 2-contd)
3. Budget with justifications (to be included in Administrative Component budget)
4. Biographical sketches: Program director and key personnel (PHS 398- Form Page)
5. Specific Aims (limited to 1 page)
6. Research Strategy (limited to 6 pages): New applications: Describe plans for the enrichment program; Renewal applications: Describe the enrichment program and indicate the program's value to Center members. Indicate how the program has grown or been adapted to better serve Center members' needs during the past funding period; Future directions and plans to ensure continuing evolution and relevance of the enrichment program; Other considerations (include plans to enhance interactions with relevant NIDDK supported T32 training programs; letters of acknowledgment and support from T32 PDs/PIs should be provided separately)

SECTION 4: REGIONAL/NATIONAL SHARED RESOURCE CORES & EXPANSION OF THE PILOT & FEASIBILITY PROGRAM [OPTIONAL]

• Biomedical research cores (two opportunities): 1) a Regional/National Shared Resource Core that is located at a different institution, and/or 2) expansion of research core services at the applicant organization to serve a wider scientific community on a geographic or national level; present each core separately; Research Strategy limited to 12 pages per core)

1. Description (PHS 398- Form Page 2)
2. Key Personnel (PHS 398- Form Page 2-cont'd)
3. Budget with justifications (PHS 398- Form Page 4)
4. Biographical sketches: Core Director and key personnel (PHS 398- Form Page)
5. Specific Aims (limited to 1 page): List in priority order, the broad, long-range objectives and goals of the proposed core. In addition, state the core's relationship to the Center goals and how it relates to the other cores at the applicant institution and in the application.
6. Research Strategy, including: Objectives of the core; Core function, including quality control; Benefits from core to current Center members and/or the wider scientific community; Proposed developmental research or training; Future directions and plans to ensure continuing evolution & relevance of the core; if applicable, describe any recharge

system that may be in place to allow investigators to utilize a core, including information on any proposed F&A charges to outside users of the core.
7. New Cores: Funded investigators who will use the core and proposed extent of use (see Guidelines Illustration V). For Existing Cores: Core use during the last grant period (see Guidelines Illustration V).

• Expansion of the Diabetes Research Center Pilot and Feasibility Program to diabetes researchers at additional institutions

1. Description (PHS 398- Form Page 2)
2. Key Personnel (PHS 398- Form Page 2-cont'd)
3. Budget with justifications (PHS 398- Form Page 4); justify any changes for future years; provide details on how F&A costs for P&F grants will be handled with the partnering institution(s).
4. Biographical sketches: Program Director and Committee (PHS 398- Form Page); provide details on how F&A costs for P&F grants will be handled with the partnering institution.
5. Specific Aims (limited to 1 page)
6. Research Strategy (limited to 12 pages): Management of the expanded pilot and feasibility program; plans for advertizing and solicitation; For applications proposing a new, expanded P&F program: eligibility requirements, review and selection process, abstracts of proposed P&F awards, and plans for research core access and usage by P&F awardees; For renewal applications with an existing, expanded P&F program: Total number of all P&F submissions received each year during the prior project period, selection process and funding success rates, single paragraph synopses of Pilot & Feasibility studies awarded during the last project period.
7. For applications proposing a new, expanded P&F program: Biographical sketches of proposed P&F Awardees (PHS 398- Form Page)

SECTION 5: SHARED RESEARCH CORES AND/OR EXPANSION OF THE PILOT & FEASIBILITY PROGRAM TO SUPPORT UNDERSERVED OR HEALTH DISPARITY POPULATIONS [OPTIONAL]

• Subcontracts for Research/Resource Cores at institutions of higher education (i.e., rural institutions, historically black colleges and universities (HBCUs), Tribally Controlled Colleges and Universities (TCCUs) and Hispanic-serving Institutions (HSIs) and Alaska Native and Native Hawaiian Serving Institutions), or other agencies/organizations that focus on underserved or health disparity populations. (**Subcontracts for this opportunity have no direct costs cap**); Research Strategy is limited to 12 pages per proposed core/activity.

1. Description (PHS 398- Form Page 2)
2. Key Personnel (PHS 398- Form Page 2-cont'd)
3. Budget with justifications (PHS 398- Form Page 4)
4. Biographical sketches: Core Director and key personnel (PHS 398- Form Page)
5. Specific Aims (limited to 1 page): List in priority order, the broad, long-range objectives and goals of the proposed core. In addition, state the relationship of the

proposed core to the Center goals and how it relates to the current cores at the applicant institution and in the application.
6. Research Strategy, including: Objectives of the core; Core function, including quality control; Benefits of the core to current Center members and the investigators at the minority-serving institution or organization; Plans for evaluating the objectives of the proposed partnership; Proposed developmental research or training; Future directions and plans to ensure continuing evolution & relevance of the core; if applicable, describe any recharge system that may be in place to allow investigators to utilize a core, including information on any proposed F&A charges to outside users of the core.
7. New Cores: Funded investigators who will use the core and proposed extent of use (see Guidelines Illustration V). For Existing Cores: Core Use during the last grant period (see Guidelines Illustration V).

• Subcontracts for expansion of the Diabetes Research Center Pilot and Feasibility Program to support investigators at institutions of higher education (i.e., rural institutions, historically black colleges and universities (HBCUs), Tribally Controlled Colleges and Universities (TCCUs) and Hispanic-serving Institutions (HSIs) and Alaska Native and Native Hawaiian Serving Institutions), or other agencies/organizations that focus on underserved or health disparity populations.

1. Description (PHS 398- Form Page 2)
2. Key Personnel (PHS 398- Form Page 2-cont'd)
3. Budget with justifications (PHS 398- Form Page 4); justify any changes for future years; provide details on how F&A costs for P&F grants will be handled with the partnering institution/organization(s).
4. Biographical sketches: Program Director and Committee (PHS 398- Form Page)
5. Specific Aims (limited to 1 page):
6. Research Strategy (limited to 12 pages): Management of the expanded pilot and feasibility program; plans for advertizing and solicitation; For applications proposing a new, expanded P&F program at a subcontracting institution include: eligibility requirements, review and selection process, abstracts of proposed P&F awards, and plans for research core access and usage by P&F awardees; For renewal applications with an existing P&F program at a subcontracting institution: Total number of all P&F submissions received each year during the prior project period, selection process and funding success rates, single paragraph synopses of Pilot & Feasibility studies awarded during the last project period.
7. For applications proposing a new, expanded P&F program: Biographical sketches of proposed P&F Awardees (PHS 398- Form Page)

SECTION 6: CENTER-RELATED INFORMATION (suggested Illustrations only)

• Suggested Illustration for Renewal Applications: Publications Citing Support from this Center during the past project period. List only those publications that clearly used Center resources (e.g. core or P&F support); do not list all publications from Center members (see Guidelines Illustration VII; include PMCID numbers).

• 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 $1,000,000 in direct costs for DRC (P30) applications unless the applicant organization proposes to provide regional or national core services as described in the Funding Opportunity Announcement. Applications proposing a Regional/National Shared Research Resource Core are limited to $1,250,000 per year in direct costs. Not included in these direct cost limits are: (a) first year equipment costs, (b) direct costs on subcontracts to historically black colleges and universities (HBCUs), 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 health disparities research in populations disproportionately affected by diabetes, and (c) F&A costs on consortium and subcontract arrangements. It is anticipated that the award budget will be directly correlated to the breadth, quality and relevance to diabetes and related areas of the research base being served by the Center

Generally, at least 20-25% of the direct costs requested in DRC 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 2-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. 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 2.4 person months (calendar year) of his/her efforts to the Center. The Center application should include salaries for individual PDs/PIs 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 DRCs 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. 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. A very important component of DRCs 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.

Criteria:

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. 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 Center 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 Center proposed).

Scored Review Criteria - Reviewers will consider each of the 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 Center that by its nature is not innovative may be essential to advance a field.

Significance Does the Center address an important problem or a critical barrier to progress in the field? If the aims of the Center 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? What are the strengths of the Center's research base (its breadth and depth) and the relevance and interrelation of the separately funded research projects to the focus/theme(s) of the Center? Is there a strong scientifically excellent research base in diabetes, its complications, and related endocrinology and metabolic diseases at the Center, which would benefit by the services/programs supported through the Diabetes Research Center? What is the likelihood that the Diabetes Research Center will increase efficiency; promote new research directions and meaningful collaborations among Center investigators; facilitate interactions and collaborations among the investigators; and prove cost-effective? In renewal applications, have the benefits of the Center been documented in the form of increased collaborations, new research directions, and cost savings?

Investigator(s) Are the PD/PIs, collaborators, and other researchers well suited to the Center? 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? Are the Center investigators responsible for the individual research projects willing to interact with each other and contribute to the overall objectives of the Diabetes Research Center? What are the scientific and administrative leadership abilities of the proposed center Director and Associate Director(s) and their commitment and ability to devote adequate time to the effective management of the Center program? If applicable, are the P&F studies submitted for evaluation from applicants eligible for P&F funding? If requested, does the Named New Investigator appear well qualified and eligible for support?

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? Does the selection process by which the individual Pilot & Feasibility (P&F) studies were selected appear appropriate; does the Center encourage 'high-risk', innovative ideas through their P&F program? Have the cores provided new methods, techniques, and/or resources and developed ways to support investigators in new areas of diabetes and its complications, and related areas of endocrinology and metabolism research, as appropriate to the purpose of the core and the research supported by the Center?

Approach Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the Center? 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 Center 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? How appropriate and relevant are the proposed cores and the modes of operation (such as potential utilization, prioritization of requests for services, cost-recovery, and quality control monitoring)? Will the cores provide opportunities not otherwise available to the investigators through other available federally funded and/or institutional resources; represent appropriate cost savings/cost sharing advantage; and stimulate the development of new approaches? Is appropriate administrative organization proposed for the following:(a) coordination of ongoing research between the separately funded projects and the Center, including mechanisms for internal monitoring;(b) establishment and maintenance of internal communication and cooperation among the Center investigators;(c) mechanism for selecting and replacing professional or technical personnel within the cores;(d) mechanism for reviewing the use of, and administering funds for, the P&F program;(e) management capabilities, including fiscal administration, procurement, property and personnel management, planning, budgeting, and other appropriate capabilities? Is there efficient and effective use and/or planned use of the limited enrichment funds, including the contribution of these activities to the stated goals of the Center?

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? Is there evidence of institutional commitment to the Center program, including lines of accountability, regarding management of the Center grant and the institution's contribution to the management capabilities of the Center? Is there clear potential for interaction with scientists from other departments and institutions?

Additional Review Criteria – Overall

As applicable for the Center proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

The following additional review criteria apply to all new and renewal Diabetes Research Center applications. Foremost, does the research base to be supported by the Center show evidence of a strong and consistent record of productivity and peer-reviewed funding in Center-related research areas? Do the proposed cores fill a need present in the diabetes research community, and will they provide services that would otherwise be unavailable, or be more cost-effective to conduct centrally? Is the necessary technical and analytical expertise available? Does the application demonstrate ability to monitor use and utility of the cores, and provide approaches to ensure continuing development and evolution of services as needs of the community change? Does the existing Center show clear evidence of successful implementation of a recharge structure to support expanded and/or evolving Center activities? Do the new proposals document a clear intent to implement a recharge structure to support expanded and/or evolving Center activities?

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 Center 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 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 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.

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

Research Base:

- Does the Center show evidence of a stable or growing research base with strong and consistent record of scientific excellence and achievement reflected in an outstanding level productivity and continuing success in securing peer-reviewed research funding?

• Does the Center show evidence of fostering multi-disciplinary collaborations among its Center investigators?

Biomedical Cores:

• Are the number and impact of research publications that acknowledge the Center sufficient to justify each core?
• Is there a significant fraction of papers that a) acknowledge the Center and b) do not have core personnel as co-authors?
• Are the number and listing of Center investigators who have used the core and resultant key advances consistent with the level of core investment?
• Do the number and listing of investigators who have used the core multiple times indicate satisfaction and continuing need for core services?
• Are there sufficient numbers of users who are not core personnel or their collaborators?
• Are the number and listing of users who are not Center personnel or members consistent with the best utilization of the core by the community?
• Are the numbers of services/tests completed by each core indicative of a growing need and sufficient to justify continued support?
• Is the capacity of each core with current resources sufficient to serve the needs of the Center community?
• Does the Center provide evidence of ability to evolve cores to meet changing needs of the research community?
• Does the Center provide evidence of Program Income and sufficient institutional support?
• Does the Center website show evidence of continuing maintenance and a high level of quality and usability?

Administrative Core:

• Has the administrative structure proven effective?
• Has the enrichment program been effective?
• Is (Are) the Center Director(s) appropriately qualified to lead the Diabetes Research Center?

Pilot & Feasibility Program:

• Are the numbers and types of P&F awards well justified?
• Are data provided to document the outcome of all P&F projects completed in the last five years, including those that failed to lead to further funding?
• Are papers generated under these awards, projects successfully funded with independent grants, and key advances linked to these awards well documented and consistent with the level of support provided?

Additional Review Considerations - Overall. As applicable for the Center proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

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; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).

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

VIII. EVALUATION AND REPORTING REQUIREMENTS

When multiple years are involved, awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the NIH Grants Policy Statement.

A final progress report, invention statement, and Financial Status Report are required when an award is relinquished when a recipient changes institutions or when an award is terminated.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the NIH Grants Policy Statement for additional information on this reporting requirement.

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.

X. ILLUSTRATIONS

ILLUSTRATION I – FOR NEW AND RENEWAL APPLICATIONS

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					
Totals					

ILLUSTRATION II – FOR NEW AND RENEWAL APPLICATIONS

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			1.0		2.4	6.0
Dr. B.		1.2			1.2 (3)	2.4	4.8
Dr. C.	0.6				2.4 (4)	3.0	
Dr. D.			0.6	*1.5		2.1	6.0
Etc.							

*Star the calendar months (see Core A) when that individual is the core director.
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 – FOR NEW AND RENEWAL APPLICATIONS

SUMMARY OF TOTAL CURRENT AND PENDING SUPPORT OF ALL CENTER PARTICIPANTS

SAMPLE EXHIBIT III-A: CURRENT DIABETES-RELATED RESEARCH BASE SUPPORT

Grants to be included: R01s, R37s, K-series, P01s (if the total funds are already listed for the Principal Investigator of the P01 funds, support for the subproject should be shown in parentheses), specialized centers (such as P30s, P50s, P60s), and peer-reviewed grants funded through other Federal Agencies or non-federal groups. Do not include this Diabetes Research Center. Include ONLY diabetes and related endocrinology and metabolic diseases research support (i.e., not general renal, digestive diseases, or other non-diabetes research).

Some institutions may have multiple NIDDK-funded centers. In such cases, grants of Diabetes Research Center investigators who participate in other NIDDK Centers should identify if the grant listed in Exhibit III is also listed as part of the research base of another NIDDK Center.

List training grants (T32) and fellowships (F32) related to diabetes LAST in the table below (III-A).

*Principal Investigator/ [Co-Investigator]	Supporting Organization/ Grant Number	Title	Project Period	Annual Direct Costs**	Identify other DK Center(s), if grant is included as part of its research base
Doe, John [Stellar, Fred]	NIH/P01 DK12345	Insulin Receptors Actions in Skeletal Muscle	4/1/2009 – 3/31/2014	$500,000	
Jones, James	NIH/R01 HD65432	Hypothalamic Control of Energy Balance	7/1/2010 – 6/30/2014	$225,000	NORC
Smith, Edith	DOD	Diabetes and its Health Effects	7/1/2007 – 6/30/2012	$180,000	O'Brien Kidney Center
Miles, Amelia	CDC	Frequency of Childhood Diabetes	9/1/20011 – 8/31/2016	$350,000	
Etc.					

* For Multiple PI grants, list the grant under the name of the Contact PI with all other PIs listed in [ ]. Do not list any grant more than **once.**
** Also sum this column (excluding T32 and F32 support) and calculate the % coming from the NIDDK and the % from government funding.

<u>ILLUSTRATION III-B</u>: PENDING DIABETES-RELATED RESEARCH BASE SUPPORT

Include the same type of grants as listed above in SAMPLE EXHIBIT III-A. Use the same column headings except the last one.

----------(AS ABOVE)----------

ILLUSTRATION IV - FOR NEW AND RENEWAL APPLICATIONS

COLLABORATIONS BETWEEN CENTER MEMBERS

	JONES	SMITH	ADAMS	CHU	EVERS	KNIGHT	OLSON	SANDS	TAYLOR	YOUNG	ZANE
JONES	X	*		*	*		*		*		*
SMITH	*	X			*		*				*
ADAMS			X	*			*	*	*		
CHU	*		*	X		*					
EVERS	*	*			X			*			
KNIGHT				*		X				*	
OLSON		*		*			X				*
SANDS			*		*			X		*	
TAYLOR	*		*						X		
YOUNG						*		*		X	
ZANE	*	*					*				X

*Indicates collaboration as evidence by joint publications, abstracts, or research grants or by joint research projects.

ILLUSTRATION V – FOR NEW AND RENEWAL APPLICATIONS

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	3/7/08-3/6/13	X X	A. 5 per month C. 100 per month
2. S. R. Jones	K08 DK00000-00	1/4/07-1/3/12	X X	B. 40 per week D. 8 per month
3. R. G. Brown	R01 GM00000-00	9/1/07-8/31/12	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."

ILLUSTRATION VI - FOR RENEWAL APPLICATIONS ONLY

PILOT & FEASABILITY (P&F) PROJECT OUTCOMES

Set up column headings:

Project Number
Investigator
Department
Funding Dates (for P&F project)
Amount of P&F (direct costs for entire P&F project period)
Title
Publications (# of papers, # of abstracts)
Applications Funded (Yes, No, Pending)
Grant Number (of the grant received most proximate in time to the P/F award, i.e. for investigators who received funding 5-10 years ago, this will usually not be current funding)
Project Period
Total Direct Cost
Still in Diabetes Research (Yes, No)

The above data must be provided for the P&F projects awarded during the most recent five-year project period; the data provided should not exceed the most recent ten years.

ILLUSTRATION VII--FOR RENEWAL APPLICATIONS ONLY

PUBLICATIONS CITING SUPPORT FROM THIS CORE CENTER GRANT

Core or P&F/P.I. Name)	Publications	Primary	Secondary
Core A/Brown	Brown, A.C; Jones R.C.; Smith, A.J. Metformin reduces hepatic glucose output. Diabetes, 2008 volume; page # PMCID#	Core A	
	Brown, A.C.; Cheng, A.G.; Anderson, J.C. Results of Islet Transplantation, Diabetes Care, 2010, volume: page#, PMCID#.	Core A	Core C
Core B/Cheng	Cheng, A.C.; Meyer, G.C Linkage studies in animal models of diabetes. Nature Genetics, 2011, volume: page#, PMCID#.	Core B	Core A
	*Smith, F.G.; Cheng, A.C Tissue Specific Knockout of Glut4 PNAS, 2009, V: page#, PMCID#.	Core B	
P&F/Smith	Smith, F.L.; Davis, S.E.; Morris, J.L. Role of macrophages in hypothalamic inflammation . J. Clin. Inv, 2010, volume: page#, PMCID#.	Core C	
P&F/Jones	Jones, T.L; Hathaway, J.B Clemmons, A.H.; Akt and hepatic lipid accumulation. J. Biol. Chem, 2010, volume, page#, PMCID#.	NONE	

Instructions: List each publication only once under the Core (or P&F project PI name) 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 research core most significantly contributing to the work should be signified as "Primary." All other contributing research cores are designated as "Secondary." Use separate headings for each research core (i.e. publications supported by each 'primary' core should be grouped together), followed by the P&F projects at the end of the listing of Center publications.