CENTERS FOR DIABETES TRANSLATION RESEARCH

ADMINISTRATIVE GUIDELINES

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

August 2010

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I. DESCRIPTION

Background

The NIDDK-supported Centers for Diabetes Translation Research (CDTRs) are part of an integrated program of diabetes research. Centers allow for cost effective collaboration among multidisciplinary groups of investigators at institutions with an established research base in translational research related to diabetes.

General Description

The mission of the CDTRs will be to serve as a key component of the NIDDK-supported research program to translate efficacious research findings into practice and the community to improve the health of Americans with, or at risk for, diabetes. CDTRs will enhance scientific progress and improve the uptake of research through support of rigorous translation research aimed at prevention and improved treatment of diabetes (type 1, type 2 and gestational) and related conditions. To meet these goals, CDTRs will provide core services and consultation locally, regionally, and nationally in areas relevant to the NIDDK translation research agenda. To learn more about the NIDDK type II translation research priorities in diabetes, please see the *Clinical Research to Practice: Translational Research* chapter in the current draft of the *Advances and Emerging Opportunities in Diabetes Research: A Strategic Planning Report of the DMICC*: http://www2.niddk.nih.gov/AboutNIDDK/ReportsAndStrategicPlanning/DiabetesPlan/PlanPosting.htm.

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 translational research related to diabetes is required. This research should be in the form of NIH-funded research projects (R34, R18, R21, R01), or other peer-reviewed research, such as that supported by other funding agencies to include Centers for Disease Control and Prevention, Agency for Healthcare Research and Quality, Robert Wood Johnson Foundation, and the American Diabetes Association. 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. Efficient management of resources and close cooperation, communication, and collaboration among involved personnel in multiple professional disciplines are ultimate objectives of core centers.

Basic Requirements for a P30 Core Center

To be eligible for a Core Center grant, the potential applicant institution must already have a substantial base of ongoing, independently-supported, high-quality research in type II translational research related to diabetes. 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 research projects other than through core usage. The major source of support for 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 used 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. However, diabetes translational researchers who are funded by NIH/NIDDK or other funding agencies and are not located the CDTR institution (and do not have a subcontract with the primary CDTR institution) may be included as a 'member' or 'affiliate member' of the CDTR. In such cases, the applicant should describe the planned use of one or more of the core services at the CDTR and clearly describe and justify the reasons why it is appropriate for these projects to be included in the research base; including the expected advantages from the collective utilization of the Core Center.

The Cores in a CDTR must primarily focus on type II translation research--defined as research focused on translating interventions/approaches that have clearly demonstrated efficacy into real world health care settings, communities, and populations at risk. Type II translational research is distinct from type I translational research. Type I translational research (bench to bedside) builds on basic science findings and focuses on early phase research to "translate" them into potential interventions or therapeutics that might ultimately be tested in clinical trials. While type I translational research is a critically important piece of the research continuum, it is not the focus of this announcement and should not be the focus of the CDTR. Type II translational research supported by a CDTR might include effectiveness, dissemination, implementation, and cost effectiveness research. The target of this type of the research can be varied to include individuals, families, healthcare practitioners or systems, communities, and/or policy makers. Examples of CDTR expertise that would be relevant to conducting diabetes translation research might include design and analysis issues in translational research (e.g. quasi-experimental designs, adaptive or practical clinical trials, modeling, analyses for complex designs and data systems, health economic analysis), methodologies such as community engagement or Community Based Participatory Research, measurement at various levels (e.g. individual, family, system, community, healthcare practitioner) and dissemination and implementation science.

Topic level expertise might include such areas as adherence, health information technology, health disparities, health literacy and/or numeracy, technology based approached to intervention delivery or measurement, diabetes self management, lifestyle change, and health communication.

At the time of initial submission, the applicant institution or consortium of institutions must have an active program of excellence in type II translational research related to diabetes. 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

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

Requirements

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

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

The final administrative structure of the Center will be left largely to the discretion of the applicant institution (subject to review by NIH peer review mechanisms). However,

NIH's experience has demonstrated that the effective development of the Center programs require close interaction between the Center director, the principal investigators, appropriate institutional administrative personnel, the staff of the awarding agency, and the members of the community in which the Center is located. Therefore, each Center applicant should establish an administrative structure that will permit the development of such interaction. Within this structure, each applicant institution must also establish a mechanism to oversee the use of any funds proposed for a 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.

A description of plans for CDTR website development, maintenance and curation should also be included in the administrative core component.

III. TRANSLATIONAL 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 type II translational research 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 translational research (bedside to the community and practice research—e.g. effectiveness, dissemination and implementation research). The relevance to diabetes of all research included in the research base should be described. Projects at other institutions may also be included if collaborations exist with scientists at the applicant institutions. Applicants should indicate how the establishment of a Center will provide added dimensions, such as greater focus and increased cooperation, communication and collaboration.

Presentation of the research base in the application should be done in two ways: (1) by completing a Table like the one shown in Illustration III, and (2) by a full description of the diabetes related translational research activities at the applicant institution and any collaborating institutions. This presentation should be organized by 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.

Appropriate presentation of the research base is very important since its assessment is a primary criterion in the evaluation of an application.

Research Cores

***Definition*:** A 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 resources or consultation that will enhance research and contribute to cost effectiveness. A recharge/consultation cost 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.

Again, type II translational research supported by a CDTR might include effectiveness, dissemination, implementation, and cost effectiveness research. The target of this type of the research can be varied to include individuals, families, healthcare practitioners or systems, communities, and/or policy makers. Examples of CDTR expertise that would be relevant to conducting diabetes translation research might include design and analysis issues in translational research (e.g. quasi-experimental designs, adaptive or practical clinical trials, modeling, analyses for complex designs and data systems, health economic analysis), methodologies such as community engagement or Community Based

Participatory Research, measurement at various levels (e.g. individual, family, system, community, healthcare practitioner) and dissemination and implementation science. Topic level expertise might include such areas as adherence, health information technology, health disparities, health literacy and/or numeracy, technology based approached to intervention delivery or measurement, diabetes self management, lifestyle change, and health communication.

Justification for proposing a core: The establishment and support of translational 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.

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 5%. A core director with requisite expertise may devote a greater effort to the core and with justification could devote up to 12 person months. Where appropriate, an established expert in the core activities could also be included as a consultant to the core. Other personnel 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 institutional resources for the cores should be given special attention. Arrangements for sufficient space and resources for core activities must be made. Centers are strongly encouraged to enter into cooperative arrangements with cores or Centers already established within their institution, or with other Centers in close proximity, when the existing cores offer the services needed (e.g. Administrative Core services). These arrangements are important whenever greater efficiency or cost savings can be realized by such an agreement.

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

When a Center is first established, individual investigator-initiated research project grants may include funds for services that will ultimately be available through the cores. At the time of their next competitive or noncompetitive continuation application, investigators should remove from their individual research project grant budgets all costs associated with services received from the cores for which they are not charged. The elapsed time

before this adjustment is made generally constitutes a very minor overlap, if any, since it is usually several months before a core is fully functional. Recharge fees to the Center should be included in the budget of the research project grant once the cores are running since these are a necessary expense and are justified by cost savings. Some mechanism should be proposed in the Center application to monitor these budgetary adjustments and to ensure that Center core users describe their relation to the Center in their individual grants.

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

Pilot and Feasibility Program

Research projects associated with a Core Center will, in general, be funded from other resources, such as R34, R18, R21, or R01 grants from NIH or similar project funding from other Federal 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 directions for established investigators in diabetes and (3) stimulate investigators from other areas to lend their expertise to diabetes translational research. Pilot and feasibility study support is not intended for large projects by established investigators that would otherwise be submitted as separate research grant applications. Pilot and feasibility funds are also not intended to support or supplement ongoing funded research of an investigator.

Requirements: If a pilot and feasibility program is included in the CDTR application, each Center must propose a minimum of 2 pilot and feasibility studies to be supported by 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

translation research who wish to apply their expertise to this area; and (3) established investigators in diabetes translation who propose innovative research that represents clear departure from their ongoing research activities. It is expected that the majority of the investigators will fall into the first category and the later categories should be the exception for use of the pilot and feasibility funds rather than the norm. All eligible investigators, however, must have faculty appointments and be independent investigators. Postdoctoral fellows or their equivalent are not eligible. Each pilot and feasibility study proposal should state clearly the justification for eligibility of the investigator under one of the above three criteria.

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

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. The pilot and feasibility proposals are reviewed for scientific merit and eligibility by the reviewers. 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 translational research. 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 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-024.html. 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. Note: This information should also be included in progress reports and will be important to include in competing continuation applications (documenting the success of the pilot and feasibility program);

(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 should include an assessment of the relevancy of the proposed individual pilot and feasibility studies and of the program as a whole to research translational diabetes 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.

Enrichment Program

The CDTR enrichment program should be designed to advance type II translational research in diabetes and promote scientific exchange among investigators with research interests in this topic area, 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 CDTR for Center participants, and document ways the Center may facilitate, enhance or foster the institutional training environment. Specifically, Center applicants should provide information on related NIDDK T32 programs at the Center institution(s), and describe how the Diabetes Center will help to integrate, facilitate and enhance activities of T32-supported trainees. A letter from the PI of any related NIDDK-funded T32 at the Center institution should be included that acknowledges and details how the PI of the T32 intends to promote cohesive interactions between the two programs.

Training postdoctoral fellows to conduct research in diabetes type II translation research is an associated activity of a Center. While stipends for fellows cannot be funded from the Center, the establishment of a Center should provide an enhanced environment for research training. Just as in the case of funding for individual research projects, funding for fellowships should be sought from NIH NRSA institutional training grants (e.g. T32, T35) and individual fellowships (e.g. F30, F32), and other sources such as private foundations, and commercial companies.

IV. LETTER OF INTENT

It is the policy of the NIDDK that new and competing continuation Center applications are only accepted in response to a Request for Applications (RFA) announced in the NIH Guide for Grants and Contracts. It is strongly encouraged that potential applicants for a Center submit a letter of intent. The letter should be sent at least one month prior to submission to allow NIDDK staff to identify potential opportunities and problems early in the development of the application. The letter of intent needs to include only: (1) names of the principal investigators and principal collaborators, (2) identification of the organization(s) involved; and (3) announcement to which the potential application is responsive. The purpose of the letter of intent is to establish communication between the

potential applicant group and NIDDK staff. It is not part of the peer review material. Upon receipt of the letter, the appropriate NIDDK program director may contact the prospective principal investigator to obtain additional information to include scientific content and objectives, organization, and clarifications. However, applicants should not construe advice given by the NIDDK staff as assurance of favorable review. The staff will not evaluate or discuss the merit of the scientific aspects of the application.

V. PREPARATION OF APPLICATION

Forms and Submission

The current PHS 398 application instructions are available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Applications must be prepared using the forms found in the PHS 398 instructions for preparing a research grant application. Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies in one package to:
Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

Personal deliveries of applications are no longer permitted.
(see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-040.html)

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

Francisco O. Calvo, Ph.D.
Chief, Review Branch
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Boulevard, Room 752
Bethesda, MD 20892-5452
(for express/courier service: Bethesda, MD 20817)
Telephone: (301) 594-8897
FAX: (301) 480-3505
Email: fc15y@nih.gov

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.

Contacts for Questions:
We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Christine Hunter, Ph.D., ABPP
Director of Behavioral Research
Division of Diabetes, Endocrinology, and Metabolic Diseases
National Institute of Diabetes & Digestive & Kidney Diseases
6707 Democracy Boulevard, Room 605
Bethesda, Maryland 20892-5460
Phone: 301-594-4728
Fax: 301-480-3503
hunterchristine@niddk.nih.gov

2. Peer Review Contacts:

Francisco O. Calvo, Ph.D.
Chief, Review Branch
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Boulevard, Room 752
Bethesda, MD 20892-5452
(for express/courier service: Bethesda, MD 20817)
Telephone: (301) 594-8897
FAX: (301) 480-3505
Email: fc15y@nih.gov

3. Financial or Grants Management Contacts:

Elizabeth Gutierrez
Grants Management Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Two Democracy Plaza, Room 712B
6707 Democracy Boulevard
Bethesda, Maryland 20892-5456
Telephone: (301) 594-8844
Fax: (301) 480-3504
Email: gutierrezel@niddk.nih.gov

General Instructions

Face Page:
Items 1-14 (See PHS Form 398)
NOTE: Awards for CDTR grants are made for **five year** project periods.

Form Page 2:
Description, Project/Performance Sites (self-explanatory)
Number the pages consecutively throughout the application.

Senior/key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells (follow 398 instructions)

Form Page 3:
Table of Contents: Provide a Table of Contents following the basic format shown in the 398 kit but modified to be appropriate for the items submitted for a center application.

Form Page 4:
Provide a consolidated budget for first year of requested support. See Illustration I. Separate budgets for each core should immediately precede the narrative of that section, using form page 4.

Form Page 5:
Budget for Entire Proposed Project Period
The total funds requested for the P/F grant program should be included in the "other expenses" category of the budget for the Administrative Core. Except for new investigators, salary support for P/F projects is discouraged. The individual P/F project budgets should be included before the narrative of each P/F project using PHS Form 398, form page 4, if desired.

Biographical Sketches:
Provide biographical sketches for all CDTR investigators (key personnel, research base investigators, consultants, and collaborators). Biographical sketches for principal investigators on P/F projects should be included with the P/F project. Follow the current NIH Form 398 instructions.

A summary of the distribution of percent of professional effort for this application is useful for reviewers and may be included after the Biographical Sketches. (See Sample Illustration II for a suggested format).

A summary of the current and pending support (e.g. R34, R18, R21, R01, P01, K-awards) for all CDTR investigators, including percent efforts, aids in the review process when presented as suggested in Illustration III. Institutional Training Grants (T32 or T35) and Individual Fellowship Awards (F31 or F32) are not part of the research base but should be listed separately as part of the current or existing support.

Resources Format 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.

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

Research Plan (Section V-PHS Form 398)

Introduction

A description of the focus and theme(s) of the CDTR and any unique aspects must be presented along with a brief narrative describing the qualifications of the Director and associate Director (or co-PIs if the multiple PI option is selected), and a plan for replacing the Director should this become necessary. A brief description of how the Center will foster and support type II translational research in diabetes should be included

Administrative Core Component

Provide a description of the administrative structure of the CDTR, including: chain-of-command, committee structures (e.g., Internal Advisory Committee; P/F review; other oversight or management committees), and core and clinical component oversight. In the event of a consortium arrangement, the decision making process across the participating organizations needs to be described in detail.

List the areas of expertise necessary for inclusion on the External Advisory Board, not the names of the individuals whom you plan to recruit to serve in this capacity.

Include budget required for Center website development, maintenance and curation.

The budget justification for the Administrative Core should include appropriate justification. For example, budgetary items that, if requested, should be included here are funds for enrichment programs and travel funds for the PI and other relevant Center staff to attend the annual meeting of CDTR directors. It is expected that a full-time administrative Core will not be required to manage the scope of the CDTR. Where applicable budgetary efficiencies (e.g. buying into existing administrative cores through other funded Centers) are encouraged.

Include a description of the mechanism for monitoring budgetary overlap between the research projects included in the research base and the funds for the core facilities of the CDTR. Describe a mechanism to monitor the budgetary adjustments made necessary by the use of core services. This will ensure that CDTR investigators using cores are able to provide a satisfactory explanation of their relationship to the CDTR and their inclusion of charge-back fees to the cores in their individual grant budgets.

While facilities (space, equipment, library, etc.) must be clearly described for each element of the application, include a more global description of the overall facilities and a statement regarding institutional commitment to the CDTR in the description of the Administration Core.

Research Base

As noted earlier, 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 related translational research activities at the applicant institution and any collaborating institutions. This presentation should be organized by 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.

Research Cores (present each Core separately)

For each core, include a budget with detailed justifications for: (1) the initial budget period, and (2) entire project period. Detail the qualifications of the core Director and the duties and qualifications of other personnel, including technical support staff. In the event a core Director is not an established investigator, highlight the institutional commitment to and career plans for the individual.

Include the rationale for establishing the core, the activities of the core, and how this core will support a need in the diabetes translation community Provide short descriptions of the services provided and the projects of the investigators who will use the core.

Present the organization and proposed mode of operation of each core. Describe plans for:

1. Prioritization of investigator use
2. Monitoring core use
3. Plan to evaluate outcomes/success as a result of core use (e.g. publications, funded grants, public health change)

Include a definition of qualified users. Provide a list of funded Center investigators who will use the core, the expected extent of their proposed use, and the anticipated benefits that investigators will derive from using core facilities. An example is provided below:

Core Name: Health Information Technology

Services/Resources Offered in the Core:

A. Consultation about software and platform interface
B. Review and advice about user interface with mobile technologies

Projects Using the Core: Funded grants include identifiable grant numbers. Services provided for grants under preparation include planned mechanism and funding agency (e.g. R18, NIDDK)

A. User (PI name): Jane Doe
B. Type of Services/Resource: Consultation about software and platform interface
C. Estimated Use(time, duration, and resources): 2 hours/every other week x 8 weeks and consultation and review of grant section

CDTRs are able to include plans to serve as regional or national resources. If such a plan is included, there also needs to be a description about how these relationships will be developed and Core resources advertized, the prioritization plan for allocating resources, and the methods to monitor use under these circumstances.

With a regional or national core, the Center will service a specific research base that is expanded beyond investigators at the Center-affiliated institution. If relevant, applicants should consider and propose opportunities to share core services or functions with other NIH funded Centers in order to expand, enhance, or increase the cost-effectiveness of research activities of the Center.

Centers must partner with institutions, regionally or nationally, that are not already strongly affiliated with the Center institution or develop a plan to serve a consultative/advisory role to those outside of the Center institution. Services or resources shared with an already associated institution, such as an affiliated teaching hospital, are encouraged but would not be a justification for additional funds. Again, applicants must demonstrate how resources will be shared and how these services or partnerships will be documented. Activities might include opening the pilot and feasibility programs to investigators outside the institution or plans to reach and advise/consult with researchers beyond the CDTR institution

<u>Pilot and Feasibility Studies Program</u>

Provide a composite budget with justifications for (1) initial budget period, and (2) proposed future years. The actual budget request for the P/F program should be listed in the "other expenses" category in the budget for the Administrative Core.

Describe the management plan for the P/F grant program, including both internal and external review mechanisms along with an outline of the plans for future years of the P/F Program. This should include how applications will be solicited, reviewed, awarded, and, if required, terminated.

Include eligibility requirements, selection process, abstract/s of proposed pilot and feasibility awards in the initial budget period/s, relevance to the focus of the Center, and justification for core use.

Enrichment Program

Describe plans for the enrichment program in as much detail as possible. Include funds for the enrichment program in the budget for the Administrative Core.

Appendices

Follow the 398 instructions for the format for submitting appendix materials.

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 $200,000 in direct costs. Not included in this direct cost limit are: 1) requests for equipment in the first year of a competitive award; 2) direct costs on subcontracts to minority serving institutions, health departments, community health centers or other agencies that focus on underserved populations for the purpose of establishing collaborations and providing access to the research infrastructure to investigators at these institutions to foster research to reduce or eliminate health disparities in populations disproportionately affected by diabetes; 3) inclusion of a pilot and feasibility program (up to $50,000 in direct costs), 4) detailed plan to provide core resources/services regionally or nationally (up to $100,000 in direct costs), and 5) Facilities and Administrative (F&A) Costs associated with any subcontract.

Budget Categories

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

No overlap of time or effort between a CDTR activity and separately funded research projects or Centers is permitted. Potentially overlapping support between CDTR and individual projects, including research project grants (R01), program project grants (P01), Career Development Awards (K-awards), Small Business Technology Transfer awards

(R41, R42), Centers (e.g. CTSA, P30, P60) and contracts, will be administratively reviewed by the NIDDK and, if appropriate, adjusted to eliminate duplication of funding.

Stipends for research trainees are not available through the CDTR. Such funding must be sought through other grant mechanisms.

Technical and Support Personnel: This may include salaries for identified positions to be filled in the Center. Technical and support personnel costs are not expected to be substantial in a CDTR. No overlap of time or effort between the Center and separately funded projects is permitted.

Equipment: In general, it is assumed that equipment needs for a CDTR will not be substantial. If pieces of specialized equipment costing more than $5,000 are requested, the application must identify similar equipment already available within the institution and provide a clear justification for purchase in terms of core service being provided to CDTR investigators. Requests for general-purpose equipment should be included only after ascertaining the availability of such items within the institution. Justify the request based on this availability. This includes all equipment in future budget years as well as the initial budget period.

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 the Clinical and Translational Science Awards (CTSA) and individually supported beds. Costs relating to the translation 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 and/or non-responsive applications will not be reviewed. 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.

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.

The specific and standard review criteria are outlined in the RFA. Please carefully review the section on Review and Selection Process included in the RFA. Some CDTR specific criteria include:

- Will the proposed CDTR resources and expertise enhance and advance diabetes type II translational research?
- What is the likelihood that the CDTR will increase efficiency; promote new research directions and meaningful collaborations among center investigators; facilitate interactions and collaborations among the investigators; and prove cost-effective?
- Are the center investigators willing to interact with each other and contribute to the overall objectives of the CDTR?
- What are the scientific and administrative leadership abilities of the proposed center leadership?
- Do they demonstrate commitment and ability to devote adequate time to the effective management of the program?
- Is there evidence of institutional commitment to the program, including lines of accountability, regarding management of the center grant and the institution's contribution to the management capabilities of the center?
- 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 in the diabetes type II translation research community, and will they provide services that would otherwise be scarce or are 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 application document a clear intent to implement a recharge structure to support expanded and/or evolving Center activities?
- Do the training opportunities proposed enhance the capacity (e.g., skills and capabilities) for type II translational research and, if applicable, are they integrated with other NIH funded training at the Institution such as T32s?

VIII. EVALUATION AND REPORTING REQUIREMENTS

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

(1) Cumulative Budget

(2) Budget for each Core

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

(4) Other support for all Key personnel

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

(6) Administrative Core: Highlight significant accomplishments, evaluation activities (e.g. publications, grants, products or outcomes supported and enhances by Center resources), and enrichment activities (e.g. seminars and symposia; regional and national presentations; collaborations with other Diabetes Centers, institutions and centers; website developments)

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

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

IX. SPECIAL CONSIDERATIONS

Each Center will be expected to develop its own program in accordance with local talents, interests, and resources. Each Center must also be responsive to national needs to develop new approaches to diabetes translation research 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.

ILLUSTRATION I

CONSOLIDATED BUDGET FOR 1st YEAR OF REQUESTED SUPPORT

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

ILLUSTRATION II

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

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

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

ILLUSTRATION III

SUMMARY OF TOTAL CURRENT AND PENDING SUPPORT OF ALL CENTER PARTICIPANTS

DIABETES RESEARCH BASE: Current Support						
Principal Investigator (Co-Investigator*)	Supporting Organization and Grant Number	Title	Project Period	Total Costs for Entire Project Period	Annual Direct Costs	Effort (in calendar months)
Example: Doe, Joe	R18 DK-00000	Translation of DPP in primary care	4/1/08-3/31/13	$3,396,240	$415,261	4.8
Jones, Sam	R21 DK-00000	Enhancing adherence to blood glucose monitoring	6/1/09-5/31/11	$370,000	$125,000	6.0
Lane, Andrea (G. Under)*	R01 DK-00000	Smart phone delivery of lifestyle intervention	7/1/07-6/30/12	$3527,922	$ 421,747	1.2
DIABETES RESEARCH BASE: Pending Support						
Principal Investigator Co-Investigator*	Supporting Organization and Grant Number	Title	Project Period Requested	Total Amount Requested	First Year Support Requested	Effort Requested
NON-CENTER-RELATED RESEARCH: Current Support (as above)						
NON-CENTER-RELATED RESEARCH: Pending Support (as above)						

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