

# ADMINISTRATIVE GUIDELINES FOR O'BRIEN KIDNEY RESEARCH CORE CENTERS

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## **I. DESCRIPTION**

### **Background**

The NIDDK-supported O'Brien Kidney Research Core Centers are part of an integrated program of kidney disease research. These Centers were originally established as Specialized Research Centers in 1987. Center grants such as these have proven to be a valuable way to promote multidisciplinary interactions and to provide the shared resources needed to address complex biomedical problems, such as therapy for many kidney diseases. Centers also can provide the basis for generating technologies that can be applied by other investigators and clinicians in many medical centers throughout the nation.

### **General Description**

The objectives of the O'Brien Kidney Research Core Centers are to bring together basic and clinical 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. The Core Center consists of several components: a single Administrative Core, several Biomedical Research Cores, and a Pilot and Feasibility Program. 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 kidney disease, is required. This research should include NIH-funded research projects and other peer-reviewed research. 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 Core 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 basic and / or clinical research aimed at the pathophysiology, diagnosis, monitoring, or treatment of kidney disease. 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), a Pilot and Feasibility Program (new initiatives), and program enrichment activities. Each Biomedical Research Core within the Center will provide services to Center participants (a detailed description of Biomedical Cores begins on page 8). 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 kidney disease research. The Core Center 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 performance of Core functions. The Core Center may also provide resources for funded projects at collaborating institutions that do not have a sub-contractual 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.

A new category of Cores that is being encouraged is the Regional/National/International Cores. These Cores serve specific scientific communities on a regional, national, or international level. The research base for cores that are used as a regional, national or international resource should be considered the "extended research base." The extended research base for a regional, national or international core could include all investigators who might expect to use the core in some way. This might include investigators who would be expected to fully compensate the core service through a charge-back, and thus would not be obtaining direct financial assistance from the Center. The list could include investigators who use the core services but otherwise have no collaborative interactions with other Center investigators. The extended research base should be defined as an entity separate from the institutional research base. For review purposes, it should be evaluated as part of the core, in order to distinguish it from the local institutional research base.

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 kidney disease. **The biomedical research base should be substantial to justify the proposed Core support.** There should be a focus on basic and translational / clinical research in kidney disease. 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**

An O'Brien Kidney Research Core Center 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 kidney disease research. This commitment will require significant effort from the Center Director. Each Center Director is expected to commit 2.4 person months (calendar year) overall effort to 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. 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:

- (1) Coordinating and integrating the Center components and activities
- (2) Overseeing the solicitation, review, and selection of pilot and feasibility studies
- (3) Reviewing the utilization and quality of core resources
- (4) Interacting with the scientific and lay communities and the NIDDK to develop relevant goals for the Center

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 project directors/principal investigators, appropriate institutional administrative personnel, the staff of the awarding agency, and the members of the community in which the Center is located. Therefore, each Center applicant should establish an administrative structure that will permit the development of such interaction. Within this structure, each applicant institution must also establish a mechanism to oversee the use of funds for the proposed Pilot and Feasibility Program. This mechanism must include review by appropriate consultants from the scientific community outside the Center institution or consortium institutions. 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 reviewed by the NIDDK Staff for eligibility in its annual evaluation of the Center program. Funds for the Pilot and Feasibility Program should be listed in the Other category in the budget of the Administrative Core. 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 and prioritized to utilize the core resources 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.

Centers need to develop policies and procedures for change of core functions. For example include: new technologies or services that should be supported might appear; existing technologies might become less important; or economic changes might obviate the need for core services, such as the availability of cost-effective commercial services or core services provided by the research institution. Cores should address the issue of allocation of resources to development of new technologies in comparison to provision of services with existing technologies.

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 kidney disease. Therefore, existence of a strong research base in this area is a fundamental requirement for and the most important aspect in the establishment of a Core Center.

Applicants should include an overview of current kidney disease 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 research in kidney disease. 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 disease 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. These focus areas should include a section on “Basic Kidney Research” and a section on “Clinical / Translational Kidney Research.” Additional areas of emphasis relevant to the goals of the Center may be included. 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 reviews, the quality of the individually 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.

The application obviously has insufficient space for a detailed presentation of the research base. However, significant research accomplishments should be cited, and it may be helpful to include a few reprints as examples of the research conducted by Center participants as an appendix to the application. Appropriate presentation of the research base is very important to justify the research need for the proposed Core services.

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 and by completing a Table like the one shown in Illustration IV, which documents the contribution of individual cores to the publications by the research base. New areas of research and acquisition of new funding should be highlighted.

## **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. It is acceptable to develop a cost recovery system to help

defray costs to the Center. This system would charge a fee to Center participants for services provided by the Core, but at a reduced rate. If such a cost recovery system is developed, a detailed charge justification must be presented and the program income section on the checklist of the PHS 398 must be completed. 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 the following categories:

- Collection, storage and distribution of data and samples;
- Provision of specialized tools and technologies or access to specialized expertise;
- Development, standardization, and distribution of reagents and/or protocols;
- Provision of technical assistance, training, and enrichment programs;
- Recruitment of patients and coordination of patient studies;
- Beta-testing and dissemination of specialty assays, methods, and services on an institutional level;
- Increasing interdisciplinary interactions at the institution through cross-project/ laboratory exchange; and
- Sharing of specialized tools, technologies and expertise between collaborating investigators.

Clinical and translational research Cores could provide biostatistical expertise for study design and data management and analysis; bioinformatics support; infrastructure for recruiting and managing clinical research subjects and/or tracking and analyzing clinical samples; technologies useful for phenotyping and characterizing subjects or exploring clinical pathophysiology; and expertise for behavioral assessment or intervention.

**Regional/National/International Cores:** Centers are encouraged to propose Cores that provide unique resources to a community outside the Institution. These could be on a regional level, a national level, or an international level. A Regional/National/International Core may define its own research base, which is expanded from that of the rest of the Center. The Core may include investigators that use this resource or service but do not have a formal collaboration with other Center investigators.

**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's 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 review.

Each Core must have in place a procedure to evaluate efficiency and to maintain appropriate quality control. Limited developmental research is an additional appropriate function of a core facility, so long as the research is related directly to enhancing the function or utility of the core and is not an undertaking that should be funded through other mechanisms. The Core should develop policies and procedures for change as technology progresses. Cores must also have well-defined policies to ensure that intellectual property is identified and appropriately protected, but these issues should not impede the sharing of resources. Teaching the investigators and/or their staff members new techniques and methodologies is also an important function of the Cores. The Cores are not intended to supplant investigator capabilities; rather, they are intended to enhance the opportunities of investigators to learn and become proficient in the technologies available through the Core.

**Personnel:** A director must be named for each Core. A Core Director must contribute at least 0.6 person months (5 percent effort). A Core Director with requisite expertise may devote a greater effort to the core and with justification could devote up to 12 person months. Where appropriate, an established expert in the Core activities could also be included as a consultant to the Core. Technicians, etc., are allowable in accordance with the volume and type of work in the Core.

**Facilities, space, and special arrangements:** Particularly in initial applications, the description of the physical arrangements and instrumentation for each Core should be given special attention. 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. However, it should be clear that the Kidney Research Core Centers can function independently.

**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:** The organization and proposed mode of operation of each Core should be presented. A plan for prioritizing investigator use of the Core should be included, 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 fields into the field of kidney disease 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.

**Relation of Core services to individual research project grants:** When a Center is first established, individual investigator-initiated research project grants may include funds for a part of the services that will ultimately be available from the Cores. At the time of renewal (competitive and noncompetitive), the budgets of individual research project grants must be reduced to reflect the costs supported by the Center grant. If there are charge backs, these should be detailed in the submitted budget justification and described as allowable budgetary items in the investigator's individual grants. 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.

**Renewal applications:** Information relative to Cores in renewal applications should generally cover all of the same points as initial applications. In addition, past performance, usage, 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 by other resources, such as grants from NIH, similar project funding from other Federal agencies, or non-Federal sources. The one exception is pilot and feasibility studies.

**Definition:** A pilot and feasibility study provides modest research support for a limited time (one to two years) to enable eligible investigators to explore the feasibility of a concept related to the mission of the Center and to generate sufficient data to pursue the concept through other funding mechanisms. The pilot and feasibility studies are intended to (1) provide initial support for early stage investigators; (2) allow exploration of possible innovative new leads or new directions for established investigators, and (3) stimulate investigators from other areas to lend their expertise to research in this area. Pilot and feasibility study support is not intended for large projects by established investigators that would otherwise be submitted as separate research grant applications. Pilot and feasibility funds are also not intended to support or supplement ongoing funded research of an established investigator.

**Requirements:** Each Center must contain a Pilot and Feasibility Program with a minimum of two projects. A maximum of four projects can be requested. The funds for the Pilot and Feasibility Program are included in the budget of the Center within the \$750,000 direct cost cap.

**Eligibility and related guidelines:** Investigators eligible for pilot and feasibility funding generally fall into three categories: (1) early stage investigators without current or past NIH research support (R01, P01) as a project director/principal investigator (current or past support from other sources should have been modest); (2) established investigators with no previous work in kidney disease who wish to apply their expertise to a problem in this area; and (3) established

investigators who propose testing innovative ideas that represent clear departure from ongoing research interests. It is expected that the majority of the investigators will fall into the first category. All eligible investigators, however, must have faculty appointments and be independent investigators. Postdoctoral fellows or their equivalent are **not** eligible. Each pilot and feasibility study proposal should state clearly the justification for eligibility of the investigator under one of the above three criteria.

A proposed pilot and feasibility study should present a testable hypothesis and clearly delineate the question being asked, detail the procedures to be followed, and discuss how the data will be analyzed. It must be on a topic related to the objectives of the Core Center. Projects should be focused, since funding for these studies is modest and is limited to two years. 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.

Pilot and feasibility projects proposing clinical studies are encouraged. Clinical and Translational Science Awards (CTSA), provide services and resources to enhance clinical research (<http://www.ctsaweb.org/>). Research Centers supported by the NIDDK are encouraged to collaborate with CTSA's at their institution to avoid duplication of effort and enhance utilization of services and resources.

The application should clearly describe and justify the pool from which potential pilot and feasibility applications will be solicited. This can be limited to investigators at the parent institution or expanded to include investigators at institutions with well defined affiliation with the 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 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. Each Center should include project descriptions for the pilot and feasibility projects they propose to fund. For new Center grant applications, the pilot and feasibility proposals are reviewed for scientific merit and eligibility by the initial review group as an example of the selectivity of their review process. 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 recommended budget for the Pilot and Feasibility Program for the first year will be based on the review of the proposed projects. 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 any period of time up to two years, studies end at various times. In addition, the studies may also be terminated by the Center administration before their approved time limit for various reasons: for example, (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 PKD research. There must also be a committee representing all the aspects of the Center that will assist the director in the management of the program. The major responsibilities of the director and the committee should be as follows:

- (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 impact 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.

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 of kidney disease and to the specific goals and objectives of the Center program.

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

In general, a competing renewal application will include the following:

- (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 relating to 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 kidney disease.

The Pilot and Feasibility Program Director may wish to highlight certain studies or certain aspects of the past studies. Collaborations that resulted in lasting relationships, acquisition of new skills by the study recipient, or other significant outcomes should be identified. The relationship of the scope of the various studies to that of the Center should be emphasized. Details such as back-up documentation (described earlier in relation to the arrangement of the Pilot and Feasibility Program) should not be included, but should be available for examination by the reviewers if requested.

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

The description of the accomplishments of the Pilot and Feasibility Program should include a list of all NIDDK-supported pilot and feasibility studies awarded. For each pilot and feasibility project awarded during the last project period, include a brief report (1-2 pages) containing

- (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.

**Funding levels for the Pilot and Feasibility Program on renewal applications:** The format for renewal of Pilot and Feasibility Programs will depend on whether the applicant is requesting (1) a number of pilot projects less than or equal to that for the previous project period or (2) an increase in the number of pilot projects.

If the applicant wishes to maintain the same number of pilot projects in a renewal application, 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 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 early stage investigator into Center related research).

## **Educational Enrichment Programs**

The establishment of a Center should provide an enhanced environment for research training. Students, fellows, and junior faculty should be encouraged to take full advantage of all

Center-sponsored seminars, courses, workshops, and symposia. If appropriate, Centers may waive fees for attendance at such events for interested students, fellows, and junior faculty members. Enrichment program-sponsored mini-sabbaticals, or other instructional opportunities, also may be appropriate for postdoctoral fellows. Stipends for fellows are never an allowable Center expense, but travel, per diem, and registration expenses may be paid from enrichment program funds.

Just as in the case of funding for individual research projects, funding for fellowships should be sought from NIH NRSA institutional training grants (T32) and individual fellowships (F32, F33), and other sources, such private foundations, and commercial companies.

#### **IV. PRE-APPLICATION PROCESS**

It is the policy of the NIDDK that new and competing continuation Center applications are accepted only 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 before 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 the following:

- (1) names of the project directors/principal investigators and principal collaborators,
- (2) identification of the organization(s) involved; and
- (3) the announcement to which the potential application is responsive.

The purpose of the letter of intent is to establish communication between the potential applicant group and NIDDK staff. It is not part of the peer review material. Upon receipt of the letter, the appropriate NIDDK program director contacts the prospective project director/principal investigator to assist in a number of areas that include scientific content and objectives, organization, and clarifications. However, applicants should not construe advice given by the NIDDK staff as assurance of favorable review. The staff will not evaluate or discuss the merit of the scientific aspects of the proposal.

## **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 will be made only for five-year project periods. Some 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 (PHS 398-Form Page 4)
  2. Budget for Entire Proposed Project Period (PHS 398- Form Page 5)
  3. Consolidated budget for first year of requested support (See Illustration I; budgets for each individual Core should immediately precede the narrative for each Core)
  4. Distribution of Professional Effort on this Center application (See Illustration II)
  
- Biographical Sketches for all Center investigators in alphabetical order (key personnel, research base investigators, consultants and collaborators)

Biographical sketches for project directors/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 participants, including professional effort levels. List support related to Basic Kidney Research first, followed by Clinical Kidney Research and then non-Center-related research support. (See Illustration III)
- 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.

- Specific Aims (limited to 1 page): Provide the broad, long-range objectives and goals of the proposed O'Brien Kidney Research Core 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. Summarize the special features in the environment and/or resources that make this application strong or unique. If the application is a renewal, the Center Program Overview section should also highlight past performance and the major accomplishments from the prior funding period as described in

the PHS 398 Instructions. For Renewals: Changes from the original Center design should be highlighted.

## **SECTION 2: ADMINISTRATIVE COMPONENT (Research Strategy is limited to 6 pages)**

- 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 (Internal advisory boards and the pilot and feasibility program oversight committee; include External advisory boards for renewal applications but **not** for new applications); Description of plans for website development, maintenance and curation; General overall description of facilities and institutional commitment; Other Considerations (include listing of other relevant Centers and cores at the institution and affiliated hospitals, and plans to integrate, harmonize and reduce redundancies in activities)

## **SECTION 3: BIOMEDICAL RESEARCH COMPONENT**

- Biomedical research base (Research Strategy is 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 kidney disease and its complications 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 O'Brien Kidney 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 an O'Brien Kidney Center on the research base. Include an indication of how the establishment of an O'Brien Kidney Center will provide added dimensions and new opportunities for kidney research, along with increased cooperation, communication, and collaboration among investigators. Discuss how an O'Brien Kidney Center will add to any resources that may already be provided to kidney investigators by other NIDDK centers at the institution(s).

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 O'Brien Kidney 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, title, 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 to investigators at the applicant institution or consortium 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 kidney disease and its complications when this is not readily apparent from the title of the grant.

Document collaborative efforts by using a format such as in the 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 (included in 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 competing 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.

7. For Renewals: Pilot and Feasibility Project Outcomes (see Guidelines Illustration VI)

- Enrichment Program (limited to 6 pages, exclusive of form pages)

1. Description (PHS 398- Form Page 2)

2. Key Personnel (PHS 398- Form Page 2-contd)

3. Budget with justifications (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 PD/PIs should be provided separately)

#### **SECTION 4: CENTER-RELATED INFORMATION (suggested Illustrations only)**

- Suggested Illustration for Renewal Applications only: 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 annual direct costs requested may not exceed \$750,000. Each pilot/feasibility study is limited to \$50,000 per year and a two-year duration of support. An exception to the \$750,000 cap will apply to Center applications that include subcontracts. Subcontract facilities and administrative costs are not included in the direct cost cap of \$750,000 (Notice OD-04-040; <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-04-040.html>). Equipment may be included in the first year of the grant, which will not be included in the direct cost cap.

### **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 project directors/principal investigators only to the extent that they provide an essential Center function. No overlap of time or effort between the Center and separately funded projects is permitted.

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

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

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

**Supplies:** Consumable supplies related to the operation of the Center are allowed and include office materials, as well as scientific supplies. 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 CTSA's 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.

**Travel:** Domestic and foreign travel of project personnel directly related to the 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. APPLICATION REVIEW INFORMATION

### Review Criteria

The goals of the O'Brien Kidney Research Core Centers are to advance our understanding of biological systems relevant to kidney disease and its complications, and to facilitate development of new methods to treat, prevent and ultimately cure kidney disease and its complications.

**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 - Overall.** 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?

**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 interrelate with each other and contribute to the overall objectives of the O'Brien Core Center? What are the scientific and administrative leadership abilities of the proposed Center Director and Associate Director and their commitment and ability to devote adequate time to the effective management of the program? 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 Core Center;(d) Mechanism for reviewing the use of and administering funds for the P&F program;(e) Management capabilities that include fiscal administration, procurement, property and personnel management, planning, budgeting, and other appropriate capabilities?

**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? Are the cores providing unique regional, national or international resources?

**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? Does the PD/PI meet one of the eligibility criteria set out in the Administrative Guidelines for pilot and feasibility studies?

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?

**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 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? Is there clear potential for interaction with scientists from other departments and

institutions? Is there efficient and effective use and/or planned use of the limited enrichment funds, including the contribution of these activities in enhancing the objectives of the Center?

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

The following additional review criteria apply to all new and renewal O'Brien Kidney Center applications.

- 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 kidney 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?
- Do the existing Centers 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.

### **Research Base:**

- Does the Center show evidence of a stable or growing research base with strong and consistent record of scientific excellence and achievement?

- Is this reflected in an outstanding level of productivity and continuing success in securing peer-reviewed research funding?
- Does the Center show evidence of fostering multi-disciplinary collaborations among Center investigators?

### **Biomedical Cores:**

- Are the number and impact of papers that acknowledge the Center sufficient to justify each core?
- Is there a significant fraction of papers that acknowledge the Center but 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 tests completed for 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?

**Pilot & Feasibility Program:**

- Are the numbers and types of P&F awards well justified?
- Were papers generated under these awards and key advances linked to these awards well documented and consistent with the level of support provided?
- Did the individual pilot projects lead to independent grant funding?

**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. Is the requested budget directly correlated to the breadth, quality and relevance to kidney disease and related areas of the research base being served by the Center?

**Review and Selection Process**

Applications will be evaluated for scientific and technical merit by an appropriate Scientific Review Group convened by the NIDDK, in accordance with NIH peer review policy and

procedures, using the stated review criteria. Review assignments will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- • May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.
- • Will receive a written critique.

## **VIII. AWARD CRITERIA**

Funding decisions will be based on the quality of the proposed Center as determined by peer review, overall balance in the O'Brien Kidney Center program, and the availability of funds.

## **IX. 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](http://www.fsrs.gov) on all subawards over \$25,000. See the Statement for additional information on this reporting requirement.

## **X. SPECIAL CONSIDERATIONS**

While each Center will be expected to develop its own program in accordance with local talents, interests, and resources, each must be responsive to national needs to develop new approaches to the prevention, treatment and cure of kidney disease and must be willing to work with the NIDDK and other organizations in furthering the overall goals of the O'Brien Kidney 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 approaches 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 that will eventually cover the spectrum of required activities. Although types of activities that should be included are indicated in the guidelines, specific approaches for their accomplishment are left to the individual applicant.

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

**ILLUSTRATION I: CONSOLIDATED BUDGET FOR FIRST YEAR OF REQUESTED SUPPORT**

<b>Budget Category</b>	<b>Admin</b>	<b>Core A</b>	<b>Core B</b>	<b>Core C</b>	<b>P&amp;F Projects</b>	<b>Total</b>
<b>Personnel</b>						
<b>Consultant Costs</b>						
<b>Equipment</b>						
<b>Supplies</b>						
<b>Domestic Travel</b>						
<b>Foreign Travel</b>						
<b>Patient Care Costs</b>						
<b>Alterations and Renovations</b>						
<b>Other Expenses</b>						
<b>Contractual Costs</b>						
<b>Total</b>						

**ILLUSTRATION II: DISTRIBUTION OF PROFESSIONAL EFFORT (calendar months) ON THIS APPLICATION**

<b>Participating Investigators*</b>	<b>Admin</b>	<b>Core A</b>	<b>Core B</b>	<b>Core C</b>	<b>P and F</b>	<b>Application Total</b>	<b>Other Support</b>
<b>Dr. A.</b>	<b>*1.2</b>			<b>1.2</b>		<b>2.4</b>	<b>6.0</b>
<b>Dr. B.</b>		<b>1.2</b>			<b>*1.2</b>	<b>2.4</b>	<b>4.8</b>
<b>Dr. C.</b>	<b>0.6</b>					<b>0.6</b>	
<b>Dr. D.</b>			<b>1.8</b>	<b>*1.2</b>		<b>3.0</b>	<b>6.6</b>
<b>Etc.</b>							

\*Star the calendar months (See Admin) when that individual is the core director or the project director/principal investigator on a pilot and feasibility study.

Minimum effort for Core Director is 0.6 calendar months. Minimum total effort for Center Director is 2.4 calendar months.

**ILLUSTRATION III: SUMMARY OF TOTAL CURRENT AND PENDING SUPPORT OF ALL CENTER PARTICIPANTS**

<b>Project Director/Principal Investigator Co-Investigator*</b>	<b>Supporting Organization and Grant Number</b>	<b>Title</b>	<b>Project Period</b>	<b>Current Annual Amount</b>	<b>Effort (Calendar months)</b>
<b>BASIC KIDNEY RESEARCH BASE</b>					
<b>Current Support</b>					
<b>Example: Doe, John</b>	<b>P01 DK00000</b>	<b>Murine Models of Diabetic Kidney Disease</b>	<b>4/1/07-3/31/12</b>	<b>\$500,000</b>	<b>4.8</b>
<b>Smith, Lisa (Doe, John)</b>	<b>K08 DK00000</b>	<b>Nedd4 in ENaC Trafficking</b>	<b>6/1/09-5/31/13</b>	<b>\$75,000</b>	<b>6.0</b>
<b>Jones, Steve</b>	<b>R01 DK00000</b>	<b>Mechanisms of Glomerular Scarring</b>	<b>7/1/10-6/30/15</b>	<b>\$200,000</b>	<b>1.8</b>
<b>Pending Support</b>					
<b>Principal Investigator/Project Director Co-Investigator</b>	<b>Supporting Organization and Grant Number</b>	<b>Title</b>	<b>Project Period Requested</b>	<b>First Year Support Requested</b>	<b>Effort Requested</b>



**CLINICAL / TRANSLATIONAL KIDNEY RESEARCH BASE**

**Current Support**

(as above)

**Pending Support**

(as above)

**NON-CENTER-RELATED RESEARCH SUPPORT**

**Current Support**

(as above)

**Pending Support**

(as above)

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

**ILLUSTRATION IV – (FOR COMPETING RENEWALS ONLY) COLLABORATIONS BETWEEN CENTER MEMBERS**

	J O N E S	S M I T H	A D A M S	C H U	E V E R S	K N I G H T	O L S O N	S A N D S	T A Y L O R	Y O U N G	Z A N E
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: USE OF CORE FACILITIES

<b>CORE: NAME</b>					
<b>Determination/Services Rendered</b>					
<b>A.</b>	<b>B.</b>	<b>Funded Projects with</b>	<b>Period of</b>	<b>Determinations/</b>	<b>Estimated Use</b>
	<b>Users</b>	<b>Identifying Number</b>	<b>Performance</b>	<b>Services</b>	<b>and Comments</b>
<b>1.</b>					
<b>2.</b>					
<b>3.</b>					
<b>CORE: Transgenic Animals</b>					
<b>Determination/Services Rendered</b>					
<b>A.</b>	<b>B.</b>	<b>Funded Projects with</b>	<b>Period of</b>	<b>Determinations/</b>	<b>Estimated Use</b>
	<b>Users</b>	<b>Identifying Number</b>	<b>Performance</b>	<b>Services</b>	<b>and Comments</b>
				<b>B C D E</b>	
<b>1.</b>	<b>J. Doe</b>	<b>R01 DK00000-00</b>	<b>3/7/97-3/7/98</b>	<b>X X</b>	<b>5 per month for 12 months</b>
					<b>A.</b>
<b>C.</b>	<b>100 per month</b>				
<b>2.</b>	<b>L. Smith</b>	<b>K08 DK00000-00</b>	<b>1/4/97-1/4/00</b>	<b>X</b>	<b>40 per week</b>
<b>through 1/4/00</b>					
<b>3.</b>	<b>S. Jones</b>	<b>R01 GM00000-00</b>	<b>9/1/01-2/1/02</b>	<b>X</b>	<b>16 per week for 6 months</b>
					<b>B. A.</b>

EXAMPLE

## **ILLUSTRATION VI: PILOT & FEASIBILITY (P&F) PROJECT OUTCOMES-(FOR RENEWAL APPLICATIONS ONLY)**

Set up column headings:

P&F Project Number

Investigator (last name, first name)

Department

P&F Funding Dates (MM/YY to MM/YY)

Amount of P&F (direct costs for entire P&F project period)

P&F Project Title

Type of P&F Investigator (New, Established, or New to Diabetes)

Type of P&F Research (Basic, Clinical, Translational)

Publications (# of papers, # of abstracts)

Subsequent Grant Applications Funded (Yes, No, Pending)

Subsequent 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)

Subsequent Grant Project Period (MM/YY to MM/YY)

Amount of Subsequent Grant Award (Total Direct Costs for Duration of Award)

Still in Diabetes Research (Yes, No)

**ILLUSTRATION VII: PUBLICATIONS CITING SUPPORT FROM THIS CORE CENTER GRANT (FOR  
COMPETING RENEWALS ONLY)**

<b><u>Core Number or P&amp;F P.I. Name</u></b>	<b><u>Publications</u></b>	<b><u>Core 1</u></b>	<b><u>Core 2</u></b>	<b><u>Core 3</u></b>	<b><u>Core 4</u></b>
1. Doe, J	Doe, J; Jones, S.; Smith, L. Albuminuria trends P in a DCCT cohort AJKD, 2004			S	
	Doe, J.; Jones, S.; Brown, P. Murine models P of Diabetic Kidney Disease. Am J Physiol Renal Physiol, 2003		S		
2. Jones, S.	Jones, S.; Black, L. Treatment of glomerulonephritis Nature Medicine, 2004.S	P		S	
	Smith, L.; Jones, S.; Defining FSGS phenotypes AJKD, 2003				

§

List each publication only once under the Core (or P&F Project PD/PI name) most significantly contributing to the work. The Core most significantly contributing to the work should be signified by a P (primary). All other contributing Cores are designated by an S (secondary).