NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

ADMINISTRATIVE GUIDELINES

FOR

CENTERS FOR POLYCYSTIC KIDNEY DISEASE RESEARCH

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TABLE OF CONTENTS

I. Description 4

Background 4
General Description 4

II. Administrative Core Component 4

Description 4
Requirements 5
Educational Enrichment Programs 6

III. Biomedical Research Component 6

Biomedical Research Cores 6

- **Definition**
- **Justification for proposing a core**
- **Personnel**
- **Facilities, space, and special arrangements**
- **Management of the core**
- **Renewal applications**

Individual Research Projects 7

Pilot and Feasibility Program 8

- **Definition**
- **Requirements**
- **Eligibility and related guidelines**
- **Initial review and management of the pilot and feasibility program**
- **Review of the pilot and feasibility program in renewal applications**
- **Funding levels for the pilot and feasibility program on renewal applications**

IV. Pre-Application Process 12

V. Preparation of Application 12

Description 12

Content Order for Applications 13

VI. Budget Considerations 15

VII. Review Process and Criteria 17

VIII. Award Criteria 19

IX. Evaluation and Reporting Requirements 19

X. Special Considerations 19

I. DESCRIPTION

Background

The NIDDK-supported Interdisciplinary Centers for Polycystic Kidney Disease Research (ICPKD) are part of an integrated program of polycystic kidney disease (PKD) research. These Centers were originally established as Specialized Research Centers in 1999. Center grants such as the ICPKD 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 of PKD. 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 studies proposed by the ICPKD should foster and extend the development of new approaches into the causes, early diagnoses, and improved treatments for both the autosomal dominant form of PKD (ADPKD) and the recessive form (ARPKD). Institutions selected for this program are domestic and have extensive scientific expertise in the areas of cellular and molecular biology, genetics, protein chemistry, structural biology, immunology, pathology, physiology, nutrition, epidemiology, clinical trials, and animal model and drug development. The objectives of the Interdisciplinary Centers for Polycystic Kidney Disease Research are to bring together basic and clinical investigators from relevant disciplines in a manner that will enhance and extend the effectiveness of their research. The Center consists of several components: a single Administrative Core, several Biomedical Research Cores, interrelated Research Projects, and a Pilot and Feasibility Program. A Center must be an identifiable unit within a single university medical center or within a consortium of cooperative institutions, including an affiliated university.

II. ADMINISTRATIVE CORE COMPONENT

Description

An ICPKD must be an identifiable organizational unit within a single university medical center or within a consortium of cooperating institutions with a university affiliation. The overall goal of an ICPKD is to bring together, in a cooperative, multidisciplinary, and integrative manner, basic science and clinical investigators to enrich the effectiveness of research on PKD. To accomplish the overall goal of these Centers, an ongoing program of excellence in biomedical research related to the study of kidney disease should exist at the applicant's institution. However, the research program need not be exclusively in kidney and can include elements related to development, creation of animal models for use in fundamental studies, and the development of innovative, pioneering human investigation protocols. Close cooperation, communication, and collaboration among all participating center personnel of many professional disciplines are characteristics of a successful ICPKD.

Requirements

An ICPKD will involve the interaction of broad and diverse elements within a single institution, or a consortium of cooperating institutions; thus, the lines of authority and sanction by the appropriate institutional officials must be specified clearly. The administration of the ICPKD will include the responsibility of coordinating the various functions of the Center.

A. Center Director

Each applicant institution will specify a Center Director to be responsible for the organization and operation of the ICPKD. It would be highly desirable that the Center Director, as well as the applicant institution, have a commitment to the investigation of molecular and cellular topics relevant to the kidney. The Center Director should be an experienced and respected individual who can provide scientific and administrative leadership for the total program. This individual must be able to coordinate, integrate, and provide guidance in establishing new programs in polycystic kidney disease research. An Associate Center Director should be named who will be involved in the administrative and scientific efforts of the ICPKD and will serve as acting director in the absence of the Center Director.

B. Internal Executive Committee

It is expected that the administrative organization of the Center will include a supportive structure, such as an internal executive committee to ensure accomplishment of (1) coordinating and integrating the ICPKD components and activities; (2) reviewing the use of funds for pilot and feasibility studies; (3) providing advice to the Director about the productivity and effectiveness of the activities of the ICPKD; and (4) interacting with the NIDDK and other appropriate individuals or groups, including the scientific and lay communities, in order to help develop relevant goals.

The final administrative structure of the ICPKD will, for the most part, be left to the discretion of the applicant institution (subject to review by the NIDDK). The NIDDK's experience has demonstrated that the effective development of an ICPKD program requires close interaction among the Center Director, collaborating investigators, appropriate institutional administrative personnel, staff of the awarding agency, and other members of the institution in which the ICPKD is located. Therefore, each ICPKD applicant should establish an administrative structure that will permit the development of such interaction. It is desirable for the Center administration to include an administrative assistant.

C. External Advisory Committee

The formation of an external advisory group to the ICPKD is encouraged. This group, comprised of 3 to 5 members, may advise the Center Director in the areas of budget, policy, collaborations, or other areas and may provide a scientific review group for the Pilot and Feasibility program.

D. Facilities

While facilities (space, equipment, library, etc.) must be described in each element in the application, a more general description of the overall facilities and a statement regarding institutional commitment to the ICPKD also should be included in the description of the administrative organization.

Educational Enrichment Programs

The ICPKD grant can budget for and provide limited support for an enrichment program, whose description and budget may be included within the administrative core. It may provide support for visiting scientists, seminars, and research forums. 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. Limited travel support is allowable for ICPKD investigators to travel to present scientific findings, to learn new laboratory techniques, to develop new collaborations, or to engage in scientific information exchange. In all cases, the enrichment program should further the overall aims and objectives of the ICPKD as well as of the scientific cores. Travel funds should be included for an annual meeting of the ICPKD directors.

III. BIOMEDICAL RESEARCH COMPONENT

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 individual research projects more efficiently and/or more effectively. Cores may be proposed in relation to any acceptable research activity of the ICPKD, but usually cores fall into one of four categories:

1) provision of a technology that lends itself to automation or preparation in large batches (e.g., radioimmunoassay and tissue culture);
2) complex instrumentation (e.g., electron microscopy or mass spectrometry);
3) animal preparation and care; and
4) technical assistance and training (e.g., molecular biology).

Justification for proposing a core: The establishment of and continued support for biomedical research cores within an ICPKD must be justified on the basis of use by Center investigators. The minimum requirement is significant usage by two or more principal investigators each with a Center project. A director must be named for each core. The organization and proposed mode of operation of each core should be described, with a plan for prioritizing investigator use of the core and criteria for determining core users or potential users.

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. Cores 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 5 percent effort. A core director with requisite expertise may devote a greater effort to the core and with justification could devote up to 100 percent effort. 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.

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. Any proposed, ongoing, or completed developmental efforts should be described. If the core is used to train investigators in special techniques, the mechanism for this training should be included.

Renewal applications: Information relative to cores in renewal applications should generally cover all of the same points as initial applications. In addition, past performance, 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.

Individual Research Projects

Criteria for designating an investigator as an ICPKD participant should be defined. Subsets of participants based on degree of participation or other measures are acceptable. Each ICPKD is encouraged to develop guidelines for ICPKD participation by investigators. Individual research projects should be interrelated and may be basic or clinical in nature.

Pilot and Feasibility Program

Definition: A Pilot and Feasibility (P&F) 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 generate sufficient data to pursue it through other funding mechanisms. P&F programs traditionally accomplish three major program goals:

1) provide opportunities for new investigators to develop preliminary data that become the basis for an application for further support;
2) provide opportunities for established investigators outside the Center to apply their expertise to a research area of interest to the Center; and
3) provide established investigators within the Center with an opportunity to pursue high impact/high risk projects or projects that are a significant departure from their usual work.

Because the career development of new clinical investigators is a high priority of the NIDDK, Centers are encouraged to use P&F support to provide opportunities for new clinical investigators to develop preliminary data for further support. It is anticipated that the majority of the recipients of P&F funding will be from the first category. However, all eligible investigators must be independent investigators. Fellows supported by National Research Service Awards (e.g., T32 and F32 fellows) may apply for P&F funds only in the final year of their training. In addition, the fellow must be sponsored by a Center member. Other postdoctoral fellows, if they otherwise meet the P&F eligibility requirements for the Center, may apply. While K-awardees are eligible for P&F funds, junior faculty without extramural funding should be the primary target for the limited funds available. P&F study support is not intended for large projects by established investigators, which otherwise would be submitted as separate research grant applications. P&F funds also are not intended to support or supplement ongoing funded research of an investigator.

Requirements: Each Center must contain a P&F 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: Each P&F study proposal should state clearly the justification for eligibility of the investigator under one of the above three criteria. A proposed P&F 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 Center. Projects should be focused, because 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 P&F study constitutes a real departure from his/her ongoing research.

Pilot and Feasibility projects proposing clinical studies are encouraged. The National Center for Research Resources (NCRR) supports approximately 80 General Research Clinical Centers (GCRCs) nationwide, which provide services and resources to enhance clinical research (www.ncrr.nih.gov/clinical/cr_gcrc.asp). Research Centers supported by the NIDDK and other NIH Institutes are encouraged to collaborate with GCRCs to avoid duplication of effort and to enhance utilization of services and resources.

Use a separate Form PHS 398 for each project, and number each project sequentially. Each P&F project should be identified clearly by the same title as that provided in the Table of Contents. Each project should begin with an abstract and budget pages followed by information requested in Sections A through I of the instructions for Form PHS 398. It should be submitted generally using the NIH research project application format, but the research plan should be limited to five pages.

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 P&F 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 P&F component of the Center.

Initial review and management of the pilot and feasibility program: Within this structure, each applicant institution must also establish a mechanism to oversee the use of funds for the proposed P&F program. This mechanism must include the use of appropriate consultants from the scientific community external to the ICPKD, for review. These same consultants may, if desired, review and assess other activities of the ICPKD and may constitute the external advisory group to the ICPKD. The projects selected to receive these funds will be described by the Director in the annual progress report and will be given special attention by the NIDDK in its annual evaluation.

Since P&F 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: 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 P&F studies with the remaining funds.

Although 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 which will assist the director in the management of the program. The major responsibilities of the director and the committee will be to:

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

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

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

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

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

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

All applicants should describe how these requirements will be met and have been met in the case of renewal applications. Also included should be an assessment of the relevancy of the proposed individual P&F studies and of the program as a whole to research on PKD 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 P&F 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 PKD.

The P&F 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 P&F 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 P&F 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 P&F program should include a list of all NIDDK-supported pilot and feasibility studies awarded. For each P&F project awarded during the last project period, include a brief report (1-2 pages) containing the following:

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 P&F 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) whether awards were made to investigators who fully met the eligibility criteria for P&F support as outlined above;
3) Center-relatedness; and
4) the success of previously supported P&F studies (e.g., publications, subsequent independent R01 or other peer-reviewed support, and/or attraction of a new investigator into Center-related research).

Conversely, should the applicant institution feel that an increased level of funding for the P&F program is justified, new P&F studies, over and above the number currently awarded, must be submitted with the competing renewal applications. These proposals would be reviewed by the initial review group in a fashion similar to the review of P&F studies during the initial review. The initial review group would assess the new proposals, along with the overall performance of the program during the previous grant period to arrive at a recommendation for a possible increased P&F funding level.

IV. PRE-APPLICATION PROCESS

Within the limits of available funding, the Centers have been established to meet a national need. Applications will be received in response to RFAs announced in the NIH Guide for Grants and Contracts. It is strongly encouraged that potential applicants for the Centers 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 the following:

1) names of the 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 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 prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the website at http://www.dunandbradstreet.com/. The DUNS number should be entered

on line 11 of the face page of the PHS 398 form. The PHS 398 document is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev 5/2001) application form (see website above) must be affixed to the bottom of the face page of the original copy of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of your application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at http://grants.nih.gov/grants/funding/phs398/labels.pdf.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, plus three (3) 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
BETHESDA, MD 20817 (for express/courier service)

At time of submission, two (2) additional copies of the application must be sent to:

CHIEF, REVIEW BRANCH
NIDDK, DIVISION OF EXTRAMURAL ACTIVITIES
DEMOCRACY 2, ROOM 752, MSC 5452
BETHESDA, MD 20892-5452

The arrangement of materials should follow both the instructions in the PHS Form 398 application kit and the more specific guidance detailed below.

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 follow. Applicants may also consult with NIDDK staff concerning the technical aspects of preparing the application.

Content Order for Applications

SECTION 1: INTRODUCTION

- Face Page (398-AA): The RFA label must be affixed to the bottom of the face page and the title, “Centers for Polycystic Kidney Disease Research@ and the RFA number must be typed on line 2 and the YES box must be marked.

- Description and Key Personnel (398-BB)
- Table of Contents
- Budgets
    1) Detailed Budget for Initial Budget Period (398-DD)
    2) Budget for Entire Proposed Project Period (398- EE)
    3) Consolidated budget for first year of requested support
- Biographical sketches for all Center participants beginning with Center Director and Associate Director and the rest in alphabetical order (398-FF)
- General description of the proposed or established Center
  For Renewals: Changes from the original Center design should be highlighted

SECTION 2: ADMINISTRATIVE COMPONENT

- Budget page with comprehensive budgetary justifications (PHS 398 form page 4 Rev. 5/2001)
- Qualifications of the Director and Associate Director
- Presentation of the administrative structure
- Relationship and lines of authority and sanction by appropriate institutional officials
- Committee structure (include committee for the pilot and feasibility program)
- General overall description of facilities and institutional commitment
- Description of plans for the enrichment program
- Other considerations

SECTION 3: BIOMEDICAL RESEARCH COMPONENT

- Overview of ongoing research and impact of Center on this research.

- For Renewals: Progress Report including description of significant findings, new participants, and new funding

- For Renewals: Publications Citing Support from this Center

- Biomedical research cores (present each core separately)

    1) Descriptive Abstract

    2) Budget with justifications (PHS 398 form 4 (rev. 5/2001))

    3) Objectives of the core

    4) Core function, including quality control

    5) Benefits from core

    6) Proposed developmental research or training

    7) Investigators who will use the core and proposed extent of use

    8) For Renewal: Core use during the last grant period

    9) Vertebrate Animal and or Human Subjects Sections if appropriate

- Pilot and Feasibility Program

    1) Composite budget with budgetary justifications for future years

    2) Introduction

    3) Director and Committee

    4) Management of the pilot and feasibility program

    5) Description of the pilot and feasibility program

    6) In initial applications include budget and justifications, justification of eligibility as well as the scientific proposals with their justification for core usage. For competing renewal applications, also include overview; listing and reports of pilot and feasibility studies; and additional pilot and feasibility proposals, if applicable, as requested for an initial application.

- Checklist

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 that 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 20 percent of his/her efforts to the Center. The Center application should include salaries for individual principal investigators only to the extent that they provide an essential Center function. No overlap of time or effort between the Center and separately-funded projects is permitted.

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

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

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

Supplies: Consumable supplies related to the operation of the Center are allowed and include office materials, as well as scientific supplies, but should not be supplement to separately funded projects.

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 use existing clinical facilities, such as General Clinical Research Centers and individually supported beds. Costs relating to the clinical research efforts of Center investigators may be funded through the Center, provided there is no overlap of funding. 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 are allowable. Travel of Center participants for attendance at annual Center directors meetings is 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 for completeness by the Center for Scientific Review (CSR). Incomplete applications will be returned to the applicant without further consideration. Evaluation of responsiveness to the program requirements and criteria stated in the RFA is an NIDDK staff function.

Those applications that are complete and responsive will be evaluated in national competition by an appropriate peer review group convened by the NIDDK. The evaluation will be in accordance with the criteria for scientific/technical merit stated below. It is essential that the written application be in a form to be reviewed on its own merit, since no site-visit is anticipated. Following this review, the applications will be given a second-level review by the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The initial review group will review each application using the criteria stated below:

- The relevance of the separate research projects to the Center objectives and the likelihood for meaningful collaboration among Center investigators must be demonstrated.

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

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

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

- The administrative organization proposed, including: coordination of ongoing research; establishment and maintenance of internal communication and cooperation among investigators; mechanisms for prioritizing usage of shared resources; mechanisms of selecting and replacing essential personnel within the Center; mechanisms for reviewing the use of, and administering funds for, the pilot and feasibility program; and management capabilities.

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

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

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

    1) Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

    2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

    3) Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

    4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)? Does the PI meet one of the eligibility criteria set out in the Administrative Guidelines for pilot and feasibility studies?

    5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific

environment or employ useful collaborative arrangements? Is there evidence of institutional support?

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

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

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

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

- The reasonableness of the proposed budget to the proposed research.

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

VIII. AWARD CRITERIA

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

IX. EVALUATION AND REPORTING REQUIREMENTS

NIH will make information on due dates for the annual Non-Competing Grant Progress Report (PHS FORM 2590) accessible electronically. Forms for PHS 2590 are available at http://grants1.nih.gov/grants/funding/2590/2590.htm For more information about electronic notification see: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-047.html

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 therapies for polycystic kidney disease and must be willing to work with the NIDDK and other organizations in furthering the overall goals of the PKD 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 which will eventually cover the spectrum of required activities. While types of activities that should be included are indicated in the guidelines, specific approaches for their accomplishment are left to the individual applicant.

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