

ADMINISTRATIVE GUIDELINES *for*
SILVIO O. CONTE
DIGESTIVE DISEASES
RESEARCH CORE CENTERS

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Table of Contents

I. DESCRIPTION	2
OVERALL.....	2
ADMINISTRATIVE CORE AND CENTER STRUCTURE	4
RESEARCH BASE.....	5
CORE FACILITIES.....	6
PILOT AND FEASIBILITY STUDIES.....	8
ENRICHMENT PROGRAM.....	10
OPTIONAL COMPONENTS.....	10
<i>CLINICAL COMPONENT</i>	10
<i>NAMED NEW INVESTIGATOR</i>	10
II. APPLICATION	11
GENERAL INSTRUCTIONS	11
SPECIFIC INSTRUCTIONS.....	11
<i>FORM PAGES</i>	11
<i>PAGE LIMITS</i>	12
<i>APPLICATION COMPONENTS</i>	13
<i>BUDGET CATEGORIES</i>	16
<i>SUPPLEMENT REQUESTS</i>	18
III. REVIEW	19
APPLICATION RECEIPT	19
REVIEW	19
<i>STANDARD NIH REVIEW CRITERIA</i>	19
<i>SPECIFIC REVIEW CRITERIA FOR DDRCCS</i>	20
<i>RENEWAL APPLICATIONS</i>	21
<i>SCORED SECTIONS OF APPLICATION:</i>	22
IV. POST-AWARD	23
V. SUGGESTED ILLUSTRATIONS	28

I. DESCRIPTION

OVERALL

Introduction

In fulfilling its mission to support research and research training, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) supports a number of grant programs, including various research, program project, and career development awards; institutional training grants and individual research fellowships; and a number of center grant programs. This document provides a description of, and the administrative guidelines for, the **Silvio O. Conte Digestive Diseases Research Core Center (DDRCC)** program. This program provides needed resources for the digestive diseases (DD) research community.

DDRCCs are meant to integrate, coordinate, and foster interdisciplinary research in digestive diseases and related disorders by a group of established investigators actively conducting programs of important, high-quality research that relates to a common DD-relevant theme. Providing an atmosphere of collegiality and cooperation will enhance the training, mentorship, and career development of future digestive diseases researchers. At the present time, the Division of Digestive Diseases and Nutrition (DDDN) within the NIDDK supports seventeen DDRCCs.

Basic Requirements

A DDRCC 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 a DDRCC is to bring together, on a cooperative basis, basic science and clinical investigators to enhance the effectiveness of their research. This goal is achieved using the P30 center grant mechanism, which provides support for shared resources, termed "cores", which enhance productivity and benefit a group of investigators working to accomplish the stated goals of the DDRCC. Thus, a DDRCC provides the capability for accomplishments greater than those that would be possible by individual research project grant support alone.

To qualify for a DDRCC grant, the applicant institution **must** already have a substantial base of ongoing, independently supported, peer-reviewed research projects related to digestive diseases. This currently funded ***research base*** provides the major support for a group of investigators who would benefit from shared resources and are the Center members. The body of research described as the research base includes only currently funded, peer reviewed research grants awarded to the applicant institution. These may be Federally or privately funded awards; training grants and fellowship awards are not considered part of the research base.

The research base must exist prior to the submission of an application and it is an important element considered during the peer review process. Focus, relevance, interrelationships, quality, productivity, and, to some extent, quantity, are all considerations in judging the adequacy of the research base. Although collaborations with investigators outside the applicant institution/consortium are encouraged, the research base includes **ONLY** support for the Center members at the applicant institution/consortium.

The DDRCC must have a central research focus or theme. This central focus must be a digestive disease, group of diseases, or functional studies relating to digestive or liver diseases. At least one-half of the research base must relate to this central focus in new Centers. Examples of a digestive disease-related central focus include, but are not restricted to, inflammatory bowel disease, functional bowel disorders, pancreatic disease, liver disease, pediatric gastrointestinal disease, and AIDS-related gastrointestinal disease. Examples of functional studies appropriate for a central focus include, but are not restricted to, gastrointestinal motility, actions of gastrointestinal hormones, role of the gastrointestinal tract in obesity, gastrointestinal physiology/development, or gene therapy for digestive or liver diseases. Applicants should consult with NIDDK staff concerning plans for the development of a DDRCC and the organization of the proposed Center.

Cores are shared facilities that serve to enhance or make more cost effective the services, techniques, or instrumentation used by the investigators within the DDRCC. Cores should extend, support, and contribute to the work of the Center members. A Center must have a minimum of two cores in addition to the **Administrative Core** (described below). The latter is a required element for every DDRCC. Each Core must be used by a minimum of two funded Center members.

Three other activities may be supported by DDRCC funds:

1. a pilot and feasibility (P/F) program;
2. an enrichment program; and
3. a clinical component.

The ***P/F program*** provides modest support for new initiatives or feasibility projects for either new investigators or for established investigators who are moving into research areas of direct interest to the DDRCC. These areas may include biomedical, epidemiological, clinical, or behavioral research as they pertain to the DDRCC goals.

The ***enrichment program*** provides limited funds to sponsor, for example, seminars, visiting scientists, workshops, and mini-sabbaticals for Center members. These activities are aimed at fostering the exchange of ideas with the goal of enhancing the productivity and efficiency of the DDRCC and its members.

The ***clinical component*** facilitates translation of research findings into practical treatments for patients and/or provides the opportunity for Center members to obtain clinical samples and patient data needed for their research. In addition to facilitating studies aimed at a better understanding of the natural history and etiology of disease, such components may support biostatistics consultation, assist with clinical study design, foster collaboration among researchers, aid in recruitment of subjects for clinical studies, provide data entry support for epidemiological studies, or provide modest funding for tissue, DNA, or serum storage. The clinical component may serve as the bridge between Center's clinical and basic science investigators. In addition, staff within the clinical component may aid investigators in effectively addressing NIH policies and reporting requirements concerning inclusion of women, children, and ethnic/minority participation in clinical studies; data and safety monitoring requirements; and educational requirements for the protection of human research participants. DDRCCs are encouraged to include a clinical component when appropriate for their members. A clinical component is not meant to duplicate or supplant services available through an Institution's NIH-funded Clinical and Translational Science Award (CTSA).

Eligibility for a DDRCC award is limited to domestic institutions.

ADMINISTRATIVE STRUCTURE

Description

Since a DDRCC involves the interaction of personnel in several departments and the allocation of resources within the institution(s), lines of authority and sanction by the appropriate institutional officials must be clearly specified. The administrative structure of the DDRCC, for the most part, will be left to the discretion of the applicant institution, as long as minimum requirements are met. The effective development of a Center requires close interaction between the Center Director, the Center members, institutional administrative personnel, the staff of the NIDDK, and other members of the institution in which the Center is located. The Administrative Core is responsible for maintaining these lines of authority, coordinating the various functions of the DDRCC, and serving as the visible contact point between the university community and the DDRCC. Therefore, each DDRCC must contain an ***Administrative Core***.

Requirements

Director: Each DDRCC must name a Director who is responsible for its organization and operation. The Director is the Principal Investigator of the P30 application for a DDRCC and is the Director of the Administrative Core. The Director must be an experienced and respected researcher who can provide scientific and administrative leadership for the entire program. The Director must be able to coordinate, integrate, and provide guidance in establishing, expanding, or focusing programs of digestive diseases research. An associate Director should be named who will be involved in both the scientific and administrative aspects of the DDRCC. The associate Director will serve as acting Director in the absence of the Director.

If advantageous for the DDRCC, the multiple-PI option may be used, with two co-Directors assuming responsibility for the duties of the Center Director.

Organization and Functions: The organization of the Administrative Core provides a supportive structure for the DDRCC. As part of this structure, for example, an Internal Executive Committee should be named whose duties include: (1) coordinating and integrating the DDRCC components and activities; (2) administering the enrichment program in a productive and efficient manner; (3) reviewing the use of funds for P/F projects; (4) advising the Director as to the productivity and effectiveness of the activities of the DDRCC; and (5) interacting with other Centers, NIDDK, and other appropriate groups and/or individuals, including both the scientific and lay communities.

External Advisory Board: Formation of an External Advisory Board to the DDRCC is mandatory. This Board advises the Director on budget, policy, scientific focus, core use assessments, and other issues related to the workings of the Center. A group of four to seven members selected for their scientific expertise and administrative oversight skills is recommended. The External Advisory Board should meet at least once a year, on site, to review the DDRCC.

The Administrative Core oversees the P/F program. The review of P/F project applications must include the use of appropriate consultants from the scientific community outside the DDRCC. This may be another function of the External Advisory Board. Typically the Director designates someone to oversee the P/F program for the DDRCC, e.g. the Associate Director or other Center member.

The Administrative Core also assumes responsibility for the Enrichment Program. The selection, oversight, and management of the Enrichment Program is often best handled by a designee of the Director, typically a Center member, the Internal Executive Committee, or an Associate Director.

Maintaining a Center website, providing editorial services, and reminding Center members of the NIH policy on Public Access are all potential Administrative Core services.

Center Membership Criteria: Criteria for becoming a DDRCC 'member' should be clearly defined. Subsets of members based on their degree of participation or other quantitative measures are acceptable. Suitable criteria include peer-reviewed independent funding, participation in DD-related research, and need for the use of core facilities. Not all core 'users' must be Center members, but all research base investigators should be Center members. Designation as a Center member without the need for the use of core facilities must be justified.

RESEARCH BASE

Description

Since the DDRCC program is aimed at fostering interdisciplinary cooperation among a group of funded investigators conducting high quality research involving the etiology, treatment, and prevention of digestive diseases and related disorders, the existence of a strong digestive diseases research base is a fundamental requirement for, and a critical component of, a DDRCC.

Requirements

For **new** DDRCC grant applications, only those in which NIDDK support comprises at least **50 percent** of the total Federal funding for the digestive diseases-related research base will be considered for funding. The absolute level of support must be sufficient to warrant the addition of a Center, typically at least \$3 million a year. Since 'Facilities and Administration' costs vary considerably between institutions, these should not be included in the calculations. Because one of the purposes of the DDRCC is to encourage collaborations with investigators in areas of research other than digestive diseases with the goal of enhancing and expanding DD research, **renewal** applications **may fall below** the 50 percent level for NIDDK funding. A decrease to less than 50 percent NIDDK funding should most often be due to the recruitment of investigators from other fields into the Center. Except in unusual circumstances, the NIDDK portion of the digestive disease-related research base should not fall below 30%. A level this low will be considered acceptable only if the overall tone and direction of the DDRCC is consistent with NIDDK program objectives.

Renewal applications do NOT have to show substantial growth in the amount of funding to remain competitive, particularly in their third or subsequent renewals. Given the minimal growth of the NIH budget, research base funding may remain constant. Too large a number of Center members (i.e. research base investigators) may dilute/reduce the impact of the DDRCC on those members since the cap on Direct Costs awarded for DDRCCs has remained constant for many years.

CORE FACILITIES

Description

A biomedical research core in a DDRCC is a shared facility or resource that provides services needed by DDRCC members. Core services enable Center members to conduct their research more efficiently and/or more effectively and to avail themselves of new technologies. Cores should be designed to furnish a group of investigators with some technique, determination, service, expertise, or instrumentation that will enhance research progress, consolidate manpower, and contribute to cost effectiveness. Often, services or techniques can be provided at less cost and potentially higher quality when performed within a core facility as opposed to being done infrequently in an individual investigator's own laboratory. A minimum of two service cores, in addition to the Administrative Core, are required to justify the existence of a DDRCC.

A clinical component is encouraged, but the requirements for that component are distinct from those of the biomedical research cores (see below).

Cores may be proposed in relation to any acceptable research activity of the DDRCC, although they usually fall into one of four categories: (1) provision of a technology that lends itself to automation or preparation in large batches (e.g., hormone measurements, cell/tissue culture); (2) complex instrumentation (e.g., electron microscopy, mass spectrometry); (3) animal preparation and care; and (4) technical assistance and instruction (e.g., molecular biology, biostatistics).

Cores are not intended to supplant investigator capabilities, but rather to enhance them. When appropriate, core staff should provide instruction for investigators, laboratory personnel, or fellows to learn and then become proficient in technologies that will become part of the repertoire of the laboratory. Teaching complex techniques and methodologies is an important function of a core.

In addition to providing products or services, a core must maintain appropriate quality control and maintain a record of use. **Limited developmental research** is also an appropriate function of a core facility as long as it is directly related to enhancing the function or usefulness of the core and is not an undertaking that should more appropriately be funded through other mechanisms.

Requirements

Use: The establishment of, and continued support for, a biomedical research core within a DDRCC is justified solely on the basis of need. The minimum requirement is significant use by two or more Center members (including the Core Director if he/she is part of the research base), each with an independently funded peer-reviewed project. Use by two members funded by the same grant does not constitute adequate core use. The number of projects being supported will also be considered in the justification for establishing a core. While investigators holding awards from the DDRCC's P/F program are appropriate users of core facilities, use by P/F recipients will not contribute substantially to the justification for establishing or continuing a core. Non-Center members may use DDRCC core facilities when it does not disadvantage Center members.

Core Director: A Director must be designated for each core. Core Directors should be acknowledged experts with independently funded research programs who will themselves use the core services. Therefore, the percent effort for the Director requested from the DDRCC will be relatively low, typically

10 to 20 percent. While it is expected that all core Directors and co-Directors will be Center members, occasionally experts in the specialty area required by the core who are not part of the research base may be appropriate. Sufficient and compelling reasons must be given for appointing any Core Director/co-Director who is not a Center member.

In instances where a junior scientist (who may or may not be a part of the research base) with appropriate expertise will devote a significant effort to the core and a more senior, established expert assumes the role of core Director, a title of 'core manager' or 'core technical director' might be appropriate for the junior scientist. The career potential of, and institutional commitment to, junior scientists who serve as core managers/technical directors will be considered in the review of the DDRCC.

Personnel: Research assistants, associates, analysts, technicians, and other qualified individuals are acceptable personnel for a core when appropriate for the volume and type of work anticipated. Postdoctoral research fellows are never appropriate personnel for a core.

Facilities: Arrangements for sufficient space for core activities or for access to established institutional facilities must be made. Centers are strongly encouraged to enter into cooperative arrangements with cores already established within their institution, or with other DDRCCs in close proximity, when the existing cores offer the services needed. These arrangements are important whenever greater efficiency or cost savings can be realized by such an agreement. It may be advantageous for a DDRCC to provide support for appropriate personnel to work specifically for DDRCC members in an existing facility/core (e.g. transgenic animal core) at the institution. In this case, the designated DDRCC core Director must work closely with the parent facility core Director to coordinate services, unless the same individual assumes both roles.

Charge-back System: A charge-back system should be developed to allow investigators to utilize any core. Charge-back 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 charge-back 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 DDRCC 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. Charge back fees to the DDRCC 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.

Operational Plan: Each core must have a pre-established plan for its operation. Qualifications required for using the core facility and plans for prioritizing use must be clear. Limited use of cores by investigators in other fields is encouraged, as is use by trainees, students, and junior faculty. The DDRCC must decide upon the approach to and extent of training being performed in each core; training is an appropriate and worthwhile activity of a core and is encouraged. Quality control is an important part of the operational plan also.

Any core with a minimum number of users must develop plans to broaden the number of core users. Such plans should be outlined for any core that is not extensively used but is considered essential by the DDRCC administration.

PILOT AND FEASIBILITY STUDIES

Definition

Although research projects associated with a DDRCC are funded from other resources, there is one exception -- pilot and feasibility (P/F) studies.

P/F project funds provide modest support (typically \$10,000 to \$50,000) for a limited time to enable eligible investigators to explore a digestive diseases-related research concept with the ultimate goal of collecting sufficient preliminary data to apply for independent support, or to prove lack of feasibility.

P/F project support is not intended for the extension of projects by established investigators for which it would be appropriate to submit a research project grant application. P/F funds are also not intended to merely fund or supplement ongoing research of an investigator.

Eligibility Criteria

Investigators eligible for P/F funding fall into three categories:

- (1) new investigators without current or past NIH research project support (R01 or P01) as a principal investigator. A new investigator's current or past support from other sources must have been modest, i.e. typically no more than \$75,000 per year, exclusive of salary. Institutional start-up funds are excluded.
- (2) established, funded investigators with no previous work in digestive diseases or DD-related areas who wish to test the applicability of their expertise to a DD-related problem; and
- (3) on rare occasions, established investigators in digestive diseases or DD-related areas who wish to test the feasibility of a new or innovative idea which constitutes a **significant departure** from their funded research. (Generally, this does not mean repeating an experiment using just a different cell type or animal model.)

The NIDDK expects that the majority of P/F project investigators will fall into the first category and only in exceptional circumstances will category 3 investigators be supported.

Trainees who are recipients of an NRSA individual award (F32) or are supported by an institutional training grant (T32) are eligible for P/F funds **only** if they are in their last year of training, have had at least one year of research laboratory experience at the postdoctoral level, and have suitable expertise and independence to design and carry out the planned experiments. Trainees requesting P/F funds should have a commitment from a senior scientist to sponsor the project. P/F funds cannot be used to supplement NRSA stipends, but may be used for supplies, technical support, special services, etc.

There is no citizenship requirement for P/F recipients, BUT visiting scientists with whom the DDRCC

investigators will not have a long-term collaborative relationship are not considered strong candidates for support. Individuals whose intention is to remain involved in DD research, either in the U.S. or elsewhere, may be supported by P/F funds. Individuals who are intending to remain in the U.S. as citizens or permanent residents may be supported by P/F funds as long as they otherwise meet the eligibility criteria above.

Each P/F project application should clearly identify the eligibility of the investigator using one of the three categories listed above. A proposed P/F project should clearly delineate the question being asked; present a testable hypothesis; detail the experiments to be performed; and discuss how the data will be analyzed. The research must involve a DD-related topic relevant to the current focus of the DDRCC or involve an avenue of new research into which the DDRCC will be moving.

P/F projects should be submitted for Center review in the general format of NIH research project applications (R03). The period of support is limited to three years or less with available funds usually ranging from \$10,000 up to \$50,000 per year. Investigators may receive P/F support only once in any five-year funding period.

Administration of P/F Program

While the management of the P/F program is left to the discretion of the DDRCC, it must include the elements listed below.

1. A mechanism must be established to advertise the availability of P/F funds.
2. A mechanism for the scientific merit review of P/F projects must be established. At least one reviewer from outside the DDRCC must be used to evaluate each application. Details of handling the review will be left to the DDRCC, although all reviewers should assign priority scores in accordance with the NIH system. Copies of all of the projects with written documentation of the reviews, priority scores, and final action should be retained by the DDRCC. These records should be available to outside reviewers and NIH staff, if requested.
3. A mechanism for making recommendations to the DDRCC Director for funding decisions should be outlined.
4. A mechanism for the oversight and review of ongoing P/F projects should be developed as a requirement for a second or third year of funding.
5. A mechanism to terminate P/F projects must be established. Studies may be terminated by the DDRCC administration before their approved time limit for various reasons such as (1) the investigator receives outside funding for the project; (2) the project was found not to be feasible; or (3) the investigator left the DDRCC institution. When a project is terminated, the DDRCC may use the unspent funds to either make new awards for P/F projects or to supplement ongoing P/F projects.
6. A plan for tracking the success of the P/F program should be established. A record of scientific publications, abstracts, and grant applications submitted/funded, as well as information on whether the investigator remains in DD-related research is important. Staff of the NIDDK uses this record to determine whether the P/F program is a useful component of the Center which serves to encourage investigators to remain in DD-related research.

Each DDRCC Director is strongly encouraged to involve the External Advisory Board in the management

of the P/F program. P/F grant recipients are encouraged to collaborate or consult with any biostatistics component supported by the DDRCC or otherwise available at the applicant institution and to utilize the core facilities or the clinical component of the DDRCC.

The P/F funds available to a DDRCC are "capped" at \$150,000 per year and their use is restricted as indicated in the Notice of Grant Award. Prior approval from the NIDDK is necessary to transfer funds from the P/F category to the cores or from the cores to the P/F program.

ENRICHMENT PROGRAM

The DDRCC grant can provide limited support for an enrichment program under the auspices of the Administrative Core. Support for visiting scientists, seminars, and research forum are appropriate items for inclusion in an enrichment program. Also, limited travel support may be requested to allow DDRCC investigators to present scientific findings, to learn new laboratory techniques, to develop new collaborations, or to engage in scientific information exchange. Mini-sabbaticals to allow Center investigators to enhance their scientific and technical expertise are allowable expenses. In all cases, the enrichment program should further the overall aims and objectives of the DDRCC as well as its cores. Creative new programs, not precluded by NIH or NIDDK guidelines, are encouraged.

OPTIONAL COMPONENTS

CLINICAL COMPONENT

All of the requirements for a Core, with the exception of the requirement for the users to be funded for ongoing clinical studies, applies to the clinical component. Since the NIDDK is interested in translating the work supported by the DDRCCs into practical therapies for digestive diseases, the clinical component should serve as a resource, a focal point, and a facilitator for this function. Investigators, therefore, need not be funded directly for clinical studies to use the services or expertise provided by the clinical component nor to justify the existence of this component. Providing the capability for translating basic research findings into a clinical setting is the ultimate goal of the clinical component.

NAMED NEW INVESTIGATOR

Each DDRCC may provide salary support for a P/F project recipient whom they designate a Named New Investigator. Support for this individual is limited to 3 years and cannot exceed \$90,000 per year, additional appropriate fringe benefits, and 80% effort. These funds are included in the Administrative Core budget. The individual selected should be a junior investigator who fits the first P/F project eligibility category as listed previously in these guidelines and is a permanent resident or US citizen.

Individuals are eligible only once for this support. Subsequent candidates for this position are nominated by the Center and reviewed by its External Advisory Board. Appointment of the Named New Investigator is contingent upon the concurrence of the External Advisory Board and the NIDDK DDRCC program director.

II. APPLICATION

GENERAL INSTRUCTIONS

Pre-Application Process

Applications for DDRCCs are accepted **only** in response to a Request for Applications (RFA) published in the [NIH Guide for Grants and Contracts](#). The schedule for the publication of DDRCC RFAs is available on the NIDDK website.

The receipt date for applications is indicated in the RFA. Individuals from institutions with an interest in applying for a DDRCC grant should contact NIDDK program staff as early as possible in the application preparation process. This consultation is crucial. Applicants should not construe advice given by the NIDDK staff as assurance of a favorable review and/or possible funding. The staff will not evaluate or discuss the merit of the scientific aspects of the application.

Application Format

It is necessary for applications to be arranged in a specific format. This not only makes it easier for NIDDK staff and reviewers to evaluate the application, but also provides a checklist for the Center Director when preparing the application. Applicants should keep in mind that the written application is the sole basis for the scientific merit review of the proposed DDRCC. It is not possible to conduct a site visit for each application.

The format is described both for new and for renewal applications. In renewal applications, accomplishments and a brief history of the DDRCC's development should be included.

The PHS Form 398 (<http://grants.nih.gov/grants/funding/phs398/phs398.html>) must be used for the application. The arrangement of materials for the DDRCC grant should follow both the instructions in the PHS Form 398 application kit and the more specific instructions detailed below to aid in the review process.

Submission

The original and three identical copies of the completed application should be mailed to the Center for Scientific Review (CSR) using the address from the 398 instructions.

At the time of submission, two additional copies of the application must be sent under separate cover to Chief, Review Branch, NIDDK; 6707 Democracy Blvd., MSC 5452., Room 752; BETHESDA MD 20817.

SPECIFIC INSTRUCTIONS

FORM PAGES

Applications use the PHS 398 forms, following the standard instructions. The Table of Contents should be modified appropriately to reflect the contents of a P30 Center application.

Provide a consolidated budget for the first year of requested support (see Illustration I).

Form Page 4: Separate budgets for each core and for the clinical component (if requested), should immediately precede the narrative of that section, using form page 4. The funds requested for the P/F program, not to exceed \$150,000, should be included in the "other expenses" category of the budget for the Administrative Core

Form Page 5: Budget for Entire Proposed Project Period (self-explanatory)

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

A consolidated list of Center Members and the Cores they use, as suggested in Illustration II.

A summary of the current and pending support for all DDRCC members, including percent efforts, aids in the review process when presented as suggested in Illustration III. K-series awards may be included in the research base. Institutional Training Grants (T32 and T35) and Individual Fellowship Awards (F30, F31, and F32) are not part of the research base, but should be listed separately.

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.

PAGE LIMITS

In keeping with the Enhancing Peer Review initiative, the following page limits are in effect for all DDRCC applications.

- Introduction to a resubmission application: 1 page
- Background and Overview: 12 pages, plus pages needed for the table suggested in Illustration II in these guidelines
- Research Base: 6 page overview plus 1 page per research base investigator, plus pages needed for the tables suggested in Illustrations III and IV in these guidelines
- Cores: 12 pages each plus additional pages for the table suggested in Illustration V in these Guidelines
- Enrichment program: 6 pages (in addition to 12 pages for rest of Administrative Core)
- Clinical component: 6 pages (in addition to 12 pages for rest of core in which it resides). If this will be a Clinical Core, then the 12 page limit applies.
- P/F program: 6 pages plus 1 page per each of the 4 P/F projects submitted. In renewals, plus 1 page per each P/F supported in the last 5 year funding period and for Illustration VI in these Guidelines.
- **Appendix** All applications must adhere to the current policy on appendix material found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-077.html>

- For renewals, sufficient pages for a consolidated publication list as suggested in Illustration VII in these Guidelines.

APPLICATION COMPONENTS

Center Overview

The research strategy for the Center Overview for a P30 DDRCC must include the following information, within the 12 page limit:

- For all applications, the rationale and need for the Center, its overarching 'theme', the strengths of its membership, how the DDRCC will interact with other relevant Centers and core facilities at the institution, special resources that make the Center unique, and any other information that will convey the need for a DDRCC and the resources it provides. The Cores proposed for the Center should be integrated into the narrative to demonstrate the overall scheme for the Center.
- For renewal applications, a short progress report on the previous funding period for the DDRCC, including changes in the membership, research base, and cores as well as major accomplishments should be included within the 12 pages.

Research Base

Include an overview of the current DD-research activities at the institution. A clear presentation of the ongoing research base is critical since it will highlight the research focus of the DDRCC 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. Emphasize the anticipated impact of the establishment of a DDRCC on the research base. Include an indication of how the establishment of a DDRCC will provide added dimensions and new opportunities for DD-related research, along with increased cooperation, communication, and collaboration among investigators.

Group DD-related research projects into aggregates of thematically related studies with similar overall goals and objectives. A majority of the research base should have a central focus or theme that is a digestive disease or related disorder, group of diseases, or functional studies relating to digestive diseases. Overly detailed descriptions of the research base projects are not possible. Therefore the presentation of the research base in the application is best done in two ways: (1) by providing information in a format such as that shown in Illustration III, and (2) **by providing narrative descriptions of no more than 1 page per research base investigator**. These narratives should include: (1) grant numbers, titles, and a few descriptive sentences, and (2) a list of the core(s) which will be used. Include a brief sentence indicating what aspect of the research justifies the use of each core. ONLY those grants awarded to investigators at the applicant institution or the applicant consortium, not to collaborators at other locations, should be included in the description of the research base. It is particularly important to provide a few sentences indicating the relatedness of a cited grant to digestive diseases research when this is not readily apparent from the title of the grant.

Document collaborative efforts by using a format such as Illustration IV, although pre-existing extensive collaborations are not a prerequisite for new applications. For renewals, this Illustration can be validated by looking at the list of publications.

For renewals, provide a list of peer-reviewed publications resulting from research supported by the DDRCC, indicating the authors who are center members. Include PMID numbers. To reduce the length of the application, a format such as Illustration VII, sorted by core, should be used.

Biomedical Research Cores (present each core separately)

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

Within the 12 page limit for each core's research strategy, include the rationale for establishing the core, the facilities to be used, and the activities of the core. Provide short descriptions of the services provided and the projects of the investigators who will use the core. Give special attention to the description of the physical arrangements and instrumentation for the core.

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

1. assuring quality control
2. prioritization of investigator use
3. monitoring core use
4. adapting to new technology and to the needs of the DDRCC members.

Include a definition of qualified users. Provide a list of funded Center members who will use the core and the expected extent of their proposed use. Illustration V is given as an example of how this may be accomplished. Emphasize the anticipated benefits that investigators will derive from using core facilities.

Use of the core by investigators who are not center members is encouraged, but rules to regulate this use should be defined. If the core is used for training, detail the approach to and extent of the training. Use of the core for training Center members is encouraged.

Describe any plans to use the core for limited developmental research, including the relevance of this research to core services, effectiveness, and adaptability.

Since DDRCCs are strongly encouraged to enter into cooperative arrangements with established cores at the applicant institution or at other DDRCCs offering a similar type of service, describe the nature of any cooperative arrangements, the prioritization plan, and the methods to monitor use under these circumstances.

For renewals, refer to the appropriate pages of the list of publications (see Illustration VII) made possible by use of the core. Tally the number of publications, regardless of primary or secondary category, for each core. The DDRCC should have been credited as a resource in all publications. This

acknowledgement provides evidence to the study section, and the NIDDK, of core use.

Provide information on past use of any core for which further funding is not being requested, as well as a brief explanation of the reasons for deleting cores, combining facilities, or creating new cores.

When cores use human subjects or animals, include complete Human Subjects and/or Animal Subject sections.

Administrative Core

Include a budget for the Administrative Core with a comprehensive justification. Most Centers find that the size and complexity of a DDRCC warrants inclusion of a full-time program administrator. Other budgetary items that, if requested, should be included here are funds for enrichment programs, travel funds for at least two persons to attend the annual meeting of DDRCC directors, and salary for the Named New Investigator. The P/F project of the Named New Investigator should be included in the P/F program.

Provide a description of the administrative structure of the DDRCC, including: chain-of-command, committee structures (e.g. Internal Advisory Committee; P/F review; other oversight or management committees); and core, enrichment, and clinical component (if included) oversight.

Include a brief narrative describing the qualifications of the Director and associate Director. It is important to include a plan for replacing the Director should this become necessary.

Provide an outline of the relationship of the DDRCC to the institution and the reporting lines of the DDRCC Director to appropriate institutional officials. If this is presented in diagrammatic form, also provide a brief explanation in narrative form.

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

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

For new applications, list the areas of expertise necessary for inclusion on the External Advisory Board, **not** the names of the individuals whom you plan to recruit to serve in this capacity. *For renewals*, list the current External Advisory Board members, and include their Biosketches in the application.

Describe plans for the **enrichment program** in as much detail as possible, including the anticipated benefits to Center members. Include funds for the enrichment program in the budget for the Administrative Core.

In renewals, describe the existing enrichment program, including its value to the DDRCC members and

how the program has been adapted to the needs of the members. Describe future plans for the enrichment program.

Pilot and Feasibility (P/F) Program

Provide a justification for amount of P/F funds requested. The actual budget request is contained in the "other expenses" category in the budget for the Administrative Core. DDRCC P/F programs are limited to \$150,000 per year.

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

Include a 1 page synopsis for each of **four** P/F project applications. For new applications, these should be the best applications received by the proposed DDRCC and reviewed in the manner proposed for review of all future P/F applications, should the Center be funded. For renewals, these should be from the most recent group of funded projects.

Each synopsis should include:

- a) budget and number of years requested
- b) eligibility of the P/F project (how it fits with the DDRCC's goals)
- c) name, department affiliation, and eligibility category of the P/F investigator
- d) proposed core use
- e) abstract of the project.

In all applications clearly indicate the **Named New Investigator**, if such a position is being requested, and how he/she was selected. Include salary support for this position in the Administrative Core personnel section.

For renewals, include an historical overview of the P/F program since the inception of the DDRCC. For no more than the most recent 10 years, provide a summary of the P/F recipients (a) who have had publications as a result of the projects, (b) who have received peer-reviewed funding as a result of the studies, and (c) who are still active in the area of digestive diseases. Identify any lasting collaborations that resulted from the P/F program. To aid in the review process, a format such as shown in Illustration VI is helpful in depicting the P/F program outcome.

BUDGET CATEGORIES

Allowable costs and current policies governing the research grant programs of the NIH will prevail for DDRCC applications.

Personnel

This category should include salary support for key personnel within the DDRCC who contribute to the allowable activities of the Center. Salary support for a full time administrator for the Center is encouraged. Salaries of professional personnel engaged in research activities supported by P/F funds are an allowable budgetary item, as are salaries of professional and technical personnel in core facilities. The salary amount charged to the DDRCC grant must be commensurate with the time spent on DDRCC activities and is subject to institutional and NIH salary policies.

The Center Director, or the combined multiple-Center Directors, is/are expected to devote no less than 20 percent effort to the DDRCC. 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.

Potentially overlapping support between DDRCC and individual projects, including research project grants (R01), program project grants (P01), Career Development Awards (K-awards), Small Business Technology Transfer awards (R41, R42), and contracts, will be administratively reviewed by the NIDDK and, if appropriate, adjusted to eliminate duplication of funding.

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

Equipment

If pieces of specialized equipment costing more than \$5,000 are requested, the application must identify similar equipment already available within the institution and provide a clear justification for purchase based on core service provided to DDRCC investigators. Requests for general-purpose equipment should be included only after ascertaining the availability of such items within the institution. Justify the request based on this availability. This includes all equipment in future budget years as well as the initial budget period.

Supplies

Consumable supplies directly related to the operational aspects of the DDRCC core facilities are an allowable expense. This includes office materials as well as laboratory supplies. The supply budgets of separately funded individual research projects must be appropriately reduced to reflect such support, thus eliminating duplication.

Research Patient Care Costs

Research patient care costs (both in-patient and out-patient) are an allowable expense. Attempts should be made to utilize existing clinical facilities, such as those supported by Clinical and Translational Science Awards (CTSAs) and individually supported beds. If the CTSA is to be used, include a letter of agreement from the principal investigator of the CTSA.

Request costs relating to the clinical research efforts of DDRCC investigators ONLY if there is no overlap with other funding. Costs already budgeted in individual projects should be appropriately reduced if such costs are to be transferred to the DDRCC clinical component or clinical Core. The DDRCC 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.

Alterations and Renovations

Funds for the alteration and renovation of an existing structure to provide suitable space for core facilities may be requested. 'Cosmetic' renovations are not appropriate.

Consultants

Include costs associated with consultants (consultant fees, per diem, and travel) when their services are required by the DDRCC, such as the members of the External Advisory Board.

Travel

Include the costs of domestic and foreign travel for core or clinical component personnel in the budgets for the individual cores, or the clinical component, only if the travel is directly related to the activities of the DDRCC. Include travel costs for the DDRCC Director, center administrator, and others as appropriate (i.e. co-Director, core Directors) to attend the annual DDRCC Director's meeting in the budget of the Administrative Core.

Total Requested Amount

Total **direct costs** requested should not exceed \$750,000 per year.

SUPPLEMENT REQUESTS

Unsolicited supplements to a DDRCC grant are not routinely accepted. If a DDRCC Director determines that a supplement to a DDRCC grant is necessary, consultation with, and approval by the NIDDK DDRCC program director is required prior to the submission of a formal request through the institution's budget office.

III. REVIEW

APPLICATION RECEIPT

Upon receipt, Center for Scientific Review (CSR) staff will screen applications to make sure they adhere to 398 submission guidelines. Rejected applications will be returned to the applicant. NIDDK program staff will screen applications for responsiveness to the program requirements and criteria stated in the RFA. If the application is not responsive to the RFA, NIDDK staff will contact the applicant.

Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the NIDDK.

The written application must be complete because site visits are not possible.

Following the initial review of both new and renewal applications, all scored applications will undergo a second level review by the National Diabetes and Digestive and Kidney Diseases Advisory Council. Applications recommended for approval by the Advisory Council will be considered for funding on the basis of (1) overall scientific and technical merit as determined by peer review, (2) program needs and balance, and (3) availability of funds.

REVIEW

STANDARD NIH REVIEW CRITERIA

All applications are subject to the standard NIH Review Criteria:

Overall Impact: Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the Center to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the Center proposed).

Scored Review Criteria: Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a Center that by its nature is not innovative may be essential to advance a field.

Significance: Does the Center address an important problem or a critical barrier to progress in the field? If the aims of the Center are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

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?

Innovation: Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the Center? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the Center involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

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?

Standard Additional Review criteria for all NIH applications include those for Protections for Human Subjects; Inclusion of Women, Minorities, and Children; Vertebrate Animals; Biohazards.

SPECIFIC REVIEW CRITERIA FOR DDRCCS

Significance: What are the strengths of the Center's research base (its breadth and depth)? Do the focus, relevance, interrelationships, quality, productivity, and, to some extent, quantity of the research base support the stated theme of the Center? What is the likelihood that the DDRDC will increase efficiency; promote new research directions and meaningful collaborations among center investigators; facilitate interactions and collaborations among the investigators; and prove cost-effective?

Investigator(s): Are the Center investigators responsible for the individual research projects willing to interact with each other and contribute to the overall objectives of the DDRCC? What are the scientific and administrative leadership abilities of the proposed Center Director and Associate Director(s) and their commitment and ability to devote adequate time to the effective management of the DDRCC? Are the Core Directors well-qualified and appropriate? If requested, does the Named New Investigator appear well qualified and appropriate for support?

Innovation: Are no more than four Pilot & Feasibility (P&F) studies submitted for evaluation as part of the review of the P&F program? Are the P&F applicants eligible and does the selection process by which the individual studies were selected appear appropriate? Does the Center appear to encourage 'high-risk', innovative ideas through their P/F program? Do the Cores provide new methods, techniques, and/or resources and demonstrate the ability to adapt when needed to support investigators in emerging areas of digestive and/or liver diseases research, as appropriate to the purpose of the Core and the research supported by the Center?

Approach: How appropriate and relevant are the proposed cores and the modes of operation (such as prioritization of requests for services)? Will at least two funded investigators who are Center members use each core? Will the cores provide opportunities not otherwise available to the investigators; represent appropriate cost savings/cost sharing advantage; and stimulate the development of new approaches? Are the criteria for membership in the DDRCC clear and appropriate? Is appropriate administrative organization proposed for the following:(a) coordination of ongoing research between the separately funded projects and the center, including mechanisms for internal monitoring;(b) establishment and maintenance of internal communication and cooperation among the center investigators;(c) mechanism for selecting and replacing professional or technical personnel within the cores;(d) mechanism for reviewing the use of, and administering funds for, the P&F program;(e) management capabilities, including fiscal administration, procurement, property and personnel management, planning, budgeting, and other appropriate capabilities? Is there efficient and effective use and/or planned use of the limited enrichment funds, including the contribution of these activities to the stated goals of the DDRCC?

Environment: Is there institutional commitment to the DDRCC, including lines of accountability 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?

RENEWAL APPLICATIONS

For Renewals, reviewers will consider the progress made in the last funding period, including: Have the benefits of the Center been documented in the forms of increased collaboration, new research directions, and cost savings to its members and the institution? Is the focus of the DDRCC reflected in the research base? Have the Cores provided appropriate methods, techniques, and/or resources and developed ways to support investigators in new areas of digestive and/or liver diseases research, as appropriate to the purpose of the Core and the research supported by the Center? Have the Cores adapted to the changing needs of the investigators? Is the use, utility, quality control, and cost effectiveness of each Core requested to continue as part of the Center documented? Are Cores no longer needed appropriately being discontinued in response to the changing needs of Center investigators? Is there a significant list of publications arising from each Core? Has the administrative structure proven effective? Are data provided to document the outcome of all completed P/F projects, including those that failed to lead to further funding? Has the enrichment program been effective?

SCORED SECTIONS OF APPLICATION:

For DDRCC applications, reviewers will be asked to evaluate the following individual sections, and the Scientific Review Officer will record these scores:

- Overall Research base, including the focus, quality of research, collaborations among members, relevance to the Center's stated research focus, and, for renewal applications, the growth or evolution of the research base.
- Each scientific core, as regards need for proposed services; number of users; qualifications of personnel; management, including prioritization and responsiveness to the needs of the users; quality control management; and any appropriate developmental work
- The Administrative Core, including committee structure, center membership criteria, and lines of communication. The enrichment program, clinical component, and Named New Investigator, if requested, will also enter into this evaluation.
- Pilot and Feasibility program, including the quality and appropriateness of the four submitted P/F applications as well as the organization of the P/F overall process of solicitation, review, and monitoring of projects.
- Center Director (PI) as regards leadership and commitment to the stated goals of the DDRCC.

The overall impact score is not the average of the scores for all these components.

IV. POST-AWARD

Background

The DDRCC program as a whole, and each Center individually, is evaluated on an ongoing basis by NIDDK staff. The activities and accomplishments of each DDRCC are documented using several approaches. The annual progress report serves to highlight each DDRCC's accomplishments, including productivity of individual investigators; significance of the research conducted by Center investigators; enhanced communication and collaboration facilitated by the DDRCC; use of P/F funds; and overall Center impact on the institution and the Center members.

In addition, NIDDK staff must periodically prepare reports for the NIDDK Director and the National Diabetes and Digestive and Kidney Diseases Advisory Council. These reports are primarily based on progress reports from the DDRCCs and on information solicited prior to the yearly Center Directors' meeting. If necessary, NIDDK staff or consultants may visit individual centers to aid in these evaluation activities. The Annual Center Directors' meeting, usually held at one of the DDRCCs, provides an opportunity for evaluation of the host center's program.

General Plan for Interim Assessment

To assist in interim assessments of the DDRCC, the following are helpful to the NIDDK staff:

- a) Yearly Center Directors' meeting – this meeting, attended by NIDDK staff and Senior management, is mandatory for all Center Directors or, if need be, the co-Director. Center administrators are strongly encouraged to attend.
- b) Minutes of DDRCC meetings - copies of the minutes of Internal Executive Committee meetings and the External Advisory Board meetings;
- c) Newsletters - current newsletters from the DDRCC and from the parent institution, if these mention or highlight the DDRCC.
- d) In-House Assessments - The Director of a DDRCC should use Center's External Advisory Board meetings to assess the activities and programs of the DDRCC. The minutes from the Advisory Board meetings may be included as part of the annual progress report OR may be sent to the NIDDK program director as they become available.
- e) Annual Progress Report - The annual Grant Progress Report, which is due two months before the anniversary date of the award, must be submitted as described in the PHS Form 2590 application instructions. Since the DDRCCs are large, multifaceted grants, a uniform reporting format for the annual progress report is desirable.

The format suggested for the narrative portion of the report follows below. Information such as External Advisory Board meeting minutes, newsletters, and other pertinent items already sent to the NIDDK program director need not be included.

FORMAT FOR ANNUAL PROGRESS REPORTS

Use this outline in conjunction with the narrative portion of the Grant Progress Report (PHS Form 2590) to provide information about the DDRCC.

All information should begin from the time of the last Progress Report. Include a Table of Contents.

Biomedical Research Component

Include the following items:

- a) concise statement of **any changes** in the goals and objectives of the DDRCC;
- b) summary of any changes in the research base (loss or addition of DDRCC members, as well as change in status from associate to full members), the reason for changes (i.e. left institution, changed research focus), and how these changes affect the DDRCC;
- c) significant research advances and accomplishments made possible by the presence of the DDRCC (e.g. through core use, collaborations fostered by the DDRCC, etc.);
- d) a consolidated list, including titles, and PMCIDs of scientific manuscripts published by Center members and/or by investigators funded by the P/F program;
- e) description of current P/F projects supported by the DDRCC (include beginning date; **one page** progress reports for ongoing projects and the abstract for new projects are suitable; see sample format at the end of these guidelines); and
- f) a list of P/F projects which have ended, for any reason, since the last progress report (i.e. the project was completed, progress was not sufficient for renewal, recipient received other funding or left the center).

Core Facilities

Include the following items for each core:

- a) concise statement of **any changes** in the purpose of the core and the services provided; and
- b) utilization (users, frequency and extent of use, collaboration among investigators fostered by the availability of the core facility).

Enrichment Program

Include the following items:

- a) list of enrichment activities sponsored by the DDRCC, including lists of speakers and topics; visiting investigators and the purpose of the visit (collaboration, training, information exchange, or other); members taking mini-sabbaticals; etc.;

- b) concise statement of **any changes** in the enrichment program;
- c) any special, innovative, or unique aspects of the enrichment program that you wish to highlight; and
- d) any examples of how the enrichment program has positively affected the DDRCC.

Administrative Information

Include the following items:

- a) concise statement of **any changes** in eligibility requirements for Center members or other investigators to use core facilities;
- b) list of investigators comprising the DDRCC's research base in the reporting year. If the DDRCC distinguishes between different levels of membership, that should be clearly indicated with appropriate lists. It is important to be concise regarding the DD-related research base. Also provide
- c) a list of awards, honors, and special recognition(s) earned by the DDRCC members and not mentioned in the previous year's report;
- d) a list of grant applications submitted as well as funding obtained based on results of P/F projects since the last report;
- e) an indication of other support to the DDRCC from donations, gifts, funds from the institution, or other special sources;
- f) a brief summary of External Advisory Board meeting(s) [since the minutes of these meetings should have been sent to the program director previously, it is not necessary to send them again]; and
- g) a statement regarding the impact of the DDRCC on the institution/community.

Special Information

Each DDRCC is encouraged to provide a special summary report, in layman's terms, of the **most significant research advances** made possible by the existence of the Center. The significance of these advances, and their possible relevance to understanding the cause(s) of digestive diseases and related disorders should be discussed. To the extent possible, the report should also describe the relationship of these advances to the early detection, treatment, and possible prevention of digestive diseases and related disorders. Where applicable, the potential for Center advances to impact on improved patient care should be highlighted. NIDDK staff use this information to prepare annual and/or specially requested reports on the DDRCC program and its accomplishments, particularly for preparing responses to Congressional inquiries.

NOTE: An abbreviated version of the progress report may be submitted for the year of support in which the renewal application is being submitted. While the Grant Progress Report may be attenuated, it MUST contain the following elements:

- face page signed by the appropriate University officials;
- budget pages, with justifications;
- list of cores and names of core directors;
- list of faculty, departmental affiliations, and research interests [can be one sentence];
- titles, principal investigator's name, and dates for P/F studies for the last budget period and for those projects that are continuing or are planned for support;
- a brief [2-5 page] summary of Center core activities, including any changes in services offered;
- at least a one page report on the most significant scientific advances from the Center in the past year, along with the appropriate publication citation, in layman's terms;
- all the usual assurances;
- any personnel changes; and
- Checklist.

SPECIAL CONSIDERATIONS

While each DDRCC develops its own program in accordance with the local talents, interests, and resources available, each DDRCC must be responsive to national needs in digestive diseases and must be willing to work with the NIDDK and other organizations in furthering the overall goals of the DDRCC program. In this regard, DDRCC directors and selected other DDRCC 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.

In the event that major changes in a DDRCC occur, it may be necessary to have an interim site visit to discuss the changes and possible budget adjustments.

These guidelines update the policies covering DDRCC grants; earlier versions should be discarded. Some redundancy exists within the guidelines to emphasize key issues related to a DDRCC. If questions remain after reading these guidelines, contact the individuals listed below.

Direct inquiries regarding programmatic issues and requests for the Administrative Guidelines to:

Judith Podskalny, Ph.D.
Director, Digestive Diseases Centers Program
Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases
Two Democracy Plaza, Room 667
6707 Democracy Blvd., MSC 5450
BETHESDA MD 20892-5450
Telephone: (301) 594-8876
Email: jp53s@nih.gov

Direct inquiries regarding fiscal matters to:

Sharon Bourque
Senior Grants Management Specialist
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Two Democracy Plaza, Room 719
6707 Democracy Blvd., MSC 5464
BETHESDA MD 20892-5464
Telephone: (301) 594-8846
Email: bourques@extra.niddk.nih.gov

This document affects all new and renewal applications effective August, 2012

V. SUGGESTED ILLUSTRATIONS

ILLUSTRATION I

CONSOLIDATED BUDGET FOR 1st YEAR OF REQUESTED SUPPORT

Budget Category	Core A	Core B	Core C	Core D	TOTALS
Personnel					
Consultant Costs					
Equipment					
Supplies					
Domestic Travel					
Foreign Travel					
Patient Care Costs					
Alterations/ Renovations					
Other Expenses					
P/F Projects					
Contractual Costs					
TOTALS					

Illustration II

Core Use by Center Members

Use this Illustration to show Core use in a simplified format. Bold the names of Core Directors. It is not necessary to list Administrative Core, only relevant major components of that core (e.g. Clinical Component, Statistical Support, etc.)

Center Member	Membership Category*	Core B (Molecular Biology)	Core C (Animal Models)	Core D (Imaging)	Clinical Component
Alexander, Martin	Member	X			X
Buffalo, Raymond	Associate Member		X		
Denning, Susan (Core D)	Member	X		X	
Etc.					

*If applicable, i.e. if only 1 'category' of membership, then delete column.

Use for anticipated core use for the period of this application, not for past use.

ILLUSTRATION III

**SUMMARY OF CURRENT AND PENDING SUPPORT OF
ALL CENTER MEMBERS**

**ILLUSTRATION III-A: CURRENT DIGESTIVE DISEASES-RELATED
RESEARCH BASE SUPPORT**

Grants to be included: R-series, individual K-series, P01s (if the total direct costs are already listed for the Principal Investigator of the P01, support for the subproject should be shown in parentheses and NOT included again in the sum), and other peer reviewed grants funded through other Federal Agencies or non-federal groups. **Do not include** any Center or training related grants in III-A.. Include ONLY DD-relevant NIDDK support (i.e. not renal, diabetes, or other non DD); indicate by 'x' if other, non-DD funding is also available. .

Principal Investigator/ [Co- Investigator]	Supporting Organization/ Grant Number	Title	Project Period	Annual Direct Costs **	Identify other DK Center(s), if grant is included as part of its research base
Doe, John	NIH P01 DK12345	Mechanisms of gastrin action	4/1/2010 - 3/31/2014	\$500,000	
Jones, James	NIH R01 HD65432	GI hormones and development	7/1/2009 - 6/30/2014	\$225,000	Pediatric Nephrology
Smith, Edith	DOD	GI complications following surgery	7/1/2011 – 6/30/2005	\$180,000	
[Stellar, Fred]	CDC	Frequency of diabetic gastritis	9/1/2009 – 8/31/2012	\$350,000	Diabetes
Etc.					
Etc.					

*** Also sum this column, **avoiding duplication**, and calculate the % coming from the NIDDK*

SAMPLE ILLUSTRATION III-B: OTHER DIGESTIVE DISEASES-RELATED RESEARCH BASE SUPPORT

Types of Grants to included: Individual Fellowships (F30, F31, F32); Institutional Training and Career Development Awards (T32, T35, K12, KL2); and Center Grants (P30, P50, U54). Grants listed should be clustered by grant category, i.e. fellowships (F-mechanisms); research training grants (T-mechanisms), institutional K-awards (K12, KL2); center mechanisms (P30, P50, P60, U54). Include Federal and non-Federal support.

SAMPLE ILLUSTRATION III-C: *PENDING* DIGESTIVE DISEASES-RELATED RESEARCH BASE SUPPORT

List the types of grants from Illustration III-A only

ILLUSTRATION IV

COLLABORATIONS BETWEEN CENTER MEMBERS

	A D A M S	C H U	E V E R S	J O N E S	K N I G H T	O L S O N	S M I T H	S A N D S	T A Y L O R	Y O U N G	Z A N E
ADAMS		*		*	*		*		*		*
CHU	*				*		*				*
EVERS				*			*	*	*		
JONES	*		*			*					
KNIGHT	*	*						*			
OLSON				*						*	
SMITH		*		*							*
SANDS			*		*					*	
TAYLOR	*		*								
YOUNG						*		*			
ZANE	*	*					*				

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

ILLUSTRATION V

USE OF CORE FACILITIES

For each proposed Core provide information on the anticipated use of the Core's services for the period of support of this application.

To avoid unwieldy tables, group services whenever possible, i.e all 'assays', all 'animals', all 'consultations' and provide more details in the core description.

CORE: Biochemistry

DETERMINATIONS/SERVICES RENDERED

- A. Gastrin, CCK, leptin measurements
- B. RNA, DNA isolations
- C. Serum, cell, tissue storage
- D. Consultation

User	Funded Project	Period of Performance	A	B	C	D	Estimated use* and comments
Adams	R01DK099999	03/1/2009 – 07/30/2012		X		X	B. 5 per month for months D. 20 hours over the course of 12 months
Knight	P/F project	07/01/2010-06/30/2011	X			X	A. 100 samples per month for 3 months D. 10 hours

*During the period of this application

In renewal applications, add a column for 'Actual Use' for the most recent funding period, or if changes in services are major, include a separate table.

List Center Members first, alphabetically, followed by users who are not Center Members, also alphabetically.

ILLUSTRATION VI – for RENEWAL applications only

PILOT PROJECT OUTCOME TABLE

Provide information on the most recent 5 or, if possible, 10 yr period.

P/F #	PI (Dept)	Dates/Amount of P/F project	Title of Project	A	P	Applications Funded/Pending	Project Period	Still in GI Research?
01	John Doe (Physiology)	07/01/10 - 06/30/11 \$10,000	Role of Substance P in Regulation of Intestinal Motility	1		NIH R01 - pending	01/01/13 – 12/31/17	Yes
02	Jeff Hathaway (GI)	07/01/10 – 06/30/12	GI Hormones in Obesity	2	1	R21DK088888	09/01/13 – 8/31/15	Yes
03								
etc								

A = Abstracts

P = Publications

* Under "Applications Funded/Pending", list the grant received most proximate in time to the P/F award, i.e. for investigators who received funding 5-10 years ago, this may not be current funding.

ILLUSTRATION VII (for RENEWAL applications only)

CONSOLIDATED PUBLICATION LIST
from last funding period

Publications	Core B - Imaging	Core C – Animal Models	Core D – Morphology	+Molecular Core
Jones, J; Smith, A.. Title, YR, Vol., page#, PMCID	P			
<i>Brown, A.</i> ; Chu, D. ; Anderson, J.C. Title, YR, Vol., page #, PMCID	P			
Cheng, C.; Olson, F. Title, YR, Vol., page#, PMCID	S	P	S	
* Sands, W. ; Cheng, C. Title, YR, Vol., page#, PMCID		P		
Smith, L.; Davis, S.; Taylor, E. Title, YR, Vol., page#, PMCID			P	
<i>Hathaway, J.</i> ; Schultz, A. Title, YR, Vol., page#, PMCID				P

Note: An asterisk (*) indicates a publication that fails to cite DDRCC support.
+Indicates a discontinued core.

Sort this table by Primary Core used, recognizing that the services of several cores might have contributed to the publication. Cores discontinued within the past 5 year period may also be listed. Center members' names should be in **bold**; P/F recipients and users from outside the Center in *italics*. In each core write-up, refer to the page number that begins that Core's publication section in this consolidated listing. The number of publications (not the list) that resulted from any use of the core, i.e. including secondary core use, should also be indicated in the core write-up.

List each publication only once, regardless of how many cores were utilized or how many Center members are authors. Individual Biosketches will list the publications to reflect the productivity of each Center Member.

In the Overview section of the application, refer to the total number of unique publications, as well as the number of publications with multiple Center Members as co-authors (i.e. to emphasize collaborations).

Sample P/F Report Form
(for RENEWAL applications and progress reports only)

TITLE:

INVESTIGATOR:

FUNDING PERIOD: [dates of award]

ELIGIBILITY: [i.e. New Investigator or Established non-DD researcher or DD researcher changing direction]

PROGRESS REPORT: [Brief description of project and results]

CORE FACILITIES USED:

GRANTS: [planned, submitted, and/or received]

ABSTRACTS: [Authors, Title, etc]

PUBLICATIONS: [Authors, Title, etc]