

ADMINISTRATIVE GUIDELINES FOR CLINICAL NUTRITION RESEARCH UNITS (CNRU)

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PART I

DESCRIPTION AND STRUCTURE OF AN CLINICAL NUTRITION RESEARCH UNIT (CNRU)

PART I: DESCRIPTION AND STRUCTURE OF A CLINICAL NUTRITION RESEARCH UNIT

A. 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 that are available to investigators. These programs include various research, program project, and career development grants; institutional training grants and individual training fellowships; and a number of center-grant programs. This document provides a description of and administrative guidelines for the Clinical Nutrition Research Units (CNRU), a core center grant program. This program provides needed resources for the clinical nutritional sciences community.

CNRUs are meant to integrate, coordinate, and foster interdisciplinary basic and clinical research in nutritional sciences, obesity, and related disorders by a group of established investigators actively conducting programs of important, high-quality research that relates to integrative nutritional sciences and obesity-related themes. At the present time, the Division of Digestive Diseases and Nutrition (DDDN) within the NIDDK supports eight CNRUs.

B. DESCRIPTION and BASIC REQUIREMENTS

A CNRU must be an identifiable organizational unit within a single university, medical center, or a consortium of cooperating institutions with a university affiliation. The overall goal of the CNRU is to bring together, on a cooperative basis, basic science and clinical investigators to enhance and extend the effectiveness of nutrition research being conducted in the fields of nutritional sciences, obesity, and related disorders. This goal is achieved using the P30 center grant mechanism, which provides support for shared resources, termed "cores," that enhance productivity and benefit a group of investigators working to accomplish the stated goals of the CNRU. Thus, the purpose of a CNRU is to provide the capability for accomplishments greater than those that would be possible by individual research project grant support alone.

To qualify for a CNRU grant, the applicant institution **must** already have a substantial base of ongoing, independently supported, peer-reviewed research projects related to the study of nutritional sciences or obesity, a portion of which should be clinical and/or translational research. This currently funded **research base** provides the major support for a group of investigators who would benefit from shared resources. The body of research described as the research base includes only currently funded, peer reviewed research grants awarded to the applicant institution/consortium. These may be Federally or privately funded awards. Peer-reviewed Federally supported research must comprise at least 50% of the identified research base. 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 the most 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 investigators at the applicant institution/consortium.

As a means of encouraging the desired multidisciplinary approach to nutritional sciences and obesity research, the NIH seeks to foster the development and operation of CNRUs. The specific objectives of a CNRU include efforts (1) to create or strengthen a focus in biomedical research institutions for multidisciplinary and interdisciplinary research in nutritional sciences and obesity; (2) to develop new knowledge concerning the etiology, development, assessment, treatment, and prevention of nutrition-related diseases, obesity, and eating disorders; (3) to understand control and modulation of energy metabolism in obesity, including the interaction between physical activity, nutrient metabolism, and food intake; (4) to understand and treat disorders associated with abnormalities of energy balance and weight management such as in anorexia nervosa, AIDS, and cancer; and (5) to strengthen training environments to improve the education of medical students, house staff, practicing physicians, and allied health personnel with regard to these conditions.

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

Three other activities may be supported by CNRU 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 CNRU. These areas may include biomedical, epidemiological, clinical, or behavioral research as they pertain to the CNRU goals. Pilot and feasibility projects evaluating the effectiveness of a model program for translating research in biomedical and behavioral science into routine clinical care also are encouraged. The availability of a clinic population with adequate representation of women and minorities that can be readily utilized by investigators will play a major role in attracting investigators to the fields of nutritional science or obesity research and will serve as a resource in the design of pilot and feasibility projects.

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 CNRU and its members.

The clinical component may facilitate clinical investigations such as translation of research findings into practical treatments for patients and/or provide 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 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. CNRUs are encouraged to include a clinical component when appropriate for their members. This clinical component may be integrated within multiple cores; however, the applicant should describe how such efforts promote clinical investigations and translational research.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research or utilization of shared equipment. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator must be included with the application.

Eligibility for an award is limited to domestic institutions.

C. ADMINISTRATIVE CORE

Description

A CNRU will involve the interaction of broad and diverse elements; thus, lines of authority and sanction by the appropriate institutional officials must be clearly specified. In the event of a consortium of institutions being involved, agreement as to how the lines of authority will be managed among the participating organizations needs to be documented. The administrative core of the CNRU is responsible for maintaining these lines of authority, coordinating the various functions of the CNRU, and serving as the visible contact point between the university community and the CNRU. Therefore, each CNRU must contain an Administrative Core.

Requirements

Director

Each CNRU must name a Director who is responsible for its organization and operation. The Director is the Principal Investigator of the P30 application for a CNRU 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 nutritional sciences or obesity research. An Associate Director should be named who will be involved in both the scientific and administrative aspects of the CNRU. The Associate Director will serve as acting Director in the absence of the Director.

Organization and Functions

The administrative structure of the CNRU, 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 investigators, institutional administrative personnel, the staff of the NIDDK, and other members of the institution in which the Center is located.

The organization of the Administrative Core provides a supportive structure for the CNRU. As

part of this structure, for example, an Internal Executive Committee should be named whose duties include: (1) coordinating and integrating the CNRU 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 CNRU; and (5) interacting with other Centers, NIDDK, and other appropriate groups and/or individuals, including both the scientific and lay communities. It may be helpful to include a non-CNRU member on the Internal Executive Committee to provide the view point of someone not using the center in setting priorities and evaluating the operations of the center.

Formation of an **External Advisory Board** to the CNRU 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. For new applications, a description of the expertise of individuals to be considered for this external advisory board should be described, but it is preferred that invitations to these individuals not be extended until the CNRU is actually in place. The External Advisory Board should meet at least once a year, on site, to review the CNRU.

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 CNRU. This may be another function of the External Advisory Board. Further details regarding the selection process for P/F projects can be found in Part I G of these guidelines. Typically the Director designates someone to oversee the P/F program for the CNRU, 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.

Center Membership Criteria

Criteria for designating an investigator as a CNRU '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 nutritional sciences or obesity-related research and need for the use of core facilities.

D. RESEARCH BASE

Since the CNRU program is aimed at fostering multidisciplinary and interdisciplinary cooperation among a group of funded investigators conducting high quality research involving nutritional sciences or obesity, the existence of a strong nutritional sciences or obesity research base is a fundamental requirement for, and the most important aspect of, a CNRU.

For new CNRU applications, the applicants must indicate how the establishment of a CNRU will provide added dimensions and new opportunities for research and increased cooperation, communication, and collaboration. Competing continuation applicants must provide a summary progress report and include added dimensions in this area since the last review; progress and accomplishments in the research base in developing multidisciplinary or interdisciplinary,

collaborative, and cooperative interrelationships; and the continued symbiotic relationship between the impact of the research base and the continued development of the CNRU. Judgment of the depth and continuing adequacy of the research base remains the most important aspect of a CNRU.

Presentation of the research base in the application should be done in two ways: (1) by completing exhibit III; and (2) by providing a descriptive narrative of nutritional sciences and obesity-related research activities at the institution and any collaborating institutions. This narrative presentation should be organized to bring out the focus and interrelationships of research being conducted by CNRU investigators. Because most, if not all, of the research base will have already undergone separate peer review, the quality of the individual funded projects will have been established. Important aspects to include in this narrative are (1) interactions and interrelationships of the research efforts (emphasizing the role of the CNRU in these interactions); (2) uses and benefits of core services; (3) plans to develop productive collaboration among CNRU investigators; and (4) in the case of renewal applications, the effect that the presence of the CNRU has had in regard to the foregoing during the funded grant period.

Nutritional science or obesity-related research projects should be grouped into aggregates of projects with similar overall goals and objectives both in the application and in any potential presentation before a review group. Neither in the application nor during a potential site visit (although a site visit is very unlikely) will it be possible for presentations of research in great detail. To augment the information available to the initial review group, an applicant may find it helpful to include a few reprints of the most significant research within each grouping as an appendix to the application. Appropriate presentation of the research base is important because it will show the research focus of the CNRU as well as the interrelationship and potential for collaboration among investigators.

E. CORE FACILITIES

Definition

A biomedical research core in a CNRU is a shared facility or resource that provides services needed by CNRU investigators. Core services enable Center members to conduct their independently funded individual research projects more efficiently or more effectively. Cores should be designed to furnish a group of investigators with some technique, determination, service, expertise, or instrumentation in a manner that will enhance the research in 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, is required to justify the existence of a CNRU.

Cores may be proposed in relation to any acceptable research activity of the CNRU, 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., radioimmunoassay, 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 CNRU is justified solely on the basis of need. The minimum requirement is **significant use by two or more** investigators (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 CNRU's P/F program are appropriate users of the core facilities, their use **will not** contribute to the justification for establishing or continuing a core. If there are other NIH core centers at participating institutions, potential overlap needs to be addressed in detail.

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 CNRU 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.

A core Director may also be a junior scientist (who may or may not be a part of the research base) with appropriate expertise who devotes a significant effort to the core. However, an established expert must be included as a consultant to the core when a junior scientist assumes the role of core Director. Furthermore, the career potential of, and institutional commitment to, junior scientists who serve as core Directors will be considered in the review of the CNRU (see Part III).

Personnel

Research assistants, associates, analysts, technicians with special expertise, dietitians, nurses, and other qualified individuals are acceptable personnel for a core when appropriate for the volume and type of work anticipated. Research fellows supported by Ruth A. Kirschstein National Research Service Awards (NRSA) are not appropriate personnel for a core.

Facilities

Arrangements for sufficient space for core activities or for access to appropriate established facilities must be made. Centers are strongly encouraged to enter into cooperative arrangements with cores already established within their institution, or with other CNRUs 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 CNRU to provide support for appropriate personnel to work specifically for CNRU members in an existing facility/core (e.g. transgenic animal core) at the institution. In this case, the designated CNRU core Director must work closely with the parent facility core Director to coordinate services, unless the same individual assumes both roles.

Particularly in initial applications, the description of the physical arrangements and instrumentation for the cores should be given special attention. In competing and non-competing continuation applications, any changes should be carefully documented. The availability of an NIH-supported General Clinical Research Center with a metabolic kitchen may be a useful adjunct. In such a case a letter of agreement from either the GCRC Program Director or Principal Investigator must be included with the application.

Charge-back System

A charge-back system may 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 CNRU 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 describe in detail the interrelationships of the support for services received from the CNRU. 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 CNRU 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. Within cores where a primary user is the Core Director or other personnel within the core, the mechanism of prioritization should specifically address the inherent real or perceived conflict of interest. Limited use of cores by established investigators in other fields is encouraged, as is use by trainees, students, and junior faculty. The CNRU 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.

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 CNRU administration.

F. CLINICAL COMPONENT

Since the NIDDK is interested in translating the work supported by the CNRUs into practical applications in nutritional sciences or obesity, the inclusion of a clinical component is encouraged to serve as a resource, a focal point, and a facilitator for this function. There are multiple ways that this clinical component can be accomplished and each CNRU is encouraged to include this component in their application. Each CNRU should provide a description of how the center will foster and support clinical investigations and applied translation. Providing the capability for translating basic research findings into a clinical setting is the ultimate goal of the clinical component.

G. PILOT AND FEASIBILITY STUDIES

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

Definition

P/F project funds provide modest support (typically \$10,000 to \$50,000) for new initiatives or feasibility research studies for a limited time to enable eligible investigators to explore a nutritional sciences or obesity-related research concept. P/F projects are intended to provide support for investigators to collect preliminary data sufficient to support a grant application for independent research support. P/F studies may (1) provide support for new investigators; (2) encourage investigators from other areas of biomedical research to use their expertise for nutritional sciences or obesity research; and (3) allow established nutritional sciences or obesity-investigators to pursue high impact/high risk projects or project that are a **significant departure** from their usual work.

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 established investigator.

Eligibility Criteria

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

(1) new investigators without current or past NIH research project support (R01 or P01) as a Principal Investigator. New investigators 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 nutritional sciences, obesity or related areas who wish to test the applicability of their expertise to a nutritional science-related problem;

(3) on rare occasions, established investigators in nutritional sciences or obesity-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.); and

(4) investigators concerned with the development and evaluation of innovative, exportable and effective materials, methods, and programs to translate and disseminate research in biomedical and behavioral sciences to patients' health care workers and administrators (model translation).

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 CNRU investigators will not have a long-term collaborative relationship are not considered strong candidates for support. Individuals whose intention is to remain involved in nutritional sciences or obesity-related 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 four categories listed above. A proposed P/F project should clearly delineate the question being asked; present a testable hypothesis; detail the procedures to be followed; and discuss how the data will be analyzed. The research must involve a nutritional sciences or obesity-related topic relevant to the current focus of the CNRU or involve an avenue of new research into which the CNRU will be moving.

P/F projects that evaluate the effectiveness of a model program developed for translating research in biomedical and behavioral science into routine clinical care are encouraged. In view of the disproportionate occurrence of obesity and its associated health risks in minority populations, the CNRU is encouraged to develop activities reflecting the expertise of the Center and directed at the problems of one or more of these populations. P/F study support is not intended for extensive projects of established investigators for which it would be appropriate to submit separate research grant applications. P/F funds also are not intended to support or supplement ongoing funded research of an investigator.

The P/F studies should be submitted for Center review in the general format of NIH research pilot/planning project applications (R03). Projects should be focused because funding for these studies is modest, usually ranging from \$10,000 to \$50,000 per year. They are limited to 3 years or fewer. Investigators may receive P/F support only once in any five-year funding cycle. P/F studies may be supported for research projects in four general areas: (1) biomedical; (2) epidemiological; (3) clinical; and (4) model translation (demonstration and education program

development).

Administration of P/F Program

While the management of the P/F program is left to the discretion of the CNRU, 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 CNRU must be used to evaluate each application. Details of handling the review will be left to the CNRU, 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 CNRU. These records should be available to outside reviewers and NIH staff, if requested.
3. A mechanism for making recommendations to the CNRU Director for initial 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 CNRU 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 CNRU institution. When such situations result in the termination of a project, the CNRU may make new awards for P/F projects with the remaining funds or supplement other ongoing 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 nutritional sciences or obesity-related research is important. Staff of the NIDDK use this record to determine whether the P/F program is a useful component of the Center, serving to encourage investigators to remain in nutritional sciences or obesity research.

Each CNRU 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 CNRU or otherwise available at the applicant institution and to utilize the core facilities or the clinical component of the CNRU.

General guidance for support of P/F studies should not exceed \$150,000 per year in the aggregate. 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.

H. NAMED NEW INVESTIGATOR

Each CNRU may provide salary support for a P/F project recipient whom they designate a Named New Investigator. Support for this individual is generally for 2 years, but may be extended to 3 years, and cannot exceed \$75,000 per year, additional appropriate fringe benefits, and 50 to 100%

effort. These funds are included in the Administrative Core budget. The individual selected should be a junior investigator who meets the P/F project eligibility criterion (1) as noted previously in Part I-G of 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 program director.

I. ENRICHMENT PROGRAM

The CNRU 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 CNRU 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 CNRU as well as its cores. Creative new programs, not precluded by NIH or NIDDK guidelines, are encouraged.

J. COLLABORATION BETWEEN CENTERS

Collaborative efforts between investigators in the various centers (at the applicant institution or other institutions) supported by the NIDDK, NIH, and other federal and non-federal sources are encouraged. These efforts may involve sharing scientific resources, distributing educational information, or sharing seminar program speakers.

PART II

APPLICATION PROCESS: FORMAT AND CONTENT

PART II: APPLICATION PROCESS--FORMAT AND CONTENT

A. GENERAL INSTRUCTIONS

Pre-Application Process

Applications for CNRUs are accepted only in response to a Request for Applications (RFA) published in the [NIH Guide for Grants and Contracts](#).

The receipt date for applications is indicated in the RFA. Individuals from institutions with an interest in applying for a CNRU 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 and Content

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 applicant institution 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 CNRU. It is not possible to conduct a site visit for each application.

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

The PHS Form 398 (<http://grants1.nih.gov/grants/funding/phs398/phs398.html>) must be used for the application. The arrangement of materials for the CNRU 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. 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. **Be sure to print out and attach the RFA label that is included in the PHS Form 398 packet.**

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 M.D. 20817.

****** Applicants should read Part III of these guidelines to understand the criteria****
used for evaluating CNRU applications.**

B. SPECIFIC INSTRUCTIONS - Forms (PHS Form 398, Section I, C)

Face Page:

Items 1-15 (See PHS Form 398)

NOTE: Awards for CNRU grants are made for **five year** project periods.

Form Page 2:

Description, Performance Sites, and Key Personnel (self-explanatory)
Number the pages consecutively throughout the application.

Form Page 3:

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

Form Page 4:

Provide a consolidated budget for first year of requested support (See Sample Exhibit I). Separate budgets for each core and for the clinical component, if requested, should immediately precede the narrative of that section, using form page 4.

Form Page 5:

Budget for Entire Proposed Project Period

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

Biographical Sketches:

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

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

A summary of the current and pending support for all CNRU investigators, including percent efforts, aids in the review process when presented as suggested in Sample Exhibits III-A through-D, with nutritional sciences or obesity-related research support listed first followed by non-nutritional sciences or non-obesity-related support. K-series awards may be included here. Institutional Training Grants (T32 or T35) and Individual Fellowship Awards (F31 or F32) are not part of the research base but should be listed separately in III A and B.

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.

C1. NEW SPECIFIC INSTRUCTIONS - Research Plan (PHS Form 398, Section IV, C)

For Initial (NEW) applications refer to this section. For Competing Continuation applications see

section C2--RENEW.

Administrative Core (New applications)

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

A description of the focus of the CNRU and any unique aspects must be presented along with a brief narrative describing the qualifications of the Director and associate Director and a plan for replacing the Director should this become necessary. A brief description of how the Center will foster and support clinical investigations and applied translational research should be included

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

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

Provide an outline of the relationship of the CNRU to the institution and the reporting lines of the CNRU 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 CNRU. Describe a mechanism to monitor the budgetary adjustments made necessary by the use of core services. This will ensure that CNRU investigators using cores are able to provide a satisfactory explanation of their relationship to the CNRU and their inclusion of charge-back fees to the cores in their individual grant budgets.

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

Enrichment Program (New applications)

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

Research Base (New applications)

Include an overview of the current nutritional sciences and obesity-related research activities at the institution. An appropriate and clear presentation of the ongoing research base is critical since it will show the research focus of the CNRU 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 CNRU on the research base. Include an indication of how the establishment of a CNRU will provide added dimensions and new opportunities for nutritional sciences or obesity-related research, along with increased cooperation, communication, and collaboration among investigators.

Group nutritional sciences or obesity-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 related to nutritional sciences or obesity. Overly detailed descriptions of the research base projects are discouraged, 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 Sample Exhibits III, and (2) by providing a narrative description of approximately one page per research project in which the duration of award, a short description of the goals and objectives, and a short description of the symbiotic relationship to and from the CNRU are described. Limiting each description to less than one page is encouraged, but not always feasible. 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 nutritional sciences or obesity research when this is not readily apparent from the title of the grant.

To augment the information available to the IRG, applicants may include a few reprints (**no more than a total of 12**) as appendix material. These publications should result from the most significant research being conducted within the research base.

Document collaborative efforts by using a format such as Sample Exhibit IV, although pre-existing extensive collaborations are not a prerequisite for new applications.

Biomedical Research Cores (present each Core separately) (New applications)

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

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 CRNU members.

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

Limited use of the core by established investigators in other fields 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 CNRUs are strongly encouraged to enter into cooperative arrangements with established cores at the applicant institution or at other CNRUs 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.

When cores use human subjects or animals, include sections E and F, respectively, of the 398 application.

Pilot and Feasibility Studies Program (New applications)

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

The management plan for the P/F grant program, including both internal and external review mechanisms should be described 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.

P/F projects will be reviewed as a group by the IRG. Each should be no longer than 10 pages of narrative text. For each P/F project proposed provide:

- a. Budget with justifications for: (1) initial budget period, and (2) entire proposed project period
- b. Justification for eligibility of the P/F project (how it fits with the CNRU's goals) and justification for eligibility of the investigator (see Part I-G)
- c. Justification for core use.

Do not describe all of the proposed P/F projects. Describe the P/F projects that best represent the P/F work of the Center. These initially proposed P/F projects must have been reviewed by

the CNRU in the manner proposed for review of future studies so that only those considered to be of the highest quality are included in the grant application. Indicate the number of applications that were received and evaluated. An assessment of the relevancy of the proposed individual P/F projects to the CNRU's specific goals and objectives is important.

Clearly indicate the **Named New Investigator** if such a position is being requested and how he/she was selected. Salary support for this position is to be included in the Administrative Core.

Also, see Part II-E for Specific Instruction regarding the Budget.

C2. Renewal SPECIFIC INSTRUCTIONS - Research Plan (PHS Form 398, Section I, C 9)

For Competing Continuation applications, use this section. For Initial applications see Part II-C1-NEW.

Administrative Core (Competing Continuations)

Include a budget for the Administrative Core with a comprehensive justification. In addition to the Center Director and co-or Associate Directors, include a full or part-time administrator as well as funds for the enrichment program, travel funds for at least two persons to attend the annual meeting of CNRU 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 brief history of the CNRU including any changes in the research base, the membership, or the focus of the Center, and how such changes affect the CNRU or are attributed to the CNRU, as well as a synopsis of accomplishments including how the Center fostered clinical investigations and /or translational research.

Provide a description of the research focus of the CNRU as well as any unique aspects of the Center. 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 a description of the administrative structure of the CNRU, including: chain-of-command, committee structures (e.g., Internal Advisory Committee; P/F review; other oversight or management committees), and core and clinical component oversight.

Since the External Advisory Board is already established, list the names of the members and their areas of expertise. Also, indicate any changes in membership that have occurred during the previous funding period or are anticipated for the upcoming funding period.

Provide an outline of the relationship of the CNRU to the institution and the reporting lines of the CNRU Director to appropriate institutional officials. If this is presented in diagrammatic form, also provide a brief explanation in narrative form. In the event of a consortium arrangement, the chain-of-command across the participating organizations needs to be described in detail.

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 CNRU. Describe the mechanism to monitor the budgetary adjustments made necessary by the use of

core services.

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 CNRU in the description of the Administration Core.

Provide a master list of all publications (author, full title, and reference) resulting from research supported by the Center in the past funding period. **Include peer-reviewed publications ONLY and underline, bold, or otherwise indicate those authors who are CNRU members.** Invited papers, book chapters, abstracts, symposia proceedings, etc. may be included in a separate list. In addition, the publications arising from the use of a specific core **should also be included** in the write-up of that core. While not mandatory, this duplication expedites the review process.

Enrichment Program (Competing Continuations)

Briefly describe the enrichment program and indicate the program's value to CNRU members. Indicate how the program has grown or been adapted to better serve Center members' needs during the past funding period.

Describe future plans for the enrichment program. Include funds for the enrichment program in the budget for the Administrative Core.

Research Base (Competing Continuations)

Provide a summary progress report that encompasses the following areas:

- a) interactions and interrelationships of the research efforts;
- b) uses and benefits of core services; and
- c) plans to develop productive collaboration among CNRU investigators.

Describe the evolution of the research base and the CNRU's contribution to this ongoing development.

Present the research base in two ways: (1) by providing information that will assist in the review of the application, in a format such as that shown in Sample Exhibits III, and (2) by a descriptive narrative of the nutritional sciences or obesity-related activities at the applicant institution and any collaborating institutions. Sample Exhibits III-A through D do not substitute for the information contained on the Biographical Sketches requested in the 398 application kit and are not required, but aid greatly in the review process.

Organize the narrative presentation of the research base to emphasize the focus of the research and the interrelationships of the CNRU investigators. **Provide a narrative description of no more than an average of one and a half pages per research base investigator; try to limit each to less than one page.** These narratives should include: (1) the grant number, title, and a few descriptive sentences, and (2) a list of the core(s) used with a brief sentence indicating what aspect of the research justifies the use of each core. Include ONLY those grants awarded to investigators at the applicant institution or consortium, not to investigators at other locations, in the description of the research base. It is particularly important to provide a few

sentences indicating the relatedness of a cited grant to nutritional sciences or obesity research when this is not readily apparent from the title of the grant.

Document collaborative efforts using a format such as Sample Exhibit IV to aid in the review process.

Biomedical Research Cores (present each core separately)(Competing Continuations)

For competing continuation applications, information regarding the cores should generally cover the same points as in the initial application as well as information on past performance of the core and its usefulness to CNRU investigators. Include the impact of the core services on investigator productivity in meeting stated goals and objectives and in promoting cost effectiveness. Emphasize the past and future benefits to investigators derived from the use of core facilities.

Include budgets with comprehensive budgetary justifications for: (1) initial budget period, and (2) entire proposed project period. Detail the qualifications of the core Director and the duties and qualifications of other personnel, including technical support staff. In the event a core Director is not an established investigator (see Part I), highlight the institutional commitment to and career plans for the individual.

Detail the objectives in continuing/establishing the core facility and describe the core. The description should include the facilities used as well as the activities of the core. Provide short descriptions of the services provided and the projects that use the core. Document any changes that have taken place since the last competitive review.

Provide details of core management, including plans for:

- a) assuring quality control
- b) prioritization of investigator use (Within cores where a primary user is the Core Director or other personnel within the core, the mechanism of prioritization should specifically address the inherent real or perceived conflict of interest.)
- c) monitoring core use
- d) adapting to new technology and to the needs of the CNRU members.

Document past use of the core. Sample Exhibit V B may be helpful. Include a list of the investigators who will use the core as well as the extent of their use. Sample Exhibit V A may be helpful. 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 developmental research performed in the core and indicate its relevance to the services offered by the core.

Since CNRUs are strongly encouraged to enter into cooperative arrangements with established cores at the applicant institution or at other CNRUs 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.

Provide a list of publications made possible by use of the core. This should be a subset of the references listed in the Administrative Core 'master list.' Include titles of publications and

indicate which core services were utilized. Also, **the CNRU 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, (see Sample Exhibit V B) 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 sections E and F, respectively, of the 398 application.

Pilot and Feasibility (P/F) Program (Competing Continuations)

Provide an overall budget with justifications for proposed future years. The annual budget for the P/F program should be listed in the "other expenses" category in the budget for the Administrative Core.

Include an historical overview of the P/F program since the inception of the CNRU. For only 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 areas of nutritional sciences or obesity-related research. To aid in the review process, a format such as shown in Sample Exhibit VI is helpful in depicting the P/F program outcomes. Identify any lasting collaborations that resulted from each P/F project and describe any new skills acquired by the P/F recipient or other significant outcomes, such as receipt of an R01 grant. The relationship of each P/F project to one of the research themes of the CNRU should be emphasized.

Include a statement that outlines how the CNRU has benefited from the P/F grant program, e.g., increased the research base, spawned a new area of research, or enabled an investigator to explore collaborative possibilities.

Describe the current management of the P/F program, including its integration with, and its relationship to, the rest of the administrative structure. Describe plans for future years of the P/F program, including how applications will be solicited, reviewed, awarded, and, if required, terminated. Do not include this information in the write-up of the Administrative Core.

Include reports (not just tabulated information) on all P/F projects completed during the **current five year project period**. These reports should be brief (one page narrative) and should provide: (a) the name of the investigator, degree(s), professional career status at the time of the award, and current professional career status (if known); (b) an overview of the project, including its significance and salient results; (c) a list of publications resulting from the project; (d) the current status of the investigator's funding, and whether in the same or a related area; and (e) any other significant and pertinent information (such as amount and time period of support, future plans of investigator). Include currently funded, ongoing projects in abbreviated form.

Do not describe all currently proposed P/F projects. Describe all currently funded or approved for funding P/F projects have been approved for funding that best represent the P/F work of the Center. The applications should be the best ones received and must have been reviewed in the manner used for all P/F applications. Each P/F project application should be no longer than 5-

10 pages of narrative text and should include:

- a) budget with justifications for: (1) initial budget period, and (2) entire proposed project
- b) justification for eligibility of the P/F project (how it fits with the CNRU's goals)
- c) justification for eligibility of the P/F investigator (see Part I-G)
- d) justification for core use.

Due to the timing of the RFA, some or all of the P/F projects may be those that are currently funded. If at all possible, however, the P/F projects should be new ones. It is important for the IRG to be able to evaluate the Center's review "process" by the merit of the P/F projects selected for funding. In either case, provide a list of currently funded P/F projects. It is also important to include the number of applications received during the most recent five-year funding period.

Clearly indicate the **Named New Investigator**, if such a position is being requested, and how he/she was selected. Include salary support for this position in the Administrative Core personnel section. If using Sample Exhibit VI, use an asterisk to indicate previous **Named New Investigators**.

D. SPECIFIC INSTRUCTIONS - Appendix (PHS 398, Section I, C 9)

(New Applications)

Include no more than 12 pertinent publications as an appendix. These should highlight major scientific accomplishments resulting from the most significant research being conducted by proposed Center investigators within the research base.

(Competing Continuations)

Include the narrative portion of the non-competing Annual Progress Report from the last budget period. Depending upon the RFA receipt date, this will most likely be from the project period just prior to the one in which the competing continuation application is being submitted. As with new applications, include no more than 12 reprints, if desired, highlighting the most significant research being conducted within the research base, as well as the collaborative nature of the research.

E. SPECIFIC INSTRUCTIONS-BUDGET CATEGORIES (both New and Competing Continuation)

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

Professional Personnel

This category should include support for salaries of key personnel within the CNRU 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 CNRU grant must be

commensurate with the time spent on CNRU activities. Salary support derived from the grant will depend on the effort provided and on institutional salary policies; however, current NIDDK practice limits annual increases to 3 percent not to exceed the direct salary cap.

The Center Director is expected to devote an appropriate proportion of his/her time to the CNRU (**no less than 20 percent effort**). The application should not include salaries for individual principal investigators on separate research or training grants unless these investigators provide an essential function for CNRU activities (e.g., Core Director). No overlap of time or effort between a CNRU activity and separately funded research projects is permitted.

Potentially overlapping support between CNRU 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 CNRU. Such funding must be sought through other grant mechanisms.

Technical and Support Personnel

This support may include salaries for identified positions to be filled within the core facilities or the P/F projects. No overlap of time or effort between the CNRU and separately funded research projects is permitted.

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 in terms of core service being provided to CNRU 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 CNRU 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 in **General Clinical Research Centers** (GCRC) and individually supported beds. If the GCRC is to be used, include a letter of agreement from either the GCRC program director at the National Center for Research Resources, NIH, or from the Principal Investigator of the GCRC.

Request costs relating to the clinical research efforts of CNRU 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 CNRU clinical component. The CNRU 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 CNRU, such as the members of the External Advisory Board.

Travel

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

Total Requested Amount

Total direct costs requested should not exceed \$750,000 per year. Not included in these direct cost limits are requests for equipment in the first year of a competitive award.

Other

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

PART III

REVIEW AND ASSESSMENT

PART III: REVIEW AND ASSESSMENT

A. REVIEW CONSIDERATIONS

Upon receipt, the Center for Scientific Review (CSR) staff will screen applications to make sure they adhere to 398 submission guidelines. Rejected applications will not be reviewed. 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 competing continuation 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 Criteria

Specific review criteria for the scientific evaluation of CNRU applications are given below.

Research Base

- The scientific excellence of the CNRU's **research base** (its strengths, breadth, and depth) as well as the relevance and interrelatedness of the funded research projects to the central theme(s) or focus of the CNRU will be evaluated. The likelihood of meaningful collaboration among CNRU investigators will be assessed. The existence of a base of established, independently supported biomedical research of high quality is a prerequisite for the establishment of a CNRU and is considered the **MOST IMPORTANT COMPONENT OF THE APPLICATION DURING THE REVIEW**. In competing continuation applications, the degree to which the research base has expanded or been strengthened since the last competing continuation will be considered.
- The qualifications, experience, and commitment of the CNRU **investigators** responsible for the individual research base grants and their willingness to cooperate with each other and contribute to the overall objectives of the CNRU will be considered. In competing continuation applications, the degree to which effective collaborations fostered by the Center and the cores have resulted in new projects will be considered.

Cores

- The appropriateness and relevance of the proposed **cores** and their modes of operation (such as how requests for services will be prioritized, quality control measures, and how use will be monitored), facilities, and potential for contribution to ongoing research will be evaluated. Competing continuation applications will be evaluated on past use, quality control, cost

effectiveness, and proposed future use of each core for which continuation is requested. Productivity and appropriateness of each core will be judged in part by the list of publications arising from projects using that core. The acquisition of relevant new services and the appropriate deletion of services no longer required will also factor into the evaluation of existing core facilities.

- Although a minimum of two users is sufficient to establish a core, a greater number of users generally should be more cost effective. When a core is proposed for which only the minimum number of users exists, the description of the efforts made (for existing cores in competing continuation applications) or to be made (for new applications and for new cores in competing continuation applications) to increase the number of core users, and thus enhance the core's productivity and cost effectiveness, will be carefully considered. When a competing continuation application is reviewed, this increase in core use will help determine the productivity of, and the need for continuing, the core.
- The qualifications of the Core Director and other personnel will be evaluated.

Clinical Component

Since the translation of research findings to the clinical setting is often accomplished without R01 or other Federal support, the clinical component will be evaluated separately from the cores.

- The appropriateness of the clinical component to the research themes of the CNRU will be evaluated.
- The services offered and the qualifications of the personnel requested as well as the number of physician scientists, and perhaps basic researchers, who will make use of clinical component services will be evaluated.
- The potential for, or past efforts of, the clinical component to develop specialized services, relevant to CNRU members, such as tissue or serum banks, patient screening or recruitment, or consultation for clinical study/trial development, will be evaluated.

Pilot and Feasibility Studies

- For both new and competing continuation applications, the study section will evaluate P/F projects in the context of the P/F program as a whole. That is, lengthy review of individual projects will not occur. Of key importance is whether each applicant is eligible (see Part I-G of these guidelines), whether the proposed hypotheses are reasonable, whether the project relates to the focus of the CNRU, and whether the project appears feasible.
- In new applications, the P/F projects will be assumed to be the best selections made using the proposed evaluation procedures described in the application.
- In competing continuation applications, the submitted P/F projects will be assumed to be the best selections made using the Center's existing review procedures as described in the application.
- The study section will recommend a level of funding for the P/F program based on the quality of the submitted P/F projects, the proposed method for management and review, and the study

section's assessment of the potential needs and opportunities for P/F studies at the CNRU.

- In competing continuation applications, the recommendation of the study section to allow a requested increase in P/F support, to maintain the current level of support, or to reduce the level of support, will be based on their assessment of the CNRU's overall P/F program. Taken into account in this recommendation will be: (1) the extent to which P/F funds were fully utilized during the previous project period; (2) the extent to which awards were made to investigators who fully met the eligibility criteria for P/F project support as outlined previously; (3) the extent to which the awards made are considered to be relevant to the current or future research themes of the CNRU; (4) the extent to which previously supported P/F projects were successful (e.g., the P/F recipients are currently funded; a new investigator was attracted into nutritional sciences or obesity-related research; or peer-reviewed publications or presentations resulted); and (5) whether the P/F recipients have remained in nutritional sciences or obesity-related research.

Named New Investigator

- The **Named New Investigator** will be reviewed separately. The associated pilot study must have been evaluated in a manner similar to the P/F projects in general. In a competing continuation application, the progress of previous Named New Investigators will be considered, i.e., whether their P/F projects led to publications and/or grant awards, and whether the investigator has remained in nutritional sciences or obesity-related research at the CNRU or elsewhere.

Enrichment Program

- Efficient and effective use and/or proposed use of the limited enrichment funds, including the contribution of these activities to fostering the objectives of the CNRU will be evaluated.

Program Director and Administration

- The scientific and **administrative leadership** abilities of the CNRU Director and Associate or co-Director(s) and their commitment and ability to devote adequate time to the effective management of the program will be assessed.

- The appropriateness of the criteria used to include individuals as center members and associate members will be considered.

- The study section will evaluate the organization proposed for the following:

- o coordination of ongoing research between the separately funded projects and the CNRU, including mechanisms for monitoring collaborative efforts and for encouraging acknowledgements of the CNRU contributions to the research efforts in all publications arising from the use of core facilities;

- o establishment and maintenance of internal communication channels among the CNRU investigators;

- o mechanism for selecting and replacing professional and technical personnel within the CNRU, particularly the Director;

o approach for administering the P/F program, including soliciting applications, the review process, and making funding decisions, as reflected by the general quality of P/F projects submitted with the application; and

o management capabilities that include fiscal administration; procurement, property, and personnel management; planning; and other appropriate capabilities.

- The institutional commitment to the Center, including lines of accountability and contributions to the management of the CNRU will be assessed. In addition, the institutional commitment to both new staff members and to investigators responsible for conducting essential CNRU functions as well as the commitment to establish new positions specifically designed to enhance the operation of the CNRU will be considered.

- The academic environment in which the CNRU activities will be conducted, including the availability of space, equipment, facilities, and the potential for interaction with scientists from other departments and institutions will be considered.

Budget

- The appropriateness of the budgets requested for the cores, the clinical component, the P/F program, and for enrichment activities will be evaluated. Total Direct Costs are limited to \$750,000 per year (including P/F program funds). At times the requested amount may exceed this limit due to facilities and administration costs incurred by contractual arrangements.

Institutional Commitment/Contribution to Centers

- o The institutional commitment to the program, including lines of accountability for management of the CNRU grant and the institution's contribution to the management capabilities of the CNRU.
- o The academic environment and resources in which the activities will be conducted, including the availability of space, equipment, facilities, and the potential for interaction with scientists from other departments and schools within or outside the institution.
- o The institutional commitment to new individuals responsible for conducting essential CNRU functions.

B. ASSESSMENT AND REPORTING REQUIREMENTS

Background

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

In addition, NIDDK staff members must periodically prepare reports for the NIDDK Director and

the NIDDK National Advisory Council. These reports are primarily based on progress reports from the CNRUs 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 CNRUs, provides an opportunity for evaluation of the host center's program.

General Plan for Interim Assessment

To assist in interim assessments of the CNRU, 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 CNRU meetings-copies of the minutes of Internal Executive Committee meetings and the External Advisory Board meetings;
- c) Newsletters-current newsletters from the CNRU and from the parent institution, if these mention or highlight the CNRU.
- d) In-House Assessments-The Director of a CNRU should use Center's External Advisory Board meetings to assess the activities and programs of the CNRU. The minutes from the Advisory Board meetings may be included as part of the annual progress report OR may be sent in 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 CNRUs 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 in Section C. Information such as External Advisory Board meeting minutes, newsletters, and other pertinent items already sent to the NIDDK program director need not be included.

C. 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 CNRU.

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 CNRU;
- b) summary of any changes in the research base (loss or addition of CNRU 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 CNRU;

c) significant research advances and accomplishments made possible by the presence of the CNRU (e.g., through core use, collaborations fostered by the CNRU, etc.) and a description of how the Center has fostered and supported clinical investigations and applied translational research;

d) a consolidated list, including titles, of scientific manuscripts and abstracts published by Center members and/or by investigators funded by the P/F grant program;

e) description of current P/F projects supported by the CNRU (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 CNRU, 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 CNRU.

Administrative Information

Include the following items:

a) concise statement of **any changes** in eligibility requirements for investigators to use core facilities;

b) list of investigators comprising the CNRU's research base in the reporting year. If the CNRU distinguishes between different levels of membership that should be clearly indicated with appropriate lists. It is important to be concise regarding the nutritional sciences or obesity-related research base. Also provide

- c) a list of awards, honors, and special recognition(s) earned by the CNRU investigators 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 CNRU 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 CNRU on the institution/community.

NOTE: An abbreviated version of the progress report may be submitted for the year of support in which the competing continuation 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 Information

Each CNRU 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 nutritional sciences or obesity-related areas should be discussed. 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 CNRU program and its accomplishments, particularly for preparing responses to Congressional inquiries.

D. SPECIAL CONSIDERATIONS

While each CNRU develops its own program in accordance with the local talents, interests, and resources available, each CNRU must be responsive to national needs in nutritional sciences or obesity and must be willing to work with the NIDDK and other organizations in furthering the overall goals of the CNRU program. In this regard, CNRU directors and selected other CNRU 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 CNRU 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 CNRU grants; earlier versions should be discarded. Some redundancy exists within the guidelines to emphasize key issues related to a CNRU. If questions remain after reading these guidelines, contact the individuals listed below.

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

Carolyn Miles, Ph.D.
Director, Obesity/Nutrition Research Centers Program
Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases
Two Democracy Plaza, Room 665
6707 Democracy Blvd., MSC 5450
BETHESDA M.D. 20892-5450
Telephone: (301) 451-3759
Email: cm294e@nih.gov

Direct inquiries regarding fiscal matters to:

Sharon Bourque
Grants Management Specialist
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Blvd. Room 719
BETHESDA MD 20892-5450
Telephone: (301) 594-8846
e-mail: bourques@extra.niddk.nih.gov

This document affects all new and competing continuation applications effective May, 2004.

SAMPLE EXHIBITS

SAMPLE EXHIBIT I

CONSOLIDATED BUDGET FOR 1st YEAR OF REQUESTED SUPPORT

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

SAMPLE EXHIBIT II

DISTRIBUTION OF PROFESSIONAL EFFORT (%) ON THIS APPLICATION

<i>Participating Investigators*</i>	<i>Core A</i>	<i>Core B</i>	<i>Core C</i>	<i>Core D</i>	<i>P/F (Project #)</i>	<i>Application Total</i>	<i>Other Support</i>
<i>Dr. A</i>	<i>*25</i>				<i>25 (3)</i>	<i>50</i>	<i>50</i>
<i>Dr. B</i>		<i>5</i>		<i>5</i>		<i>10</i>	<i>40</i>
<i>Dr. C</i>	<i>5</i>				<i>10 (4)</i>	<i>15</i>	<i>70</i>
<i>Dr. D</i>			<i>10</i>	<i>*10</i>		<i>20</i>	<i>55</i>
<i>Etc.</i>							

**Star the percent effort (See Core A) when that individual is the Core Director*

SAMPLE EXHIBIT III

SUMMARY OF TOTAL CURRENT AND PENDING SUPPORT OF ALL CENTER MEMBERS

SAMPLE EXHIBIT III-A: CURRENT NUTRITIONAL SCIENCES and OBESITY-RELATED RESEARCH BASE SUPPORT

Grants to be included: R01s, R37s, K-series, P01s (if the total funds are already listed for the Principal Investigator of the P01 funds, support for the subproject should be shown in parentheses), specialized centers (such as P30s, P50s, P60s), and peer reviewed grants funded through other Federal Agencies or non-federal groups. **Do not include** this Clinical Nutrition Research Unit Grant. Include ONLY nutritional sciences and obesity-relevant NIDDK support (i.e., not renal, digestive diseases, or other non-nutritional sciences); indicate by 'x' if other, non-nutritional sciences or obesity funding is also available. List this other funding in Exhibit III-C.

List training grants (T32) and fellowships (F32) related to nutritional sciences and obesity LAST in the table

Principal Investigator/ [Co-Investigator]	Supporting Organization/ Grant Number	Title	Project Period	Annual Direct Cost**	% Effort	Non-Nutritional Sciences or Obesity Funding also
Doe, John	NIH P01 DK12345	Mechanisms of Vitamin E Action	4/1/2002 – 3/31/2005	\$500,000	10	
Jones, James	NIH R01 HD65432	Vitamin K and Bone Density	7/1/1995 – 6/30/2004	\$225,000	40	x
Smith, Edith	DOD	Obesity and its Health Effects	7/1/2000 – 6/30/2006	\$180,000	25	
[Stellar, Fred]	CDC	Frequency of Childhood Obesity	9/1/2002 – 8/31/2004	\$350,000	50	
Etc.						
ETC.						

** Also sum this column (excluding T32 and F32 support) and calculate the % coming from the NIDDK

SAMPLE EXHIBIT III-B: PENDING NUTRITIONAL SCIENCES AND OBESITY-RELATED RESEARCH BASE SUPPORT

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

------(AS ABOVE)-----
SAMPLE EXHIBIT III-C: ALL CURRENT SUPPORT OTHER THAN NUTRITIONAL SCIENCES AND OBESITY-RELATED

For those members indicated by an 'X' in Exhibit 111-A.

------(AS ABOVE)-----
SAMPLE EXHIBIT III-D: ALL PENDING SUPPORT OTHER THAN NUTRITIONAL SCIENCES AND OBESITY-RELATED

For those members indicated by an 'X' in Exhibit 111-A or B

------(AS ABOVE)-----
** If co-investigator's name is used, put principal investigator's name in parentheses below.*

SAMPLE EXHIBIT IV
COLLABORATIONS BETWEEN CENTER MEMBERS

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

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

SAMPLE EXHIBIT V
USE OF CORE FACILITIES

CORE: Name

DETERMINATIONS/SERVICES RENDERED

- A.
- B.

<u>USERS</u>	<u>FUNDED PROJECTS WITH IDENTIFYING NUMBER</u>	<u>PERIOD OF PERFORMANCE</u>	<u>DETERMINATIONS/SERVICES</u>	<u>ESTIMATED USE AND COMMENTS</u>
1.				
2.				
3.				

-----EXAMPLE-----

CORE: Chemistry

DETERMINATIONS/SERVICES RENDERED

- A. CCK Determinations
- B. Lipid Determinations
- C. Epinephrine Determinations
- D. Phosphokinase Determinations

<u>FUNDED PROJECTS WITH IDENTIFYING NUMBER</u>	<u>PERIOD OF PERFORMANCE</u>	<u>DETERMINATIONS/SERVICES</u>					<u>ESTIMATED USE AND COMMENTS</u>	<u>USERS</u>
		<u>A</u>	<u>B</u>	<u>C</u>	<u>D</u>	<u>E</u>		
1. J.F. Smith R01 DK 67031-02 (renewal not anticipated)	3/7/2001-3/7/2002	X		X			A. 5 per month for 12 months C.100 per month)	
2. S.R. Jones K02 HL00000-00	1/4/2001-6/30/2002				X		B. 40 per week through 6/30/2002	
3. R.G. Brown (P/F project) (Feasibility Study)	5/1/2002 – 11/1/2002					X	A. 16 per week for 6 months	

In competing continuation applications, the above EXHIBIT will be EXHIBIT V-A. There should be an EXHIBIT V -B with the last column entitled Actual Usage.

Sample P/F Report Form

TITLE:

INVESTIGATOR:

FUNDING PERIOD: [dates of award]

ELIGIBILITY: [i.e., New Investigator or Established non-nutritional sciences researcher or nutritional sciences 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]