Research Core Center Guidelines

National Institute of Arthritis and
Musculoskeletal and
Skin Diseases

National Institutes of Health

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GUIDELINES FOR RESEARCH CORE CENTERS

NATIONAL INSTITUTE OF ARTHRITIS & MUSCULOSKELETAL & SKIN DISEASES

I.   INTRODUCTION

This document provides administrative guidelines for the NIAMS Core Center (P30) program. Applications for Core Centers are sought through Requests for Application (RFA) and the topic areas for the focus of the Core Center are listed in the RFA.

The overall goal of a Core Center is to provide shared facilities and services to groups of established, currently funded investigators in order to improve efficiency, accelerate the pace of research, and ensure greater productivity.   Any institution or consortium with an active program of excellence in basic and clinical biomedical research in an area suggested by the Request for Applications may qualify for support through a Core Center. A strong biomedical research base is the prerequisite for establishment of a Core Center and an important component in considering continuing funding of an established center.

A Core Center must be an identifiable organizational unit either within a single university medical center or representing a consortium of cooperating institutions that includes an affiliated university. Greater scientific productivity is an ultimate objective of the Core Center. Applicants should clearly demonstrate the ways in which the Core Center will build the local research program, will support on-going projects and will attract both senior and new investigators to the research base.

The Core Center will provide funding for both biomedical research components and an administrative unit to support the research components. The research components are either Research Core facilities or Pilot and Feasibility Projects. Research Cores are defined as shared resources that enhance productivity or in other ways benefit a group of investigators working in areas related to the stated goals of the Core Center. Two or more core facilities must be proposed in a Core Center. The Pilot and Feasibility Program provides modest support for new initiatives or for feasibility studies for established or new investigators who are engaged in research of direct relevance to the Core Center. Up to $100,000 direct costs per year may be requested to support two to five projects budgeted @ $20,000 - $50,000 for 1 – 3 years. An Administrative Unit coordinates Core Center activities and promotes collaborative research through the Cores. Limited funds for program enrichment such as seminars and visiting scientists may also be requested.

II.   APPLICATION AND REVIEW PROCESS

Preapplication Process and Letter of Intent

Core Center applications are solicited by Requests for Applications (RFAs) published in the NIH Guide for Grants and Contracts. See the NIAMS website for current funding opportunities: http://www.niams.nih.gov/Funding/Funding_Opportunities/filter.asp

Individuals from institutions with potential interest in applying for a Core Center grant are encouraged to contact the NIAMS staff as early as possible after the RFA has been issued. Consultation between NIAMS staff and potential applicants prior to submission of the formal application may be useful. Applicants should not construe advice given by the NIAMS staff as assurance of favorable review. The staff will not evaluate or discuss the merit of the scientific aspects of the proposal.

To facilitate Institute planning, applicants are requested to submit a letter of intent on the date listed in the RFA. This letter should provide a descriptive title of the research projects and cores requested and the key participants. The letter of intent, and any inquiries about the program, should be directed to the Scientific/Research Contact identified in the RFA.

Application Procedure

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

Telecommunications for the hearing impaired: TTY 301-451-0088.

Because of their specialized nature, Core Center applications require modifications of the standard PHS 398 format. The recommended format is described in detail below, and illustrated in the sample Table of Contents provided as Exhibit I. Briefly, a Core Center application consists of three sections. First, a **General Material** section includes a brief description of the Core Center, and provides overall budgets, biographical sketches, and other basic information. Second, a series of **Narrative Sections** describes the Core Center in terms of its leadership, research base, institutional environment, recent progress (if previously supported), and management of Pilot and Feasibility projects. Finally, each **Budgeted Component** of the Core Center (such as the Administrative Unit, individual Cores, and Pilot and Feasibility Projects) is described in PHS 398 format. For each Budgeted Component, the key sections, corresponding to Specific Aims, Background and Significance, and Research Design and Methods, together may not exceed a total of 15 pages.

Receipt dates for Core Center applications are announced in the Request for Applications. *For applications submitted in response to RFAs, the application must ARRIVE AT NIH on or before the receipt date.*

The original and three (3) signed, exact photocopies of the application should be sent to:
> Center for Scientific Review
> National Institutes of Health
> 6701 Rockledge Drive, Room 1040 - MSC 7710
> Bethesda MD 20892-7710
> [Bethesda, MD 20817 (for express/courier service)]

In addition to mailing the application to the Center for Scientific Review send two (2) copies of the application and ALL 5 copies of any appendix material to:

> Chief, Review Branch
> NIAMS/NIH
> 6701 Democracy Blvd., Suite 800 – MSC 4872
> Bethesda, MD 20892-4872
> [Bethesda, MD 20817 (for express/courier service)]
> Telephone: (301) 594-4952

All appendix material must be clearly marked with the name of Center Director and the appropriate project or core. Separate copies of appendix material should be supplied for each core or project to which it is applicable (See Section V.B.9).

Review Process

Applications for Core Center grants will first be screened for completeness by the Center for Scientific Review and for responsiveness by NIAMS staff. Applications which are complete and responsive will be evaluated for scientific merit, in accordance with NIH peer review procedures (http://grants1.nih.gov/grants/peer/), by a group of expert consultants convened by the Review Branch of the NIAMS. Each application should be complete upon submission. Site visits are not anticipated. A second level of review will be performed by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Center Evaluation Procedure

Since the NIAMS is interested in funding only the most highly meritorious research, individual components of lesser quality may not be funded, even if recommended, under the "umbrella" of the Center grant mechanism. Each core and pilot project (including the administrative unit) will be individually reviewed for scientific merit and assigned a rating by committee consensus. Merit ratings will also be determined for the center elements: qualifications of the center leadership, the research base, the institutional environment and resources. If this is an application for competitive renewal, the progress during the last funding cycle will also be evaluated. To be funded, there must be two or more highly meritorious research cores.

As part of the scientific peer review, all applicants will undergo a selection process in which only those applicants deemed to have the highest scientific and technical merit will be discussed and assigned an overall priority score. This score will reflect not only the individual quality of the cores, administration and pilot projects, but also the quality of the research base and how the proposed Core Center will enhance the research base. The overall score may be higher or lower than the "average" of the descriptors based on the assessment of whether the "whole is greater than the sum of its parts."

In addition to the standard criteria of significance, approach, innovation, investigators, and environment, the following elements will be evaluated for the overall priority score:

> The scientific excellence of the Core Center's research, since the existence of a base of established independently supported biomedical research of high quality is a prerequisite for establishment of a Core Center.

> The application must convey how the proposed Core Center will enhance significantly the established research base of the host institution. In a competing continuation application, the application should document an impact of the Core Center. This includes the qualifications, experience, and commitment of the Core Center investigators and their willingness to interact with each other. This also includes efficient and effective use and/or planned use of enrichment funds including the contribution of these activities in enhancing the realization of the Core Center concept.

> The appropriateness, quality and relevance of the proposed cores, and the modes of operation, facilities, and potential for contribution to ongoing research.

> The proposed management of the pilot and feasibility program and the scientific merit of the pilot and feasibility projects for which funds are requested from the Core Center grant. The effectiveness of the proposed program will serve as a basis for recommendations concerning the level at which pilot and feasibility studies will be supported throughout the project period.

> The overall environment for a Core Center. This includes the institutional commitment to the program, including lines of accountability regarding management of the Core Center, and the institution's partnership with the Core Center, and the institutional commitment to individuals responsible for conducting essential Core Center functions. This also includes 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.

III. CONTENT OF THE APPLICATION

This section describes the required components of the proposed Core Center and the review criteria to be applied. The suggested content order for the overall application will be covered in Section V. Note that these applications will be reviewed by a committee that will have three or more applications to review. Having a uniform format and using cross- references in each application greatly assists the reviewers in finding information and therefore giving a more favorable review. A detailed Table of Contents is especially invaluable in providing a key for cross-references, e.g., *see Section I.A.2. for more details.* Exhibit I is an example of a detailed Table of Contents.

III.A. Narrative Sections

Overview

Each application should have an OVERVIEW - a narrative section that serves as a synopsis of the key elements of the proposed Core Center, the qualifications of the Center Director, Associate Director and executive committee, the research base, and the resources and environment for the Center. The Overview serves to introduce the proposed program, to state the Center objectives, and to identify the scope of research addressed in the proposed Center. *This section is intended to be read by all reviewers, even if they are not assigned to projects within this application, so that each reviewer can get a comprehensive view of the proposed Center.*

An additional purpose of the Overview is to provide reviewers with a sense of how the Center will leverage its resources. A Center operates on two levels. The first level is to assemble outstanding proposals and carry out the proposed research. The second level is to provide leadership at an institutional or broader level to promote quality research through the intellectual and material resources of the Center.

Qualifications of the Center Leadership

The emphasis in this section should be on the qualifications of the Center leaders. The details of the administrative structure should be presented in the budgeted component for the Administrative Unit (see Section IV.F.) The Director of the Core Center, aided by an Associate Director and an executive committee, is expected to provide leadership for the research base of the proposed center. Describe the qualifications of the Center Director and Associate Director to lead the Core Center. Describe the qualifications of each member of the executive committee and the rationale for including these individuals in the leadership of the Center. Reviewers will be instructed to judge whether the Director and Associate Director have the leadership and research qualifications to lead a Center, and whether the leadership team (Director, Associate Director, and executive committee) have the collective expertise to assure focused development and implementation of the Core Center.

Research Base for the Core Center

A strong research base is a fundamental requirement for, and a major factor in, establishment of a Core Center. **The most important point to be made in the application is how establishment of a Core Center will improve efficiency, accelerate the pace of research, and ensure greater productivity within the research base.** This section should present an overview of current research conducted at the institution(s) participating in the Core Center, in sufficient detail to allow reviewers to judge its extent and the interrelationships of ongoing research.

Begin with a brief summary of the research base, and continue with a descriptive narrative of research activities related to Core Center focus at the primary and any collaborating institutions. This narrative presentation should be organized to address the focus and interrelationships of research conducted by Core Center investigators. Since most, if not all, of the research base will have undergone separate peer review, the quality of the individual funded projects will be established.

To document the research base of the proposed Core Center, it is helpful to prepare a table listing the grants, their duration, the current year direct dollars, and their principal investigators. It is helpful to group the grants into aggregates of projects with similar overall goals and objectives. Give the bottom line current year dollar amount for research grant support in the research base of the Core Center. A suggested format is given in Exhibit II.

Criteria for designating an investigator as a Core Center investigator should be defined in terms of the responsibilities and privileges associated with a Core Center investigator. Relevance of research to the objectives of the Core Center will be evaluated by the initial review group. Biographical sketches of those investigators can be included in the application in the center biographical sketch section.

Provide a brief narrative of the proposed cores and their expected impact on the research base. The more important aspects will be: (1) interactions and interrelationships of the research efforts; (2) uses and benefits of core services; and (3) plans to develop productive collaboration among Core Center investigators. Indicate if any of the proposed cores will utilize or expand cores already existing at the institution. Provide a table of those core costs that are estimated for support of pilot and feasibility projects (see Exhibit III for suggested format.)

Reviewers will be instructed to address the following review criteria: Is there a substantial productive and funded research base? Is the research base sufficiently broad to foster new research? Will the proposed cores enhance the research base? Is there a definition of who will be a Center investigator and what this designation might mean?

Institutional Environment and Resources

Briefly describe the features of the institutional environment that are relevant to the effective implementation of the proposed Core Center. As appropriate, describe available resources, such

as clinical and laboratory facilities, participating and affiliated units, patient populations, geographic distribution of space and personnel, and consultative resources. Campus maps and floor plans of space for the cores of the Core Center are helpful. Include a list of who occupies specific space, the square feet and equipment in that space, and a designation of the Core Center functions associated with the spaces designated. What institutional commitments for space or other resources are there for the proposed Core Center? Include any letters of support for the proposed Center by appropriate institutional officials, including Directors of a General Clinical Research Center (GCRC) or Clinical Translational Science Award (CTSA) funded by the NIH National Center for Research Resources, if applicable.

Reviewers will be instructed to address the following review criteria: Is there evidence of a supportive institutional environment for the proposed Core Center? Will the Core Center add an important research element to the institutional environment? Does the proposed Core Center utilize available resources well? Is there support and commitment from the institutional authorities?

Progress Report (if application is a Renewal or Competing Continuation Application)

All applications for competitive renewal must provide the following information in the progress report:

- A description of the changes that have resulted from the presence of the Center (e.g., increased numbers of research grants and research papers);

- A description of the activities before the existence of the Center (or at the beginning of the last award period) compared with any changes brought about by the Center's activities;

- The results of each core supported by the Center during the previous grant period;

- The results of each pilot project supported by the Center over the past 10 years (if applicable); and

- A list of publications that have resulted specifically supported with Center funding.

Reviewers will be instructed to judge whether the progress report reflects significant accomplishments that were derived from the Core Center, as reflected in publications and new research directions.

Pilot and Feasibility Program Management

The Administrative Unit will oversee the use of funds for the proposed Pilot and Feasibility Program. A management plan for the Pilot and Feasibility Program should be described. This plan should include designating a director who is an established investigator. There should be a committee to assist the director in the management of the program. The major responsibilities of the director and the committee will be to:

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

(2) Arrange and preside over the scientific merit review of pilot proposals submitted;

(3) Make recommendations to the Core Center Executive Committee (or equivalent) for final decisions;

(4) Maintain oversight and review of ongoing pilot and feasibility studies;

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

(6) Maintain, insofar as is possible, a record of subsequent status of the research developed (funding and manuscripts) and the further career development of each pilot and feasibility study recipient.

Using the management plan described, an initial set of pilot and feasibility proposals should be solicited and evaluated for inclusion in the Core Center application. All reviewers should assign priority scores in accordance with the NIH system. At least one reviewer from outside the applicant institution must be used for each proposal selected. Other details on handling the internal review will be left to the Core Center.

Review of the Core Center application will include review of the selected pilot and feasibility proposals. The quality of the proposals submitted and the management plan described are major criteria in evaluating the Core Center application. A dollar amount up to $100,000 in direct costs yearly will be recommended for supporting future pilot and feasibility studies.

Since pilot and feasibility studies may be awarded for any period of time up to three years, studies may be ending at various times during the overall duration of the grant. In addition, studies may also be terminated by the Core Center administration before their approved time limit for various reasons: (1) the investigator may receive outside funding for the project; (2) the project is found not to be feasible; (3) the investigator may leave the Core Center institution; etc. When such situations result in the termination of the study, the Core Center, using the mechanism described, may make new awards for pilot and feasibility studies with the remaining funds. After the initial review of pilot and feasibility proposals, responsibility for review and decisions for funding of individual pilot and feasibility studies during the remainder of the project period will reside within the Core Center itself. Future pilot and feasibility studies to be identified should be budgeted as a block under "Other expenses" in the Administrative unit.

Reviewers will be instructed to judge whether the management plan described is appropriate and adequate for reviewing proposals for, and administering funds in, the Pilot and Feasibility Program.

III.B. Budgeted Components

Each budgeted component should be presented in PHS 398 format, without page 1 (Face Page). Text corresponding to sections 2 through 5 of the standard PHS Table of Contents (Specific Aims, Background and Significance, Preliminary Studies, and Research Design and Methods) must not exceed 15 pages for a given budgeted component. Comprehensive budgetary justifications should be given for all items.

Administrative Unit

In place of a research plan, this part of the application should discuss:

(1)   The roles of the Director and Associate Director;
(2)   Relationships and lines of authority and sanction by appropriate institutional officials;
(3)   Committee structure (including the committee for the Pilot and Feasibility Program).

The functions assigned to the Administrative Unit should be described. These functions may include:

(1)   Coordination and integration of the Core Center components and activities;

(2)   Reviewing the utilization of funds for pilot and feasibility studies and for cores;

(3)   Advising the Core Center Director about the activities of the Core Center;

(4)   Implementing an enrichment program.

The use of outside consultants for the Core Center is strongly encouraged. Such consultants may play a role in reviewing progress of cores and pilot studies and be a part of the enrichment program of the center. It is helpful to have a diagram of the interactions to be fostered by the Core Center.   The Administrative Unit may request support for personnel, administrative functions, enrichment activities, and travel.

Personnel should include the Center Director, who is responsible for the organization and operation of the Center, and an Associate Director, who will be involved in the administrative and scientific aspects of the Center, and will serve as Acting Center Director in the absence of the Director. An Executive Committee representing the research base for the Center should also be identified. Their collective expertise should reflect the research breadth included in the research base of the Center. (Their qualifications are to be presented elsewhere in the application in a section on Qualifications of the Center Leadership - see Section IV.B.1.) Administrative support personnel may be budgeted at no more than one full time equivalent (FTE) that may be divided among one or more positions. This FTE must be fully justified.

The Core Center grant may also include limited funds for program enrichment (i.e., seminars, visiting scientists, etc); these should be included in the description and the budget of the Administrative Unit.

Travel of the Core Center Director and one Co-Director to and from the Washington, D.C. area should be included in the Administrative Core for attendance at an annual Core Center meeting.

Future pilot and feasibility studies to be identified should be budgeted as a block under "Other expenses" in the Administrative Unit.

Reviewers will be instructed to address the following review criteria:

> Does the proposed Core Center document coordination of ongoing research between the separately funded projects and the Core Center including mechanisms for internal monitoring? Is there a plan for the establishment and maintenance of internal communication and cooperation among the Core Center investigators, core leaders and an executive committee? Are there plans for outside review and input?

> Is the management proposed appropriate for fiscal administration, procurement, property and personnel management, planning, budgeting, etc.? Are the Core Center budgets appropriate for the proposed and approved work to be done in core facilities, for pilot and feasibility studies, and for enrichment in relation to the total Core Center program?

> Is there a plan for an enrichment program (e.g., a seminar series with outside and internal speakers)?

> Is there scientific and administrative leadership, commitment and ability, and adequate time commitment of the Core Center Director and Associate Director for the effective management of the Core Center program? Have institutional lines of authority and sanction been documented for the Core Center?

Research Cores

To be funded, a core center must have two or more highly meritorious research cores.

<u>Definition</u>
A research core in a Core Center is a shared facility that provides a service that enables Core Center investigators to conduct their independently funded individual research projects more efficiently or more effectively. Cores should be designed to furnish a group of investigators some service, technique, assay, or instrumentation in a manner that will enhance the research in progress, consolidate manpower effort, and contribute to cost effectiveness in terms of providing a service at less cost or of higher quality than if each investigator were to attempt the same thing individually. A core should also attract new investigators to an area of research by offering specialized services not easily duplicated in an individual laboratory.

Cores may be proposed in relation to any acceptable research activity of the Core Center, but usually fall into one of four categories: (1) provision of a technology that lends itself to automation or preparation in large batches (e.g., histology and tissue culture); (2) complex instrumentation (e.g., electron microscopy); (3) animal preparation and care; and (4) service (e.g., molecular biology, biostatistics, patient data base).

In addition to providing a product or a service, a core must maintain appropriate quality control. Training in complex techniques and methodologies for Core Center investigators is also an important function of these cores. The cores are not intended to supplant investigator capabilities, but rather are intended to enhance their opportunities to learn and become proficient in the core technologies.

Limited developmental research is also an appropriate function of a core facility so long as it is directly related to enhancing the functioning or utility of the core and is not an undertaking that should be funded through other mechanisms.

Note that NIH has policies for animal and human subjects, including the inclusion of women, minorities and children which **must** be addressed in **each** core, even if only to indicate why a full discussion is not applicable. The reviewers will be instructed to address the adequacy of inclusion plans for the work proposed as part of the scientific and technical merit evaluation. These policies may be accessed at the following sites:
Women & Minorities: http://grants.nih.gov/grants/funding/women_min/women_min.htm
Children: http://www.nih.gov/grants/funding/children/children.htm

Justification for proposing a core
State the reasons a core is needed. What value will be added to the research base? This is an especially important point to document if the proposal is to buy into an existing institutional core.

The establishment of research cores within a Core Center may be justified only on the basis of use by independently funded Core Center investigators. The minimum requirement for establishment of a core facility is significant usage by two or more investigators with peer reviewed projects that are independently funded. How the core will enhance the research productivity of these investigators should be described. While investigators holding awards from the Core Center pilot and feasibility program may be appropriate users of the core facilities, their use does not contribute to justification for establishment or continued support of a core. Additionally, the minimum of two funded investigator users does not in itself provide sufficient justification. Establishment of a core with a minimal number of users calls for particular justification on the part of the applicant and will receive close scrutiny during review.

Personnel
A director should be named for each core. Core directors may be acknowledged experts with an independently funded research program that will use the core services. In such cases, the percent effort on the grant is usually relatively low. Alternatively, a core director may be a more junior scientist with reasonable expertise who may devote a greater effort to the core. Rarely would a core director devote 100 percent effort; justification for this would be given very close scrutiny.

In the case of a core director who is not yet an established investigator, an established expert must be included as a consultant to the core. The career potential and institutional commitment to junior scientist core directors will be considered in the review. A technician is allowable as a participant in accordance with the volume and type of work in the core, but a technician cannot be a core director.

Facilities, space, and special arrangements
The description of the physical arrangements and instrumentation for the cores should be given special attention. Institutional commitment to provide space or to cost share in equipment should be documented if possible. In renewal applications, any changes should be carefully documented. Whenever possible, Core Centers are encouraged to enter into cooperative arrangements with established cores in other centers or resource grants offering a similar type of service at the applicant institution.

Management of the core
The organization and proposed mode of operation of each core should be presented. Included should be a plan to prioritize investigator use of the core as well as a definition of qualified proposed and potential users. This need not be a narrow definition, since some use of a core might be an enticement to established investigators in other fields to lend their expertise to the research base. If the core is used to train investigators in special techniques, the extent of, and approach to, this training should be included.

It is expected that center investigators using the core will provide some reimbursement to the core. This reimbursement plan will offset some of the costs specific for a project using the core. The reimbursement plan should be described.

Research Core Format Guidelines

Present each core separately using Form PHS 398 without page 1.

Descriptive page: Use PHS form 398 page 2. Include a description and key personnel.

Budget: It is important to provide comprehensive budgetary justifications; and to discuss mechanisms for reimbursing core services. To assist reviewers in understanding how the core budget will be distributed to pilot and feasibility studies within the Core Center, it is helpful to provide a table of supplies and expenses in the core budget associated with each pilot and feasibility study (see Exhibit III). Avoid duplication of budget items in the cores and the pilot and feasibility studies.

Resources and Environment: Special attention should be given to describing the space and resources available for the core service(s) proposed.

Specific aims: Describe the broad, long-term objectives, and describe concisely the specific aims to be accomplished by the core. Include developmental research or training, if proposed.

Background and Significance: Describe the background information and gaps that lead to the proposal of the core. A table such as that in Exhibit IV is helpful to describe for reviewers the projected use of the proposed core by funded investigators.

Research Design and Methods: Each proposed technique or service should be described in enough detail to allow the reviewers a comprehensive evaluation. Include how the core will be organized and how use will be prioritized. Where applicable, include sections on quality control and data analysis. See Exhibit V as an example for the kind of information that would be helpful to the reviewers.

Other: Include the sections on Human Subjects, including the inclusion of women and minorities, Vertebrate Animals, Consultants/Collaborators, Consortium/Contractual Arrangements, and Literature Cited. If not applicable, mark them N/A.

Reviewers will be instructed to address the following review criteria:

Significance: Will the core have utility to the Core Center research base (minimum: two independently funded investigators)?

Approach: Is the quality of services high? Are there procedures for quality control? Is the core cost effective? How is cost reimbursement proposed?

Innovation: Are unique services offered?

Investigators: Are the personnel appropriate?

Environment: Are the facilities and equipment adequate? Is there institutional commitment to the core?

Pilot and Feasibility Projects

Research projects associated with a Core Center will be funded from other resources, most notably individual research grants (R01) or program project grants (P01) from NIH and similar project funding from other Federal agencies or non-Federal sources. Exceptions to this outside support are pilot and feasibility studies funded as part of the Core Center.

Up to $100,000 direct costs yearly may be budgeted for pilot and feasibility studies.

Definition
The pilot and feasibility program provides modest research support ($20,000 to $50,000 yearly) for a limited time (1 to 3 years) to enable investigators to explore the feasibility of a concept related to the research supported by the Core Center and obtain sufficient data to pursue it further through other funding mechanisms. Pilot and feasibility study support is <u>not</u> intended for large undertakings of established investigators for which it would be appropriate to submit separate research grant applications. Pilot and feasibility funds are also not intended to support or

supplement ongoing supported research of an investigator. A given investigator can receive pilot and feasibility funds no more than once every 5 years.

Eligibility and related guidelines

Investigators eligible for pilot and feasibility funding generally fall into three categories:

(1)   New investigators without current or past NIH research project support (e.g., R01 or P01) as a principal investigator to engage in innovative research (see http://grants1.nih.gov/grants/new_investigators/resources.htm#definition for the definition of a new investigator). In addition, they should not have extensive research experience. However, although investigators should be clearly independent with clear potential to be a productive independent investigator, they do not need to have a faculty appointment. Serving as a PI of a pilot and feasibility project will not change one's status as a new investigator.

(2)   Established investigators with no previous work in research related to the focus of the Core Center who are willing to test the applicability of their expertise on a problem related to the Core Center focus; and

(3)   Established investigators in the Core Center with a proposal for testing the feasibility of a new or innovative hypothesis that is related to the research focus of the Core Center, but represents a clear and distinct departure from the investigator's ongoing research interest.

Each pilot and feasibility study proposal should state clearly the justification for eligibility of the investigator under one of the above three criteria at the beginning of the proposal. Indicate why this is a pilot study and where it might lead. A pilot and feasibility study should present a testable hypothesis and clearly delineate the question being asked, detail the procedures to be followed, and discuss how the data will be analyzed. It must be on a topic related to the research base. Items 2 – 5 of the Research Plan (Specific Aims, Background and Significance, Research Design and Methods) may not exceed a total of 15 pages. This page limitation does not apply to subsections 6 – 17. Note that preliminary studies are not required. Each project should be submitted using Form PHS 398.

Note that NIH has policies for the use of vertebrate animals and for human subjects, including the inclusion of women, minorities and children which **must** be addressed in **each** pilot proposal, even if only to indicate why a full discussion is not applicable. The reviewers will be instructed to address the adequacy of inclusion plans for the work proposed as part of the scientific and technical merit evaluation. These policies may be accessed at the following sites: Women & Minorities: http://grants.nih.gov/grants/funding/women_min/women_min.htm Children: http://www.nih.gov/grants/funding/children/children.htm

Pilot and Feasibility Project Format Guidelines (see Exhibit I)

Present each study separately using Form PHS 398 without page 1 (unless from a consortium

institution). Follow the instructions and include:

(1)   Description page, using PHS form 398 page 2.

(2)   Budget with justifications;

(3)   Justification of eligibility of the principal investigator and also of the study as a pilot study (including where the project could lead);

(4)   Scientific proposal as outlined in form PHS 398 (including justification for core use if applicable); note that items 2 - 5 of the Research Plan (Specific Aims, Background and Significance, and Research Design and Methods) may not exceed a total of 15 pages. This page limitation is exclusive of subsections 6 – 17;

(5)   Include the sections on Human Subjects, including the inclusion of women and minorities, Vertebrate Animals, Consultants/Collaborators, Consortium/Contractual Arrangements, and Literature Cited. If not applicable, mark them N/A.

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Reviewers will be instructed to address the following review criteria:

Significance: Will the proposed work likely yield meaningful preliminary data leading to a research proposal?

Approach: Are the experimental approaches adequate?

Innovation: Is the research topic one that promotes innovative new research related to the Core Center?

Investigators: Does the investigator meet one of the criteria for P&F investigators? (If not, the project should not be considered further.)

Environment: Is the project appropriate to the research base of the Core Center? Does one or more of the cores offer needed materials/assistance?

IV.   APPLICATION FORMAT (see Exhibit I)

General Information and Appendix Material

It is desirable for Core Center applications to be arranged in a specified format. This not only makes it easier for NIAMS staff and reviewers to find all the center components to be reviewed, but it can also serve as a checklist for the applicant institution in preparing the application.

PHS 398 is required for all applications. Each Budgeted Component (Administrative Unit, Research Core, or Pilot and Feasibility Project) should be written as an individual project using form PHS 398. For pilot projects, items 2 – 5 of the Research Plan (Specific Aims, Background and Significance, and Research Design and Methods) may not exceed a total of 15 pages. This page limitation is exclusive of subsections 6 – 17.

To aid in the review of these applications, the applicant should assemble the component units following the format described below. Applicants may also consult with NIAMS staff concerning the technical aspects of preparing the application.

Appendix Material.
Include key reprints and other supporting material. See instructions on appendices in the instruction manual for Form PHS 398. Different sections of the Core Center application may be reviewed by different reviewers. Appendices are not required, but if submitted, each piece of appendix material should be labeled with the Center Director and the project, core, or other category to which it belongs. EXAMPLES: Appendix 1 – John Doe – Project 1; Appendix 2 – John Doe – Core B. All 5 copies of appendices should be sent to:
> Chief, Review Branch
> NIAMS/NIH
> 6701 Democracy Blvd., Suite 800 – MSC 4872
> Bethesda, MD 20892-4872
> [Bethesda, MD 20817 (for express/courier service)]
> Telephone: (301) 594-4952

Content Order for the Core Center Application

Face Page of Form PHS 398.
Complete all items on the face page as directed. In the title block, item 1, put "Core Center." Mark item 2 "yes" and write in the RFA code as listed in the NIH Guide to Grants and Contracts and "NIAMS: Core Center" for the title.

Page 2, Description:
Describe the proposed program indicating the goals and objectives of the projects. Do not exceed the space allowed. Key personnel are those doctoral level investigators with a percent effort on the grant: component/core Directors or Co-Directors, principal investigators of pilot and feasibility studies, and consultants.

Table of Contents.
Discard this page from Form PHS 398 and write a Table of Contents appropriate for the Core Center grant application. This is paginated to follow the list of Key Personnel. **Do not use letters (e.g. 4a, 4b, 4c, etc.)** The Table of Contents should list all pilots and cores for which funding is sought. See Exhibit I for a suggested format. Each pilot and feasibility study and core should be listed by the title and Principal Investigator. Specifically list the locations of the checklist and the various requested supporting documents, e.g. animal and human subject assurances, other support, and bibliographic sketches.

Budgets.
For budget pages, see Exhibits VI, VII and VIII Use the forms found as form pages 4 and 5 in PHS Form 398 for all budgets. Justify and document all costs for current and future years throughout.

The overall Center budget, "Summary Center Budget," is to be presented first using PHS Form 398 page 4 entitled "Detailed Budget for First 12-Month Period" (see Exhibit VI). Note that no details need be given for the individual categories. Page 5 of PHS Form 398, "Budget Estimates for All Years of Support Requested Direct Costs Only", should then follow, summarizing all individual budgets (see suggested format in Exhibit VII). To provide budget information in a format that is clear to reviewers and therefore provides the most positive review possible, presentation of a consolidated budget for the first 12 months in a tabular form such as the sample shown as Exhibit VIII is suggested. For the purpose of establishing future year budget requests, the applicant should use cost escalations specified in the RFA or less.   However, **the direct cost budget cannot exceed $400,000 in any year**. This does not include the indirect costs of subcontracts. (See NOT OD-04-040: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-040.html)

Individual budgets, both first 12 month and 5 year, should be included later, *with each pilot and feasibility study (1 to 3 years) and core (5 years) for which funding is sought*. Details and justifications for all budget items must be part of the individual budgets. Read carefully the instructions for PHS 398 on how to prepare budget pages and justifications.

- This grant mechanism is not intended for the acquisition of equipment. Costly items of equipment should be funded through other sources. Under unusual circumstances, where costly items of equipment are requested, the application must document available equipment within the institution and provide clear justification in terms of core service to be provided by the Core Center investigators.

Biographical Sketches.
Biographical sketches are required for all professional level personnel who are listed with a percent effort (including consultants) in the Core Center application. Biographical sketches are also desirable for those investigators designated as Core Center Investigators without a dedicated percent effort. The forms found in Form PHS 398 should be used. Begin with the Center Director and place the remaining individual sketches in alphabetical order after the budget pages. These pages should not be duplicated in the individual component projects and cores.

Assurance Documentation.
See sample suggested table, Exhibit IX. In addition to the assurance pages, a master table listing the status of vertebrate animals and human subject approval dates and the human subjects education requirement certification will aid in the timely processing of your application.

Narrative Sections.
See Section IV for content information. Present in the following order using continuation pages:

- o **Overview**
- o **Qualification of the Center Leadership**
- o **Research Base for the Core Center and Impact of Proposed Research Cores**
- o **Institutional Environment and Resources and Impact of Proposed Research Cores**
- o **Progress Report (if a Renewal or Competing Continuation Application)**
- o **Pilot and Feasibility Program Management**

Budgeted Components
See Section IV for content information. Present each individual core and pilot study in the following order using the PHS 398 forms. Text corresponding to sections 2 through 5 of the standard PHS Table of Contents (Specific Aims, Background and Significance, Preliminary Studies, and Research Design and Methods) must not exceed 15 pages for a given budgeted component. This page limitation is exclusive of subsections 6 – 17.

- o **Administrative Unit**
- o **Research Cores (minimum of 2)**
- o **Pilot and Feasibility Studies**

V. REPORTING REQUIREMENTS AND ANNUAL EVALUATION

Annual progress reports, submitted as part of the annual noncompeting continuation application are due two months before the anniversary date of the award. These reports are used by the NIAMS and advisory committees to review the Core Center and its progress. They serve to verify in detail the achievement of the objectives outlined in the initial application and award and are an important source of material for program staff in preparing annual reports, planning programs, and communicating scientific accomplishments.

A progress report containing the following information is to be submitted with the annual continuation application. The report should include the following:

1. A summary (equivalent to no more than 2-4 single-spaced pages) of the goals and significant activities of the Core Center. This summary should be prepared for a general audience;

2. A discussion of the effectiveness of the Core Center in furthering the goals of the Core Centers Program. This should include a summary of the specific accomplishments that can be attributed to the Center grant. List what has been accomplished with the Core Center and what would not have been done without it; e.g., new research funding, persons educated, changes in curricula, patients seen, or organizational improvements within the institution;

3. A discussion of any problems which impede accomplishment of the stated goals in the administration of the Core Center grant;

4. Itemize all collaborative efforts which the Core Center has established and is conducting with other Core Centers. This should include a description of each activity, identification of the other Core Center(s) involved, and any results obtained so far;

5. **A copy of each new pilot and feasibility application to be funded by the Core Center.** These applications should be complete and should follow the guidelines for pilot studies in Section IV.H.of these guidelines. <u>IACUC and IRB approvals should be included</u>.

6. A detailed summary of each Core Center activity and project including the title, principal investigator and key personnel, their percent efforts, budgets, description, progress and evaluation. This progress report should include all Core Center supported projects initiated during the budget period, all continuing Core Center supported projects, and any Core Center supported projects terminated during the budget period. It is especially important that the significance and ultimate utility of each project be discussed in the summary description;

7.	A budget of the estimated use of funds for each core and project. In conjunction with the programmatic description, this report will describe allocations in the usual budget categories (i.e., personnel, equipment, travel, etc.) as well as the total expenditures. Separate budget pages should be used for each project and core in addition to a composite budget for the entire Core Center;

8.	An updated table of assurances. (See Exhibit IX);

9.	A table showing all support associated with the Core Center. This should include both federal and non-federal support. At a minimum, this would include all individual research grants, program projects, training grants, National Research Service Awards, Clinical Investigator Awards, etc. The table should list, for each source of support, the title of the project, name of the principal investigator, identifying number of the grant, percent effort of the investigator, dates of support, current annual support, and total support. If the Core Center has no other associated support, state this fact;

10.	Other information that, from year-to-year, may be requested by NIAMS staff.

The expanded progress report is in addition to, and does not replace, other management reports required by PHS policy.

In addition to the annual progress report, the NIAMS Centers Program Director may conduct site visits to gain added insight into the various aspects of the Core Center operations. The NIAMS will hold a meeting at various intervals for the Core Center Directors and Co-Directors to review the operation of the Core Center program as a whole.

EXHIBIT I -- Format & Table Of Contents

Sample of Suggested Format
ABC University
Application for a Research Core Center
Table of Contents

EXHIBIT II -- Grants Supporting The Research Base
Sample Of Suggested Format

Supporting Organization & Grant Number	Key Personnel	Title	Project Period	Current Annual Amount
NIH 5 R01 ARnnnnn	Chen, Chin-Mei (PI) Doe, John	New Therapeutic Agents for Autoimmune Disease	3/1/2004 – 2/28/2009	$467,000
			TOTAL	

EXHIBIT III -- Distribution Of Core Unit Costs Among Research Projects
Sample of Suggested Format

PROJECTS	CORE A	CORE B	CORE C	CORE D
P&F 1	$ 3,000		$ 1,500	
P&F 2	$ 4,000	$ 6,000	$ 1,500	
P&F 3	$ 3,000		$ 2,500	$ 5,500
P&F 4	$ 10,000	$ 6,000	$ 1,500	$ 2,500
TOTALS	$ 20,000	$ 12,000	$ 7,000	$ 8,000

Only those supply costs and other expenses specific to a project are to be listed. Personnel and equipment maintenance costs should <u>not</u> be prorated.

EXHIBIT IV -- Use Of Core Facilities
Sample Of Suggested Format

_____

CORE: *NAME*

Determinations/Services Rendered
A.
B.

Users	Funded Projects with Identifying Number	Period of Core Use	Determinations/Services	Estimated Use & Comments
1.				
2.				
3.				

_____

EXAMPLE

_____

CORE: Cell Culture

Determination/Services Rendered
A. Fibroblast Cell Cultures
B. Cell Isolations
C. Special Media Preparation
D. Isotopic Labeling

Users	Funded Projects with Identifying Number	Period of Core Use	A	B	C	D	Estimated Use & Comments
1. J.F. Smith	R01AR42846-02	3/06 - 2/09		X	X		B. 4 per mo C. 15 per mo
2. S.R. Jones	K01AR41654-04	6/06 - 5/09	X			X	A. 2 per mo D. 6 per mo

_____

EXHIBIT V-- Sample of Information Useful to Reviewers

Sample of information useful to reviewers in evaluating a core. This example was developed for a tissue acquisition core.

I. What types of samples are needed?
   A. Diseases
   B. Numbers of samples
   C. Source of samples
   D. Age
   E. Sex
   F. Tissues

II. What patient population is available? Is it sufficient?

III. What tissues are potentially available?
   A. Neonatal foreskins
   B. Surgical specimens of normal skin

IV. Ability to communicate needs with clinicians:

   A. Is there regular contact between the core director and clinicians? A Ph.D. core director may be less desirable because of lack of patient contact and lack of regular contact with clinicians, especially clinicians not part of the research effort.

   B. How will needs be communicated to clinicians, especially residents and clinicians not engaged in research?

V. Ability to harvest tissues and transport tissues and supplies:

   A. Who will harvest tissues? (Same clinician who sees patients in a busy clinical setting; Residents; designated member of the tissue acquisition core)

   B. Will these be biopsies required for patient care or will the biopsies be only for research purposes? Is it feasible to expect additional biopsies to be performed in a busy clinic?

   C. How will the clinicians obtain needed special supplies required for harvesting certain tissues (flash freezing or special fixatives for EM)? Who will either transport these supplies to the clinic or maintain a stock in the clinic?

   D. Who will transport tissues to the core? This is especially critical with frozen tissues and tissues requiring viability.

VI. Proof of previous ability to obtain similar samples:

   A. Publications and preliminary data demonstrating success at sample collection.

   B. Was it necessary to pay donors?

Justify budget and required technician effort by estimating volume of samples and slides.

EXHIBIT VI – Composite 1st Year Budget

EXHIBIT VI – Composite 1st Year Budget

Principal Investigator/Program Director (Last, First, Middle):

EXHIBIT VI

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY					FROM 4/01/2006	THROUGH 3/31/2011	

PERSONNEL (Applicant organization only)		TYPE APPT. (months)	% EFFORT ON PROJ	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED (omit		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	Principal Investigator						
SUBTOTALS ⟶					161,272	48,311	209,583
CONSULTANT COSTS							6,000
EQUIPMENT (Itemize)							0
SUPPLIES (Itemize by category)							84,994
TRAVEL							2,515
PATIENT CARE COSTS	INPATIENT						
	OUTPATIENT						
ALTERATIONS AND RENOVATIONS (Itemize by category)							
OTHER EXPENSES (Itemize by category)							34,223
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD						$	337,315
CONSORTIUM/CONTRACTUAL COSTS				DIRECT COSTS			62,686
				FACILITIES AND ADMINISTRATIVE			55,791
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page) ⟶						$	455,791

SBIR/STTR Only: FEE REQUESTED

EXHIBIT VII – Composite 5 Year Budget

Principal Investigator/Program Director (Last, First, Middle):   **EXHIBIT VII**

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS		INITIAL BUDGET PERIOD *(from Form Page 4)*	ADDITIONAL YEARS OF SUPPORT REQUESTED			
			2nd	3rd	4th	5th
PERSONNEL: *Salary and fringe benefits. Applicant organization only.*		209,586	166,932	166,932	166,932	166,932
CONSULTANT COSTS		6,000	6,000	6,000	6,000	6,000
EQUIPMENT						
SUPPLIES		84,994	51,144	51,144	51,144	51,144
TRAVEL		2,515	2,515	2,515	2,515	2,515
PATIENT CARE COSTS	INPATIENT					
	OUTPATIENT					
ALTERATIONS AND RENOVATIONS						
OTHER EXPENSES		34,223	110,723	110,723	110,723	110,723
SUBTOTAL DIRECT COSTS		337,315	337,313	337,313	337,313	337,313
CONSORTIUM/ CONTRACTUAL COSTS	DIRECT	62686	62,686	62,686	62,686	62686
	F&A	55791	55,791	55,791	55,791	55791
TOTAL DIRECT COSTS		455791	455,790	455,790	455,790	455,791

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD *(Item 8a, Face Page)* ▬ ▬ ▬ ▬ ▬ $ 2,278,950

SBIR/STTR Only Fee Requested					

SBIR/STTR Only: Total Fee Requested for Entire Proposed Project Period
(Add Total Fee amount to "Total direct costs for entire proposed project period" above and Total F&A/indirect costs from Checklist Form Page, and enter these as "Costs Requested for Proposed Period of Support on Face Page, Item 8b.) $

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

EXHIBIT VIII -- Consolidated Budget For 1st Year Of Requested Support
Sample Of Suggested Format

BUDGET CATEGORY	Project 1	Project 2	Project 3	Core A	Core B	Core C	TOTAL
Personnel							
Consultant Costs							
Equipment							
Supplies							
Domestic Travel							
Foreign Travel							
Patient Care Costs							
Alteration and Renovation							
Contractual Costs							
Other Expenses							
Total Direct Costs							

EXHIBIT IX – Animal & Human Subjects Assurance Tables
Sample Of Suggested Format
HUMAN SUBJECTS APPROVAL DATES
HUMAN SUBJECTS EDUCATION REQUIREMENT
ANIMAL SUBJECTS APPROVAL DATES

GENERAL:

1. Initial application: IRB approval and certification is not required with the submission or prior to review and may be listed as pending prior to the review.   The certification of IACUC approval must be submitted with the application or within 60 days after the application receipt date.

2. Initial funding: This table may need updating. The NIH no longer requires IRB approval and certification prior to NIH review. This information will be required when a decision is made to fund the application.   Certifications for the Human Subjects Education Requirement may be submitted at the time of application but are not required until a funding decision is made. If the Human Subjects Education Requirement certification is not included in the application, please mark Apending@.

3. Yearly progress reports: This table should be updated and included with each yearly progress report. Human Subjects Education Requirement Certifications are needed only for investigators new to the grant. Mark Apreviously submitted@ for continuing investigators.

SPECIFIC:

Please make a table for each Performance Site. If there is only one performance site, then only one table is needed. A certification letter must be attached for each project using Human Subjects. Each letter should include the registered IRB number from the Office of Human Research Protections.

Performance Site: University A				
Principal Investigator	**Project**	**IACUC Approval Date***	**IRB Approval Date***	**Human Subjects Education Requirement ***
Dr. A	1	8/3/2006	9/5/2006	Yes
Dr. B	2	4/8/2006	9/5/2006	Yes
Dr. C	3	6/7/2006	8/5/2006	Yes
Dr. E	5	7/7/2006	9/5/2006	Yes
Dr. B	Core A	8/3/2006	NA	NA
Dr. D	Core B	4/8/2006	NA	NA

Performance Site: University B Human Subjects assurance number: Animal welfare assurance number.				
Principal Investigator	**Project**	**IACUC Approval Date***	**IRB Approval Date***	**Human Subjects Education Requirement***
Dr. X	1 (subproject)	4/15/2006	9/6/2006	Yes
Dr. D	4	4/15/2006	8/5/2006	Yes
Dr. Y	Core B (subproject)	4/15/2006	NA	NA

* Attach certification letter