

# Guidelines For Multidisciplinary Clinical Research Centers

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**National Institute of Arthritis and  
Musculoskeletal and  
Skin Diseases**

**National Institutes of Health**

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# **The NIAMS Grant Guidelines for a Multidisciplinary Clinical Research Center**

## **I. THE NIAMS MULTIDISCIPLINARY CLINICAL RESEARCH CENTER PROGRAM**

### **I.A. Introduction**

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) leads the federal effort for the conduct and support of research into the causes, treatment and prevention of arthritis and musculoskeletal and skin diseases, the training of basic and clinical scientists to carry out this research, and the dissemination of information on research progress in these diseases.

In fulfilling its mission to support research and research training, the NIAMS employs a number of support mechanisms. These include various types of research projects, program projects, and career development programs; institutional training grants and individual training fellowships; and a number of center grant mechanisms. The center grants are interrelated to and interdependent upon all of the other support mechanisms.

The Multidisciplinary Clinical Research Center (MCRC) program began in 2001 with the funding of three centers. Six additional centers were funded; three in 2002 and three in 2003. The MCRC program was reissued in 2005 and 2006, which led to the renewal of five centers and funding of three new centers. For a list of the currently funded MCRCs, see: [http://www.niams.nih.gov/Funding/Funded\\_Research/multidisciplinary\\_clinical\\_research\\_center\\_s.asp](http://www.niams.nih.gov/Funding/Funded_Research/multidisciplinary_clinical_research_center_s.asp).

The following guidelines augment the funding opportunity announcement and provide information about the MCRC program, suggestions for preparation of an application and criteria for review.

### **I.B. Overview of the Multidisciplinary Clinical Research Center Program**

The aim of the MCRC program is to support a full range of outstanding multidisciplinary clinical research on arthritis and musculoskeletal and skin diseases or conditions (see Section III.A.). Each MCRC is organized around a Methodology Core and must include a minimum of two highly meritorious projects. The projects can be focused on one or more diseases/conditions. The Methodology Core must demonstrate that it can provide support for multidisciplinary approaches

for clinical projects within and outside the MCRC. The disease areas can be found at the NIAMS webpage, [http://www.niams.nih.gov/Funding/Funding\\_Opportunities/Supported\\_Scientific\\_Areas/default.asp](http://www.niams.nih.gov/Funding/Funding_Opportunities/Supported_Scientific_Areas/default.asp). It is anticipated that some MCRCs may bring a multidisciplinary clinical approach to closely related, but distinct diseases or conditions for which there is a paucity of clinical research nationally. Other MCRCs may focus on advancing clinical research on diverse diseases within the mission of the NIAMS. The scientific focus of the MCRC may also be developed around already collected or ongoing significant cohorts or other patient resources.

The Methodology Core is the foundation of the Center, providing key support for the development and implementation of clinical projects. The Methodology Core is expected to provide expertise and support to ongoing projects within the research base of the MCRC and to other emerging research opportunities funded elsewhere. The director of the MCRC, aided by an executive committee and the Methodology Core, provides leadership to focus all research projects **on clinically relevant issues to prevent disease or to assess and/or to improve patient outcomes** and to assure a rigorous research approach. The proposed director should document this leadership with examples showing collaborations and the ability to network with colleagues from clinical and other areas of biomedical research.

The MCRCs are expected to leverage existing institutional infrastructure resources. A meritorious research base in patient-oriented research, biobehavioral and social sciences, epidemiology and/or health services is a prerequisite for proposing an MCRC. Each MCRC defines its research base, goals for promoting clinical research utilizing that research base, and how multidisciplinary research will be promoted. Interactions with a Clinical and Translational Science Award (CTSA), if present, must be documented.

Each clinical research project must address a critical issue that directly involves prevention, assessment and/or outcomes for patients with conditions within the mission of the NIAMS. Clinical approaches that could be utilized by the centers may include, but are not limited to:

- Epidemiology
- Outcomes and health services research
- Biomarker analysis
- Human genetics
- Bio-psychosocial/behavioral research

Research on animals and animal models should not be proposed in the MCRC application. Clinical trials of any phase will not be supported by this funding mechanism.

Center grant awards are made for up to five years. The total yearly direct cost requested may not exceed a maximum direct cost of \$800,000 per year (exclusive of facilities and administrative costs of subcontracts with collaborating organizations) during any year over the 5-year grant period. Collaboration among institutions is permitted to bring in added expertise and/or patient populations.

In summary, the key elements of an MCRC must include:

- A Center Director, Associate Director and executive committee with outstanding credentials for promoting clinical research (see Section III.B.);
- A research base that encompasses diseases/conditions within the NIAMS mission and provides professional and patient resources for developing clinical projects (see Section III.C.); A Methodology Core that will 1) play a key role in providing support for multidisciplinary approaches for clinical projects within and outside the MCRC (see Section III.G.) and 2) contribute to the clinical research training environment of the center; and
- A minimum of two highly meritorious clinical research projects that 1) target one or more diseases/conditions within the NIAMS mission, 2) each utilizes the Methodology Core.

Optional elements of an MCRC are:

- A pilot/feasibility project (no more than one may be proposed) supported by the Methodology Core, with a yearly budget of up to \$50,000 in direct cost, and lasting no more than three years (see Section III.J.), and
- Other Core(s) supportive of two or more of the proposed projects (see Section III.H.).

## **II. APPLICATION AND REVIEW PROCESS**

### **II.A. Pre-application Process and Letter of Intent**

Applications are solicited by Requests for Applications (RFAs) published in the NIH Guide to Grants and Contracts. See the NIAMS website for current active RFAs:  
[http://www.niams.nih.gov/Funding/Funding\\_Opportunities/filter.asp](http://www.niams.nih.gov/Funding/Funding_Opportunities/filter.asp)

Individuals from institutions with potential interest in applying for an MCRC 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 applications.

The Letter of Intent should indicate which two or more diseases and/or conditions will be studied in the projects supported by the center.

To facilitate Institute planning, applicants are requested to submit a letter of intent on or before 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:

Justine F. Buschman, M.S.  
 National Institute of Arthritis and Musculoskeletal and Skin Diseases  
 One Democracy Plaza

6701 Democracy Boulevard, Suite 877  
Bethesda, MD 20892  
Telephone 301-496-4811  
Email: [buschmanj@mail.nih.gov](mailto:buschmanj@mail.nih.gov)

For fiscal and administrative matters, contact:

Natalie Reyes  
Grants Management Branch  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
6701 Democracy Boulevard, Suite 800  
Bethesda, MD 20892  
Telephone: 301-451-3648  
FAX: 301-480-5450  
Email: [reyesn@mail.nih.gov](mailto:reyesn@mail.nih.gov)

## **II.B. Application Procedure**

The research grant application form PHS 398 Rev (6/09) should be used in applying for these grants. These forms are available at: <http://grants.nih.gov/grants/funding/phs398/phs398.html>. For questions related to Application Procedures/Forms Submission, please contact GrantsInfo at [grantsinfo@nih.gov](mailto:grantsinfo@nih.gov) or 301-435-0714.

Each project and each Core included in the MCRC application should be written as an individual project using form PHS 398. Page limitations will apply to the individual projects and Cores. It is desirable for MCRC applications to be arranged in a specified format. A detailed Table of Contents is strongly suggested (see Exhibit I). This not only makes it easier for reviewers to use, but it can also serve as a checklist for the applicant institution in preparing the application. The arrangement of materials should follow both the instructions in form PHS 398 application kit and the more specific instructions detailed in Section IV of the Guidelines.

Receipt dates for MCRC applications are announced in the RFA. *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 (regular USPS or USPS Express mail)  
[Bethesda, MD 20817 (Express/courier Non-USPS Service)]  
Phone: 301-435-0715  
Address Labels are provided at the end of the forms.

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

Dr. Charles Rafferty  
Chief, Scientific Review Branch  
NIAMS/NIH  
6701 Democracy Boulevard, Suite 800 – MSC 4872  
Bethesda, MD 20892-4872  
[Bethesda, MD 20817 (for express/courier service)]  
Telephone: 301-594-5019

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 IV.D.).

### **II.C. Review Process**

Applications for MCRC 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 by a group of expert consultants convened by the Scientific 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.

### **II.D. 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 research project and Core will be individually reviewed for scientific merit and assigned a rating by committee consensus. Center elements, including qualifications of the center leadership, the research base, the institutional environment and resources, will also be considered in arriving at an overall impact/priority score for the Center. 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 a highly meritorious Methodology Core and at least two highly meritorious projects (not including the pilot/feasibility project, if any).

As part of the review process, an application may be judged as non-competitive and not scored, or may be discussed and assigned an overall impact/priority score. This score will reflect not only the quality of the individual projects, Cores, and administration, but also how the proposed MCRC will bring together all these elements in a workable unit. (See Section III.K.)

### III. PRESENTATION OF THE PROPOSED CENTER

This section describes the required and optional components of the proposed MCRC and the review criteria to be applied. The suggested content order for the overall application will be covered in Section IV. Note that these applications will be reviewed by a committee that will have a number of applications to review. Not every reviewer will necessarily read in detail every application. It is very helpful for reviewers to include cross-references in these center applications. A detailed Table of Contents is especially valuable 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.

Note that NIH has policies for the protection of human subjects and inclusion of women, minorities and children, which **must** be addressed in **each** project proposal and 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:

Research Involving Human Subjects: <http://grants.nih.gov/grants/policy/hs/>

Women, Minorities, and Children:

[http://grants.nih.gov/grants/peer/guidelines\\_general/Human\\_Subjects\\_Protection\\_and\\_Inclusion.pdf](http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf).

The NIH expects investigators supported by NIH funding to make their research data available to the scientific community for subsequent analysis based on a data sharing plan approved as part of the award; see the NIH Data Sharing Policy website at

[http://grants.nih.gov/grants/policy/data\\_sharing/](http://grants.nih.gov/grants/policy/data_sharing/). This requirement on data sharing is an extension to NIH policy regarding sharing research resources, which expects that recipients of NIH support will provide prompt and effective access to research tools. The data sharing plan for the Center should be described in the Administrative Core.

Each application should have a narrative section that serves as a synopsis of the key elements of the proposed MCRC, including an overview, the qualifications of the MCRC Director, Associate Director and executive committee, the research base, and the resources and environment for the 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 narrative sections is to provide reviewers a sense of how the MCRC will leverage its resources. An MCRC 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 MCRC.

### **III.A. Overview**

The Overview serves to introduce the proposed program, to state the MCRC objectives, and to identify the scope of patient problems to be addressed in the proposed Center. This includes a rationale of the diseases/conditions to be addressed. It is anticipated that some MCRCs may bring a multidisciplinary clinical approach to closely related, but clinically distinct, diseases for which there is a paucity nationally of clinical research - e.g., juvenile rheumatic diseases. Other MCRCs may focus on advancing clinical research on disparate diseases within the mission of the NIAMS because of unique multidisciplinary expertise. Describe the disciplines brought together for the proposed MCRC and explain the strategy for achieving the objectives of the overall program. It is important to indicate prior collaborative arrangements between investigators in the group, to emphasize the events that have led to the current application, and **especially to describe the anticipated unique advantages that would be gained by the research within the proposed MCRC**. Briefly describe each of the proposed projects, identifying how that project addresses a clinically relevant issue to prevent disease or to assess and/or to improve patient outcomes with a rigorous research approach. Briefly describe the Methodology Core and indicate how this Core will assist each of the proposed projects. Describe the role of any additional supporting Cores.

### **III.B. Qualifications of the Center Leadership**

The emphasis in this section should be on the qualifications of the Center leaders. The administrative plans are presented in the Administrative Core (see Section III.F. of the Guidelines.)

The Director of the MCRC, aided by an Associate Director and an executive committee, is expected to provide leadership to focus all research projects on clinically relevant issues to prevent disease and to assess and/or to improve patient outcomes and to assure a rigorous research approach. The collective expertise should reflect direct clinical interactions with the diseases included in the research base of the Center and experience with the recruitment of patients (and caregivers, if applicable) for the type of projects undertaken. The leader of the Methodology Core should be a member of the executive committee.

Describe the qualifications of the MCRC Director and Associate Director to lead the MCRC. Describe the qualifications of each member of the executive committee and the rationale for including these individuals in the leadership of the MCRC. Applicants are advised to include sufficient information to address the review criteria for this aspect specified in Section III.K.

### **III.C. The Research Base for the MCRC**

Describe the research base upon which the MCRC builds, including descriptions of independently funded research projects so that reviewers can determine the extent and quality of research activities related to the proposed MCRC. The descriptions should include: the principal investigator and other key research personnel; the project's objectives and progress toward them; the project's relevance to a NIAMS disease area; and important publications that have resulted from this research in the past five years. In addition, it is helpful to include a table of the relevant research grants (see Exhibit II). Describe how members of this research base will interact with the proposed MCRC. Will there be services or activities available through the proposed MCRC for investigators who are not directly involved in the MCRC funded projects (i.e., Center investigators)? The research base should also serve as a source for new projects that the MCRC may mentor and assist in obtaining resources through NIH or foundation research support programs. Describe the vision for this process. Applicants are advised to include sufficient information to address the review criteria for this aspect specified in Section III.K.

#### **III.D. Institutional Environment and Resources**

Briefly describe the features of the institutional environment that are relevant to the effective implementation of the proposed program. As appropriate, describe available resources, such as the availability of space and equipment, clinical and laboratory facilities, participating and affiliated units, patient populations, geographic distribution of space and personnel, consultative resources, and the potential for interaction with scientists from other departments and schools. Indicate if any of the proposed Cores will utilize or expand Cores already existing at the institution.

In addition, describe what institutional commitments for space or other resources there are for the proposed MCRC, including any letters of support for the proposed Center by appropriate institutional officials. The institutional commitment to the program also includes lines of accountability regarding management of the MCRC, the institution's partnership with the MCRC, and the institutional commitment to individuals responsible for conducting essential MCRC functions.

Applicants from institutions that have a Clinical and Translational Science Award (CTSA) funded by the NIH National Center for Research Resources may wish to identify the CTSA as a resource for conducting the proposed research. Details of the interactions of the MCRC staff with the CTSA staff and research personnel may be provided in a statement describing the collaborative linkages being developed. A letter of agreement from the CTSA Program Director must be included with the application.

Applicants are advised to include sufficient information to address the review criteria for this aspect specified in Section III.K.

#### **III.E. Renewal Applications: Additional Material Required**

All applications for competitive renewals must provide the following information in the progress report (part of the Research Strategy per PHS 398):

- A description of the changes that have resulted from the presence of the MCRC (e.g., increased numbers of research grants and research papers);
- A description of the activities before the existence of the MCRC (or at the beginning of the last award period) compared with any changes brought about by the MCRC's activities;
- The results of each project supported and conducted by the MCRC during the previous grant period;
- A synopsis of the activities of the Methodology Core including the implementation of human subject protection for clinical projects; (A more complete report should be found in the Methodology Core.)
- A synopsis of other Core units (if any) in operation during the previous award period and an evaluation of their usefulness to the Center; (A more complete report should be found in the Core.) and
- A list of publications that have resulted specifically from MCRC funding.

### **III.F. Administrative Core**

The purpose of an MCRC is to promote research on clinically relevant issues to prevent disease and to assess and/or to improve patient outcomes in the many diseases within the mission of the NIAMS. The Administrative Core is responsible for the planning, development, coordination, and overall administration of the MCRC. A key role of this Core is to foster productive interactions at the host institution through MCRC personnel and appropriate committees.

The MCRC Director is responsible for the organization and operation of the MCRC. An Associate Director should be named 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 MCRC and including the Methodology Core leader should also be identified. The Director, Associate Director and executive committee provide the leadership to identify and focus research projects on clinically relevant issues. Their collective expertise should reflect direct clinical interactions with the diseases included in the research base of the MCRC and experience with the recruitment of patients (and caregivers, if applicable) for the type of projects undertaken. (Their qualifications are to be presented elsewhere in the application in a section on Qualifications of the Center Leadership - see Section III.B.)

The proposed administrative framework for the MCRC should be described. The emphasis should be on coordination of administrative needs in the MCRC. The MCRC Director is expected to devote substantial effort to the overall administration of the Center, generally no less than 1.2 person months (10 percent effort), but not more than 3.0 person months (25 percent effort). An Associate Director is expected to have no less than 1.2 person months (10 percent effort), but not more than 2.4 person months (20 percent effort). If the Director and/or Associate Director also serve as the PI/PD of a clinical project, then their efforts should be budgeted separately in each of those components. Members of the executive committee may also be

budgeted in the Administrative Core. However, if a member has a substantial role in another component, such as the director of the Methodology Core, then one role of that position should be to serve as a member of the executive committee and that should not be budgeted in the Administrative Core. Administrative support personnel may be budgeted in at no more than one full time equivalent (FTE) which may be divided among one or more positions. This FTE must be fully justified.

Describe the plan for the administrative oversight of the MCRC. Describe the mechanisms by which the Director, Associate Director and executive committee will provide the leadership for the MCRC. Experience has demonstrated that Centers benefit from having outside advisors as well. Describe plans for using outside advisors individually or as an Advisory Committee.

The NIH expects investigators supported by NIH funding to make their research data available to the scientific community for subsequent analysis based on a data sharing plan approved as part of the award; see the NIH Data Sharing Policy website at [http://grants.nih.gov/grants/policy/data\\_sharing/](http://grants.nih.gov/grants/policy/data_sharing/). The data sharing plan for the Center should be described in the Administrative Core.

Applicants are advised to include sufficient information to address the review criteria specified in Section III.K.

### **III.G. Methodology Core**

A Methodology Core is a required component of the MCRC and must serve **all** projects proposed in the MCRC.

- The Core should have sufficient professional personnel to provide an interactive leadership role not only in supporting the projects within the MCRC, but also promoting rigorous methodological and biostatistical support for the research base. At a minimum, the Methodology Core should provide professional expertise in biostatistics and clinical research design. However, additional professional expertise will be appropriate as justified by the research supported and the research base.
- The Methodology Core should propose a plan for enhancing the clinical research training environment at the Center. In addition to providing guidance and feedback on the design of clinical projects and the writing of proposals and manuscripts, the Core should provide opportunities such as seminars, courses, workshops or computer based training to enhance the capabilities of faculty, staff, students and fellows associated with the Center to conduct clinical research using a wide range of approaches.
- The Methodology Core designs and implements an independent process to maintain data integrity and assist with development of safety plans for the projects funded by the MCRC, if needed.
- The Methodology Core may include support services for the projects such as subject recruitment, electronic data entry or database management. These services should not be

extended to non-MCRC funded projects without cost sharing. Such arrangements should be described.

- Describe the qualifications of the professional and support personnel in the budget justification. In the research plan indicate the scope of services to be provided and the mechanisms by which the Core will provide both support and oversight for the proposed projects.

Applicants are advised to include sufficient information to address the review criteria specified in Section III.K.

### **III.H. Other Cores (optional)**

Other Cores supporting two or more of the proposed MCRC projects may be requested. Applicants are advised to include sufficient information to address the review criteria specified in Section III.K.

### **III.I. Clinical Research Projects**

A minimum of two highly meritorious clinical research projects, **each with a focus to prevent disease or to assess and/or improve outcomes of patients**, must be present in an MCRC. Each MCRC project will define the patient problem under study and the anticipated improvement in preventing disease or in assessment and/or outcome for the patient that might be realized through this project. Clinical approaches that could be utilized by the Centers may include, but are not limited to:

- Epidemiology
- Outcomes and health services research
- Biomarker analysis
- Human genetics
- Bio-psychosocial/behavioral research

Clinical Research: NIH defines human clinical research as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research. Note: Studies falling under Exemption 4 for human subjects research are not considered clinical research by this definition.

Animal studies should not be included in the MCRC program. In addition, clinical trials will not be supported by this funding mechanism.

A unique feature of an MCRC clinical project is that the principal investigator must clearly

identify the clinical assessment and/or outcome or approach to disease prevention under study in the background section of each project proposal. What are the data that support this as a clinically important issue? What difference will the answer provided by this research make to prevention, or to the assessment or outcomes of patients? What is original about the approach taken in this study? If the research is a refinement of an existing approach, what important insights will be gained?

A clinical project may use an existing large database or registry that serves as a resource for research. Examples of such national databases include, but are not limited to: Medicare, the National Health and Nutrition Examination Survey, the Women's Health Initiative, the Study of Osteoporotic Fractures, the Framingham cohort and the Nurses' Health Study. However, it is not the primary purpose of an MCRC to develop registries or databases.

Each project should be written in compliance with the guidelines for a research project using form PHS 398. Note that the sections on protection of human subjects and inclusions of women, minorities and children are not part of the 12 page limitation and should be complete.

Applicants are advised to include sufficient information to address the review criteria specified in Section III.K.

### **III.J. Pilot/Feasibility Project (optional)**

An optional component in an MCRC is a development/feasibility project lasting no more than three years and with a yearly direct cost budget of \$50,000 or less. When the Pilot/Feasibility Project has ended, there should be a plan for redistributing this part of the budget into the remaining projects and Cores.

The goal of the development and feasibility project is to gather preliminary data or to develop a resource or tool for a future study. The pilot/feasibility research proposal should document that the goal is to address a clinically important issue and to describe the potential impact seen in future work, if successful. The Principal Investigator should have a faculty position.

Each project should be written in compliance with the guidelines for a research project using form PHS 398. Note that, if applicable, the sections on protection of human subjects and inclusions of women, minorities and children are not part of the 6 page limitation and should be complete.

### **III.K. Application Review Information**

#### **Overall Impact**

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the entire Multidisciplinary Clinical Research Center (MCRC) to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the overall MCRC and its components

proposed). This overall impact/priority score will reflect not only the individual quality of the projects, Cores, and administration, but also how the proposed MCRC will bring together all these elements in a workable unit. 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."

### **Review Criteria - Overall Application**

Reviewers will consider each of the review criteria below in the determination of scientific merit. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

### **Significance**

Does the proposed MCRC address an important problem or a critical barrier to progress in the field? If the aims of the MCRC and its components are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Do the Director and Associate Director have the leadership and research qualifications to lead a Center? Does the leadership team (Director, Associate Director, and executive committee) have the collective expertise to assure focused development and implementation of high quality and meaningful clinical research projects?

### **Investigator(s)**

Are the PD/PIs, collaborators, and other researchers well suited to the MCRC and its components? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise? Are their leadership approach, governance and organizational structure appropriate for the project?

### **Innovation**

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

### **Approach**

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

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

### **Environment**

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the MCRC benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Is there evidence of sufficient institutional commitment for the MCRC? Will the MCRC add an important multidisciplinary element to the institutional environment? Does the proposed MCRC utilize available resources well?

### **Research Base**

Is there a substantial productive and funded research base? Is the research base sufficiently broad to foster new multidisciplinary research? Is there a definition of who will be a Center investigator and what this designation might mean? Does the application convey how the proposed MCRC will enhance the research base of the host institution?

### **Integration**

Does the proposed MCRC leverage existing institutional resources? Is there evidence of interaction between the proposed clinical projects and the Methodology Core? Are there clear advantages of conducting the proposed research as MCRC rather than through separate research efforts?

### **Past Progress of a Renewal MCRC (if applicable):**

Does the progress report reflect significant accomplishments and impact of the MCRC during the last funding cycle? Is the work of the MCRC reflected in new concepts and publications?

### **Scored Review Criteria – Individual Clinical Research Projects (if applicable):**

#### **Pilot/Feasibility Project:**

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. The overall impact/priority score will take into consideration: the scored review criteria and any specified additional review criteria; the extent to which the individual project enhances the strength of the overall MCRC; and the importance of the individual project to the success of the MCRC. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

#### **Significance**

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

a Pilot/Feasibility project is proposed, is it likely to yield meaningful preliminary data as the basis for the development of a successful full-scale research proposal?

### **Investigators**

Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise? Are their leadership approach, governance and organizational structure appropriate for the project?

### **Innovation**

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? If a Pilot/Feasibility project is proposed, is the research topic one that promotes innovative research related to the MCRC?

### **Approach**

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Does the project utilize the multidisciplinary resources of the MCRC, especially the Methodology Core? If a Pilot/Feasibility project is proposed, does the project utilize the multidisciplinary resources of the MCRC, especially the Methodology Core and does it employ useful collaborative arrangements?

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

### **Environment**

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? If a Pilot/Feasibility project is proposed, is the project appropriate to the research base of the center? Does one or more of the Cores offer needed materials/assistance?

### **Review Criteria for the Methodology Core:**

The required Methodology Core must provide essential methodological, biostatistical and educational functions as well as maintenance of data integrity and development of safety plans for all projects in the MCRC. The merit of the Methodology Core will be assessed based on the

following criteria:

**Purpose**

Is the proposed Methodology Core well matched to the needs of the overall MCRC? Does it serve all research projects proposed for the Center? Are unique services offered? Is the process for maintenance of data integrity and assistance with development of safety plans for the projects supported by the MCRC adequately addressed? Is there evidence that the Methodology Core can and will support clinical research projects in more than one chronic disease or condition of interest to the NIAMS.

**Quality and Quality Control**

What is the overall quality of the proposed Core services? Are there adequate quality control processes proposed for the services provided by the Methodology Core (including procedures, techniques, and quality control)? What are the criteria for prioritization and usage of Core products and/or services? Is the Methodology Core likely to promote multidisciplinary research?

**Leadership**

Are the qualifications, experience, and commitment of the leader of the Methodology Core and other key personnel adequate and appropriate for providing the proposed services?

**Cost-effectiveness**

Is the Core cost effective? How is cost reimbursement proposed?

**Environment**

Is the environment for the Methodology Core adequate and appropriate to support the MCRC as proposed? Are the facilities and equipment adequate and appropriate? Is there evidence of institutional support?

**Training Activities**

Does the Methodology Core propose an adequate plan for enhancing the clinical training environment at the Center? Will the Core provide opportunities such as seminars, courses, workshops or computer based training to enhance the capabilities of faculty, staff, students and fellows associated with the center to conduct clinical research using a wide range of approaches?

**Review Criteria for the Other Cores (if applicable):**

**Purpose**

Is the proposed Core well matched to the needs of the overall program? Will the Core have utility to at least two of the MCRC projects? Do the services offered best fit within a Core structure? If this is an add-on to a preexisting Core, what is the benefit to the MCRC over direct purchase of services from the existing Core?

**Quality and Quality Control**

What is the overall quality of the proposed Core services? Is the quality of services high? Are there procedures for quality control?

**Leadership**

Are the qualifications, experience, and commitment of the leader of the Core and other key personnel adequate and appropriate for providing the proposed facilities or services?

**Cost Effectiveness**

Is the Core cost effective? If the Core offers new services that may be used by non-MCRC funded projects, how will the non-MCRC funded projects purchase these services from the Core?

**Environment**

Are the facilities and equipment adequate? Is there institutional commitment to the Core?

**Review Criteria for the Administrative Core:**

The Administrative Core provides for leadership and management of all MCRC activities. The merit of the Administrative Core will be assessed based on the following unscored criteria:

**Purpose**

Is the proposed Administrative Core well matched to the needs of the overall center?

**Management**

Is the management proposed appropriate for scientific administration as well as fiscal administration, procurement, property and personnel management, planning, budgeting, etc.? Are there scientific and administrative leadership, commitment and ability, and adequate time commitment of the MCRC Director and Associate Director for the effective management of the MCRC program? Is a plan for data sharing included?

**Leadership**

Do the Director and Associate Director have the leadership and research qualifications to lead a MCRC? Do the proposed MCRC Director, Associate Director and executive committee have the collective expertise and leadership to identify and focus research projects on clinically relevant issues?

**Communication**

Is there an appropriate plan for establishment and maintenance of internal communication and cooperation among the MCRC investigators, Core leaders and executive committee? Are there appropriate plans for outside review and input?

**Environment**

Is the environment for the Administrative Core adequate and appropriate to support the overall program project as proposed? Is there evidence of institutional support for the management of MCRC?

**Additional Review Criteria**

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority

score, but will not give separate scores for these items.

### **Protections for Human Subjects**

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects; 2) adequacy of protection against risks; 3) potential benefits to the subjects and others; 4) importance of the knowledge to be gained; and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption; 2) human subjects involvement and characteristics; and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

### **Inclusion of Women, Minorities, and Children**

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

### **Vertebrate Animals**

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section](#).

### **Biohazards**

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

### **Resubmissions**

If Resubmissions are not allowed for this FOA (i.e., are not included in Section II. Award Information – Application Types Allowed), replace the text with “Not Applicable”. Otherwise, do not change.

Resubmissions applications are not permitted in response to this FOA.

## **Renewals**

If Renewals are not allowed for this FOA (i.e., are not included in Section II. Award Information – Application Types Allowed), replace the text with “Not Applicable”. Otherwise, do not change.

For Renewals, the committee will consider the progress made in the last funding period.

## **Revisions**

If Revisions are not allowed for this FOA (i.e., are not included in Section II. Award Information – Application Types Allowed), replace the text with “Not Applicable”. Otherwise, do not change.

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not for recommended approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

## **IV. SUGGESTED CONTENT ORDER FOR APPLICATION**

### **IV.A. Face Page, Abstract Page, Table of Contents**

Form PHS 398 is required for all applications. (See II.B. for how to obtain this form). Each budget unit (project or Core) should be written in the style and within the page limitation described in the PHS 398 instruction kit. The Research Strategy section (Item 3) of the Research Plan for each project or Core is limited to 12 pages, and the optional Pilot/Feasibility project is limited to 6 pages. The Narrative section (Exhibit I, section II.A-D.) is limited to 12 pages excluding Letters of Support. The progress report for renewal applications (section I. M) is limited to 12 pages, excluding publication list and inclusion enrollment report. 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.

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

**Page 2 – Project Summary and Relevance:** Describe the proposed program in concise language, indicating the goals and objectives of the projects and making reference to the health relatedness. Do not exceed the space allowed. **Key personnel** are typically individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation.

**Table of Contents:** Discard this page from form PHS 398 and write a Table of Contents appropriate for the MCRC 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

- Each summary narrative
- Each Core or project for which funding is sought *with the Core or project listed by the title and Principal Investigator*; subsections should also be identified (see Exhibit I for suggested format)
- The location of the checklist pages
- The location of the various required sections, e.g., human subject assurance, biographical sketches.

#### **IV.B. Budgets and Other Supporting Forms**

**Budget: See Exhibits III, IV and V.** To aid in the review of your application, it is suggested that the forms found as pages 4 and 5 in form PHS 398 be used 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 form PHS 398, page 4 entitled "Detailed Budget for Initial Budget Period" (see Exhibit IV). Note that no details need be given for the individual categories. 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 III is suggested. Page 5 of form PHS 398, "Budget for Entire Proposed Period Direct Costs Only", should then follow, a composite like that in Exhibit IV, summarizing all individual budgets (see suggested format in Exhibit V). For the purpose of establishing future year budget requests, the applicant should use cost escalations as specified in the RFA or less. However, **the direct cost budget cannot exceed \$800,000 in any year**. For purposes of establishing the \$800,000 direct cost limit, the F&A (indirect) costs of subcontracts will not be counted.

Both first 12 months and 5 year individual budgets should be included *in the sections for each project and Core*. Details and justifications for all budget items must be part of the individual budgets. Read carefully pages I-32 to I-35 (Part I) of the Instructions for PHS 398 on how to prepare budget pages and justifications.

- A separate, detailed budget for each project subcontracted to a consortium institution is required with a form PHS 398 face page signed by the Principal Investigator and appropriate officials in the consortium institution as well as a PHS 398 checklist form page.
- This grant mechanism is not intended for the acquisition of costly equipment which 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.
- It is not the purpose of a Center grant to provide funding for alterations or renovations.

- The production of audiovisual material with Center grant funding is not appropriate.
- The travel of personnel to attend Center-sponsored symposia is not appropriate.

**Biographical Sketches:** Biographical sketches are required for all professional level personnel who are (1) listed with a percent effort (including consultants) in the MCRC application; (2) serving as advisors; and (3) members of the research base. The forms found in Form PHS 398 should be used. Place individual sketches in alphabetical order after the budget pages. These pages should not be duplicated in the individual component projects and Cores.

## **IV.C. Presentation of the Proposed MCRC**

### **IV.C.1. Narrative Sections**

In a narrative fashion, present the components described in Sections II.A. - II.D.: Overview, Qualifications of the Center Leadership, Research Base for the MCRC, and Institutional Environment and Resources. It is helpful for the reviewers to locate each of these components in the Table of Contents (See Exhibit I).

### **IV.C.2. Budgeted Components**

The components with budgets are described in Sections III.A. through III.F.: Administrative Core, Methodology Core, Other Cores (optional), Clinical Research Projects (minimum of two), and Pilot/Feasibility Project (optional).

Each component should be written up as a separate unit following these supplemental instructions and the instructions accompanying form PHS 398. It is important that each component include a section on human subjects, gender and minority inclusion, and inclusion of children as participants in research involving human subjects, even if to indicate that a full discussion is not applicable. An individual target enrollment table must be included with each project. Cores may cross reference detailed presentations to projects and vice versa as appropriate to avoid lengthy repetitions of complex arrangements.

- A cover page for an individual component is needed only when that component will be administered through a subcontract to another institution. Facilities and administrative (indirect) costs from these subcontracts do not count against the \$800,000 cap for direct costs for an MCRC.
- An abstract and key personnel page must be included for each component.
- A detailed budget for the initial budget period and budget for the entire proposed period of support [pages 4 and 5 of form PHS 398] must be included with each component. The budget justification should be thorough. Do not assume that any item or percent effort is

obvious. If this is a project for which specific services are to be performed in one of the Cores, the person month effort of specific personnel and the associated costs should be detailed at the end of the budget justification. Similarly, the budget justification for each Core (but not the Administrative Core) should include the specific person month and costs to service each individual project. It is recognized that 100 percent of Core costs need NOT be justified by service to specific projects to allow for teaching, quality control and other research-base functions.

- The biographical sketches are put centrally in one location (see IV. B.) and should not be duplicated in the individual component.
- A resources page should be included for each component.
- The checklist page needs to be included with each institutional cover page.

#### **IV.D. Appendices**

See the instructions in the PHS 398 booklet for appropriate appendix materials.

Following these suggestions will insure that correct appendix material can be sent to the appropriate reviewers:

- The five sets of all appendix material as well as a CD including all appendices should be sent directly to the Scientific Review Branch, NIAMS (see Section II.B. page 5 for the address) and **NOT** to the Center for Scientific Review.
- Each piece should be marked with (1) the name of the MCRC Director - not the name of the component PI - and (2) a **single** component of the application to which it pertains - MCRC Leadership, Research Base, Resources and Environment, Past Progress, Administrative Core, or individual Cores and projects.
- The marked materials should be grouped by the identified components. Thus, all five copies of appendices pertaining to a given project or component should be grouped together.

## V. NONCOMPETING APPLICATIONS: ANNUAL REPORTING REQUIREMENTS

Annual progress reports, submitted as part of the noncompeting continuation application, are due two months before the anniversary date of the award. These reports are used by the National Institute of Arthritis and Musculoskeletal and Skin Diseases to review the 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 reports, planning programs, and communicating scientific accomplishments.

The application for continuation of a PHS Grant, PHS Form 2590, is sent each year. In addition, an overall progress report containing the following information should be included:

- A summary (equivalent to no more than 2-4 single-spaced typewritten pages) of the goals and significant activities of the Center. This summary should be prepared for a general audience. *Honors and/or promotions of professional personnel should be mentioned.*
- A discussion of the effectiveness of the Center grant in furthering the goals of the Centers program. This should include a summary of the specific accomplishments that can be attributed to the Center grant, e.g., new research funding, changes in curricula, or organizational improvements within the institution and in the community.
- An itemization of collaborative efforts the Center established.
- A discussion of problems that impede accomplishment of the stated goals in the administration of the Center grant.
- The administrative component report should include a list of administrative meetings held, evaluations from advisory committees, speakers or symposia sponsored. These may be included as appendix material.
- A table listing the IRB (institutional review board for use of human subjects in research) and certifications education for the protection of human research participants for key personnel for all Center-funded projects is optional, but will assist the timely processing of your award. (See Exhibit VI). The notice describing the requirement for education for the protection of human subject participants may be found at:  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html>.
- A detailed summary of each Center-funded component (including the Administrative Core) and project, including the title, principal investigator and key personnel, their percent effort, proposed budgets, description, progress, and evaluation. This progress report should include all Center-supported projects. It is especially important that the significance and ultimate utility of each project be discussed in the summary description and that this discussion be in terms understandable to an informed nonscientist.

- A budget page for the coming year for each component and project funded by the Center. The timely review of your application will be facilitated by the inclusion of a composite budget for the entire Center as illustrated in Exhibit IV.
- Other information that, from year to year, may be requested by the NIAMS staff.

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

## **VI. GUIDELINES FOR REVISION APPLICATIONS**

Revision applications submitted for an NIAMS MCRC program must have prior approval of the NIAMS. Applications submitted without prior approval will be withdrawn and returned to the applicant. Approval will be based upon the following:

- A component research project was recommended for less time than was the rest of the P60 grant in order to permit an early assessment of progress;
- A persuasive case can be made that an alternative, additional or expanded project is important for the MCRC program AND the new total direct cost budget for the MCRC will not exceed the budget cap;
- The proposed project is in response to well defined NIAMS program initiatives and/or rapidly developing health areas related to the NIAMS' mission.

Additional pilot/feasibility studies may NOT be requested.

Revision applications will undergo a competitive review by the Initial Review Group (IRG) convened by the NIAMS Review Branch. In general, applications should be submitted so that at least two years remain on the parent grant at the time of award of the revision application. Major factors to be considered in the evaluation of a revision application will include:

1. The relevance of the proposed research to the MCRC concept outlined in these guidelines;
2. If a request for continuation, what findings have been developed that justify additional years;
3. Scientific merit of the proposed project, including significance, approach and innovation;
4. Competence of the investigators to accomplish the proposed research goals, their commitment, and the time they will devote to the research program;
5. How the MCRC environment enhances the project;
6. Appropriateness of the budget for the proposed program; and
7. Appropriateness of plans to include children, women, and minorities in the study populations.

A revision application will be assigned a priority score based on its merit as an individual research project. The review will also comment on how the proposed project fits with the MCRC program. Funding will be based on merit, program relevance and availability of funds.

**EXHIBIT I - TABLE OF CONTENTS**  
 ABC University  
 Application for a Multidisciplinary Clinical Research Center  
**SAMPLE OF SUGGESTED FORMAT**

Page #

I. General Material	
A. Face Page.....	
B. Abstract.....	
C. Key Personnel.....	
D. Table of Contents – this page, Exhibit I.....	
E. Consolidated Budget for the First Year – See Exhibit III.....	
F. Detailed Summary (Composite) Center Budget – See Exhibit IV .....	
G. Overall Budget for Entire Proposed Period of Support – See Exhibit V .....	
H. Biographical Sketch – Principal Investigator .....	
I. Other Biographical Sketches – for Key Personnel in alphabetical order .....	
J. Human Subjects Approval Dates (See Exhibit VI).....	
K. Human Subject Education Certifications .....	
L. Overall Resources.....	
1. Organizational Resources	
2. Table of Grant Support for Research Base – See Exhibit II .....	
3. Progress Report for renewal applications (if applicable)	
II. Narrative Sections	
A. Overview .....	
B. Qualifications of the Center Leadership.....	
C. Research Base for MCRC .....	
D. Institutional Environment and Resources.....	
1. Letters of Support .....	
III. Budgeted Components	
A. Title page - Administrative Core: .....	
1. Summary/Performance Site/Key Personnel .....	
2. Table of Contents .....	
3. Detailed Budget for Initial Budget Period.....	
4. Budget for Proposed Period of Support.....	
5. Budgets Pertaining to Consortium/Contractual Arrangements.	
6. Resources.....	
7. Research Plan .....	
a) Specific Aims .....	
b) Research Strategy .....	
(1) Leadership and Organizational Structure .....	
(2) Internal Advisory Committee .....	
(3) External Advisory Committee.....	
(4) Administrative/Leadership Goals .....	
(5) Data Sharing Plan.....	
c) Bibliography and References Cited.....	
d) Protection of Human Subjects (NA/see individual projects).....	

- e) Inclusion of Women and Minorities (NA/see individual projects) . . . .
- f) Targeted/Planned Enrollment Table (NA/see individual projects) . . .
- g) Inclusion of Children (NA/see individual projects)
- h) Consortium/Contractual Arrangements . . . . .
- i) Letters of Support . . . . .
- B. Title Page: Methodology Core: . . . . .
  - 1. Summary/Performance Site/Key Personnel . . . . .
  - 2. Table of Contents . . . . .
  - 3. Detailed Budget for Initial Budget Period . . . . .
  - 4. Budget for Proposed Period of Support . . . . .
  - 5. Budgets Pertaining to Consortium/Contractual Arrangements . . . . .
  - 6. Resources . . . . .
  - 7. Research Plan . . . . .
    - a) Specific Aims . . . . .
    - b) Research Strategy . . . . .
    - c) Bibliography and References Cited . . . . .
    - d) Protection of Human Subjects (NA/see individual projects) . . . . .
    - e) Inclusion of Women and Minorities (NA/see individual projects)
    - f) Targeted/Planned Enrollment Table (NA/see individual projects)
    - g) Inclusion of Children (NA/see individual projects)
    - h) Consortium/Contractual Arrangements . . . . .
    - i) Letters of Support . . . . .
- C. Title Page: Other Cores: see above example (optional)
- D. Title Page – Clinical Research Project 1: . . . . .
  - 1. Summary/Performance Site/Key Personnel . . . . .
  - 2. Table of Contents . . . . .
  - 3. Detailed Budget for Initial Budget Period . . . . .
  - 4. Budget for Entire Proposed Period of Support . . . . .
  - 5. Budgets Pertaining to Consortium/Contractual arrangements . . . . .
  - 6. Resources . . . . .
  - 7. Research Plan . . . . .
    - a) Specific Aims . . . . .
    - b) Research Strategy . . . . .
    - c) Bibliography and References Cited . . . . .
    - d) Protection of Human Subjects . . . . .
    - e) Inclusion of Women and Minorities . . . . .
    - f) Target/Planned Enrollment Table . . . . .
    - g) Inclusion of Children . . . . .
    - h) Consortium/Contractual Arrangements . . . . .
    - i) Letters of Support . . . . .
- E. Clinical Research Project 2: see above example
- F. Clinical Research Project 3: see above example (if applicable)
- G. Pilot/Feasibility Project see above example (optional)
- IV. Checklists . . . . .

**EXHIBIT II – GRANTS SUPPORTING THE RESEARCH BASE**  
**SAMPLE OF SUGGESTED FORMAT**

<b>Supporting Organization &amp; Grant Number</b>	<b>Key Personnel</b>	<b>Title</b>	<b>Project Period</b>	<b>Current Annual Amount</b>
NIH 5 R01 AR XXXXX	Chen, Chin-Mei (PI) Doe, John	New Therapeutic Agents for Autoimmune Disease	4/1/2009 – 3/31/2014	

**EXHIBIT III -- CONSOLIDATED BUDGET FOR THE FIRST YEAR OF REQUESTED SUPPORT**

*SAMPLE OF SUGGESTED FORMAT*

<b>BUDGET CATEGORY</b>	<b>Administrative Core</b>	<b>Methodology Core</b>	<b>CORE B</b>	<b>Project 1</b>	<b>Project 2</b>	<b>Project 3</b>	<b>Project 4</b>	<b>D/F1</b>	<b>TOTAL ALL UNITS</b>
PERSONNEL									
CONSULTANT COSTS									
EQUIPMENT									
SUPPLIES									
TRAVEL									
INPATIENT COSTS									
OUTPATIENT COSTS									
ALTERATIONS/RENOVATIONS									
OTHER EXPENSES									
SUBTOTAL DIRECT COSTS									
CONSORTIUM/ CONTRACT COSTS									
<b>TOTAL DIRECT COSTS</b>									

