National Center for Research Resources
National Institutes of Health
Department of Health and Human Services

Division of Research Infrastructure Program Guidelines

Research Centers in Minority Institutions (RCMI) Program
RCMI Faculty Development (FD) Award
RCMI Clinical Research Infrastructure Initiative (RCRII)
RCRII Clinical Research Faculty Development (CRFD) Award
RCMI Planning Grant (PG)

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GLOSSARY

RESEARCH CENTERS IN MINORITY INSTITUTIONS (RCMI) PROGRAM

PURPOSE

The RCMI Program is designed to expand the national capability for research in the health sciences by providing grant support to predominantly underrepresented minority institutions that offer the doctorate degree in the health professions or in a health-related science.

The primary goal of the RCMI Program is to enable predominantly underrepresented minority health professional schools and graduate institutions to become more successful in obtaining competitive extramural support for the conduct of biomedical and/or behavioral research.

The Program assists eligible institutions in strengthening their research environment by improving their human and physical resources for the conduct of biomedical and/or behavioral research. These grants also provide limited support for developmental and pilot projects and for collaborative research projects. The Program also expands the capacity for clinical research at eligible minority institutions that have affiliated medical schools by providing resources to develop the appropriate infrastructure.

ELIGIBILITY REQUIREMENTS

The RCMI Program develops the research infrastructure (e.g., renovation of biomedical and clinical research laboratories and animal facilities, recruitment of new faculty, support of pilot projects, acquisition of research equipment) of institutions with a traditionally high (50 percent or more) enrollment of students underrepresented in biomedical sciences (African American,

Hispanic, Native American, Alaskan Native, Native Hawaiian, and Pacific Islander) and that award doctorates in the health or health-related sciences. Eligible academic institutions within the United States and its territories must award an M.D., D.D.S., Pharm.D., D.V.M. or other doctoral degree in the health professions and/or a Ph.D. in the health or health-related sciences.

MECHANISM OF SUPPORT

The G12 support mechanism is used for these minority research resource center grants.

The applicant will be solely responsible for planning, directing, and executing the grant award. The total requested project period may not exceed five years. Awards of up to $1.5 million/year (direct costs) per institution may be requested. Support for developing an infrastructure for research related to AIDS, cerebrovascular and cardiovascular diseases, diabetes mellitus, human genome research, or other high-priority RCMI Program initiatives is exempt from this dollar limitation.

In accordance with NCRR policy, the recurring direct costs (direct costs excluding equipment and other one-time costs) requested for the first year of a competing continuation (Type 2) center application cannot exceed the final non-competing year's direct recurring costs budget by more than 20 percent. Where this policy may significantly limit the scope of the proposed program, the applicant may request a waiver of the 20-percent ceiling. A letter, clearly justifying the request for a waiver, must be submitted to the Director, Division of Research Infrastructure, six weeks prior to the application receipt date. The waiver of the ceiling must be approved in writing by the Director, DRI, before the Center's competing continuation application may be submitted.

Supplemental grant applications that will complement the approved scope of the parent grant may be submitted during the first three years of a five-year project period. Applicants are encouraged to discuss these plans with Program staff. Supplemental applications may not exceed 25 percent of the approved budget of the parent grant, or $400,000 in direct costs per year.

ALLOWABLE COSTS

Requested allowable costs of activities should focus primarily on the establishment of biomedical research infrastructure at the applicant institution. All requested items must be related to the needs identified in the institution's RCMI implementation plan and be specifically and thoroughly justified.

RCMI funds are awarded and may be used only for specifically approved activities, not as discretionary funds for formula-type or general distribution within the institution, and not for broadly defined institutional needs. Thus, in managing RCMI funds, there must be a clear focus on the institutional development plan as proposed and approved for funding.

CENTRAL FACILITIES

Support of central facilities and resources should be requested only in proportion to their use for RCMI goals. The development of core laboratories and acquisition of state-of-the-art instrumentation is encouraged. Requests for core laboratories must include documentation that the core will be utilized by at least three projects conducted by different investigators.

RENOVATIONS

Costs for renovations associated with core laboratories and pilot projects may not exceed $500,000 per year, or one-third of the total direct costs, whichever is less.

EQUIPMENT

Expenditures for equipment are limited to the amount justified via the peer review process.

PILOT PROJECTS

Requests for up to five relevant pilot projects and developmental and collaborative research projects may be included but may not exceed one-third of the direct cost budget in any given year.

CONTRACTUAL COSTS

Limited research-related costs at collaborating institutions are allowable as contractual costs. These costs must be related to the collaborative research, and should augment existing resources.

STUDENT DEVELOPMENT

Support for up to four graduate students may be requested in the parent RCMI application at a cost not to exceed $34,200 per student per year. Support for these positions should be included in the administrative budget. A detailed mentoring plan for these students must be included.

OBJECTIVES AND SCOPE

BACKGROUND

The Congress noted in the FY 1985 appropriation language for NIH that "The Secretary's most recent annual report on health in the U.S. has focused renewed attention on disparities in health status between minority and white Americans," and that "Minority educational institutions have traditionally trained a large proportion of the professionals who provide health care to the minority community. Improving the quality of these institutions has long been a special concern of the Committee." Although "...a report on NIH initiatives with respect to historically black colleges and universities...finds that NIH funding for research and research training at minority institutions has grown dramatically since the 1960s..., it appears that predominantly minority institutions as well as the larger universe of smaller, less prominent four-year, public and private

colleges and universities, which provide undergraduate training for a significant number of our nation's research scientists have not shared adequately in the growth of NIH extramural program."

"Therefore, the Committee has included $10,000,000 in the appropriation for NIH Office of the Director to be used to strengthen the research environment in educational institutions which offer the degrees in the sciences related to health but which heretofore have not received significant amounts of NIH support.... A portion of these funds should be used to establish research centers in those predominantly minority institutions which offer doctoral degrees in the health professions or the sciences related to health. Another portion of these funds should be used to develop research in other institutions which offer undergraduate or graduate degrees in the sciences related to health but which historically have not been major participants in NIH programs."

NIH established the RCMI Program in September 1985 by funding seven RCMIs for a total of $5 million.

PROGRAM CHARACTERISTICS

Governance

Principal Investigator

The Principal Investigator (PI) should be the President of the applicant institution or his/her designated representative for implementation of the institution's RCMI Program. In addition, the governance structure must include a Program Director (PD), and an RCMI Advisory Committee (RAC), as described below. The PI should be available for consultation with the PD to resolve issues related to the management of the RCMI grant. The PI selects the members of the RAC and is responsible for the overall development of the RCMI program at the grantee institution.

Program Director

The Program Director (PD) is nominated by and responsible to the PI, and must be an experienced biomedical scientist willing to devote the time and effort necessary for effective management and implementation of the institution's RCMI program. The PD is responsible for coordinating and managing the program in a manner consistent with the overall institutional plan for strengthening health sciences research capability as presented in the RCMI grant application, and for facilitating continued support of resources initially provided by the RCMI Program. The PD is responsible for the organization and operation of both the administrative and research and research-related efforts. The PD must be recommended for approval through the NCRR peer-review process or approved by the Director, DRI, if changes are made after peer review.

RCMI Advisory Committee

An RCMI Advisory Committee (RAC) that is advisory to the PI and PD must be established prior to submission of the application, as part of the application development process. Neither

the PI nor the PD may serve as the chairperson or be a voting member of the Committee. The RAC must be composed of an external subcommittee and an internal subcommittee. Depending on the scope and complexity of the RCMI program, each of these subcommittees may consist of eight to twelve members. Ideally, the members should be appointed on a rotating basis. The efforts and recommendations of these subcommittees should be coordinated. Meetings of the external subcommittee must be held at least annually; the internal subcommittee must meet at least quarterly. Official minutes of these meetings must be kept on file. It is particularly important to document problems and issues, along with any necessary recommendations.

Conflicts of interest (or the appearance of conflicts of interest) must be avoided in selecting members and at all times in carrying out the Committee's responsibilities. For this reason, consultants to or collaborators with RCMI-supported pilot projects may not be members of the external subcommittee.

It is essential that the RAC be knowledgeable of the institution's strengths and weaknesses in biomedical research capabilities, needs, and overall goals. It should possess among its members the experience and knowledge to provide appropriate guidance for the program, and identify and recommend expert consultation from other leaders in specific scientific disciplines as needed to provide the critical mentoring and other input necessary to develop and maintain a competitive RCMI program.

Functions of the RAC include:

- Providing advice and guidance on planning, developing, implementing, and evaluating RCMI program-related activities
- Developing operational policies for the program
- The external subcommittee
- conducts institutional self-assessment
- develops concepts
- helps to plan the program
- structures and critiques draft grant applications
- evaluates progress toward stated goals
- recommends changes, refinements, and improvements
- encourages faculty development and mentoring
- identifies alternative resources
- assures that significant efforts are being made to support the program and maintain a productive competitive research environment
- The internal subcommittee
- develops general operating policies
- monitors overall operations and program management
- recommends program priorities
- regularly monitors program accomplishments
- helps in the identification of other resources
- Both subcommittees
- oversee application development and make recommendations throughout the process, from development of concept and scope to the final content

- identify external peers to evaluate the scientific merit of pilot projects
- assure that programmatic issues or concerns raised during NCRR staff reviews are addressed appropriately prior to formal submission of the application

By continuous monitoring of the funded program, the RAC assures a high-quality effort, clearly focused on achievement of the institution's stated goals for expanding its biomedical research capacity. An active RAC provides for prompt resolution of problems, periodic evaluation of all research-related activities, and timely adjustments when indicated for improved program performance.

Nature and Scope

The nature and scope of an RCMI application may vary widely in different institutional settings. However, based on the 2000 evaluation of the RCMI Program, the RCMI application must be "focused on developing specific areas of research, rather than being broad-based and directed toward many different scientific areas." Each applicant must assess and address its own needs. The applicant must describe and justify how existing and requested resources will be utilized to implement the institutional plan to create and maintain an environment and framework suitable for achieving the objectives of the RCMI program.

Program plans for enhancement of biomedical research capacity must be consistent with the long-range goals of the applicant institution and must include an evaluation component to determine the extent to which program goals are achieved.

Once the general approach for an RCMI program has been determined, efforts can be focused on developing the specific research and research-related infrastructure necessary to implement the plan. The RCMI Program is designed to allow maximum flexibility in requesting the types of research resources required for accomplishing RCMI program goals at the applicant institution. The most important criterion for inclusion of any component in the RCMI application is the extent to which the activity will enable the program to achieve the stated goals.

While it is highly desirable for a proposed RCMI program to include areas with major impact on diseases and health problems of special importance to minority populations, at a minimum the proposed RCMI program must be suitable as the basis for expanding research and research training in health-related areas.

Research Infrastructure

The aforementioned flexibility notwithstanding, the major focus of RCMI funding is institutional resource development, i.e., research infrastructure. In most instances, at least two-thirds of the requested funds are expected to be directed to multi-user resources, rather than to support individual research projects.

The RCMI Program is not intended to duplicate or supplant funding from the wide array of programs currently available for support of specific investigator-initiated research projects.

Some examples of infrastructure that may be appropriate for support are:

- A Program Director and staff
- Recruitment and hiring of additional faculty investigators and research support personnel
- Mentoring of faculty
- Renovation of laboratories and animal facilities
- Development of core laboratories and new technologies
- Acquisition of state-of-the-art instrumentation
- Enhancement of grants management and research development offices (support will be limited to the initial application and phased-out in subsequent renewals)
- Biostatistical and computer resources
- Other institutional infrastructure activities that will enable the institution's faculty to become more competitive in obtaining support for biomedical and behavioral research

Pilot Projects

Note: No more than 5 pilot projects can be proposed.
Developmental or pilot investigations may receive no more than five years of support (even if the project covers two different project periods) if they are considered essential to the development of a critical mass of faculty in a research discipline identified in the corporate plan as an institutional research development goal. A minimum time commitment of 50 percent or more is required for the principal investigator of a pilot project, and the request for support must include a realistic plan for development of the faculty member's research program that will enable the investigator to obtain independent support within the five-year period. New pilot projects may be added only after they are peer-reviewed and approved as part of a competing application for additional (supplemental) support ("Type 3").

The research progress/productivity of each pilot project will be evaluated annually by the external advisory committee of the RAC using traditional metrics. Pilot projects may be terminated based on the committee's recommendation. In addition, the investigator of a pilot project must submit one or more investigator-initiated external peer-reviewed grant applications during the first three years of a pilot project in order to receive continued support for the fourth and fifth years.

Use of collaborations and consultative resources is strongly encouraged. Pilot project support may not exceed one-third of the direct costs requested in the parent application.

A clear plan for the development and graduation of investigators who are provided research support from the RCMI program should be included. This plan should detail the long-term goals as to how the institution intends to make the transition from the research support of multi-disciplinary RCMI projects to competitive grant support through applications submitted by its faculty members to relevant NIH institutes and centers or to other appropriate Federal or non-Federal agencies or organizations. This must include both formative and summative evaluation strategies with specific milestones. Faculty development should include a mentoring plan for junior investigators that involves oversight by established senior faculty members assigned as mentors, constructive evaluations by members of the RAC, and coordinated management of all of these individuals by the PI of the RCMI program.

Each junior investigator should be assigned to at least one mentor. The mentor is an established faculty member who has demonstrated the ability to advise others through the acquisition of external support and the maintenance of an independent research laboratory. In some instances a suitable mentor may not be available within the applicant's institution and it is therefore acceptable to enlist appropriate mentors from outside institutions. Mentors may request between 10- and 15-percent effort and should be listed in the Administrative Budget section of the application and not in the individual projects' budget sections. The junior investigators should clearly designate in the text the identity of their mentors and describe the qualifications, both scientific and advisory, that make them appropriate to assist in the oversight of the project.

The award of a Research Project Grant (RPG) to the principal investigator of a pilot project should be viewed as a milestone and a basis for that investigator's assuming a new role (e.g., becoming a mentor) in the RCMI program. In addition, an investigator may be graduated from the RCMI program if the PI and/or the RAC deem that the investigator has achieved independent status.

The receipt of an award that overlaps or is significantly similar to that described in the RCMI program is sufficient justification to graduate a junior investigator from the program. However, if the specific aims of the investigator's RPG are significantly different from the project described in the RCMI, then the investigator has an obligation to remain in the program to complete his/her RCMI project.

UP-TO-DATE INFORMATION

All applicants and grantees must ensure they have the latest information about the RCMI Program and its policies and procedures by visiting the RCMI Web page at http://www.ncrr.nih.gov/resinfra/ri_rcmi.asp.

APPLICATION PROCEDURES

GENERAL INFORMATION

Applicants must use the *Application for a Public Health Service Grant*, form PHS 398 (Rev. 04/2006), following standard instructions except where modified according to the RCMI section of the Appendix to these Program Guidelines: *Supplemental Instructions for the PHS 398 Grant Application - RCMI*.

Applicants must also review the **General Information for DRI Applicants and Grantees** section of these Guidelines for other important information.

An applicant planning to submit a grant application with $500,000 or more in direct costs for any year is required to contact RCMI Program staff at least six weeks before the anticipated submission date. If the requested dollars are significantly greater than $500,000, then approval should be sought even earlier. The Principal Investigator must include a cover letter with the application identifying the Program staff member and stating that NCRR has agreed to accept

assignment of the application. An application received without indication of prior staff concurrence and identification of program staff contacted will be returned to the applicant without review. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html

It is important to communicate with RCMI Program staff early in the planning process to ensure that both national Program goals and institutional goals are being addressed appropriately in the proposed approach for expanding health-related research capacity. Successful applicants have found it useful to maintain communication with RCMI Program staff throughout the application development process. Staff is available to provide programmatic advice in the preparation of an application.

The RAC must be an integral part of the planning and development process that should begin with a self-assessment of the institution's current status in terms of its biomedical and/or behavioral research capabilities.

Once existing resources and competencies have been identified, a general approach can be formulated to move the institution to a higher level of competitive health-related research capability in concert with the national RCMI Program goal. It is critically important to keep in mind that to be a meaningful and successful effort, the approach chosen must contribute to and be synergistic with the overall mission and long-range plans of the institution.

The general plan must be realistic: it must be achievable within the proposed time-frame and convincing as a logical approach to expand biomedical/behavioral research capability at the applicant institution, taking into account the institution's previous track record in these areas and its current developmental status. Communication with RCMI Program staff, directors of successful RCMI programs at similar institutions, and scientific leaders in the research areas of interest may be useful to the RAC and to institutional officials in formulating a workable plan. It is important to seek constructive evaluations of each research/research-related RCMI activity for which funds are sought from established scientists in the relevant disciplines. These critiques of draft proposals, which may be obtained simultaneously with Program staff feedback, have proven invaluable to many successful applicants.

SPECIFIC REQUIREMENTS

Special attention should be given to all budget justifications, review of protocols for use of human subjects or vertebrate animals, and the application instructions for detailed information in these areas. It is crucial that the applicant refer to the sections in the *Application for a Public Health Service Grant,* form PHS 398 (Rev. 04/2006) that address these items, and follow the instructions carefully (see *Application for a Public Health Service Grant,* form PHS 398 (Rev. 04/2006); *Guidance for Preparing the Human Subjects Research Section*, pages 36 through 39; and *Vertebrate Animals*, page 39 of the Instructions).

In addition, it is important to emphasize that for all competing continuation and supplemental applications, a critical component is an assessment of the impact of RCMI grant funds in the following areas:

- Institutional development
- Organizational and administrative improvements
- Research environment
- Research infrastructure
- Faculty development and achievement
- Research productivity

Baseline information on all elements of the criteria identified to measure progress and program impact (**Evaluation Plan**, below) is necessary and must be included in the initial application for RCMI support. Institutional officials and the RAC need to ensure that all of these elements are addressed in the monitoring and evaluation process so that appropriate information is available for annual progress reports, periodic review of program accomplishments, and guidance for improving program performance.

These categories are described in further detail in the supplemental instructions.

SUGGESTED STEPS IN PLANNING AN RCMI APPLICATION

- Start by thoroughly reviewing these Guidelines 12 to 18 months before target submission date
- Communicate with RCMI Program staff as soon as there is interest in applying
- Establish an RAC and use it throughout the planning process
- Conduct a self-assessment to determine the current status of health-related research resources (physical, human, and financial) at the institution
- Communicate with directors of other RCMI programs and scientific leaders in the areas to be developed for further insight and suggestions
- Develop a brief concept paper outlining the corporate plan to move to a more competitive level in biomedical research within the proposed period of RCMI support; provide the concept paper
- to the RCMI Program staff for programmatic advice on the nature and scope of the overall plan, preferably eight to twelve months before submission
- Develop specific components as needed to implement the plan, focusing on infrastructure development; seek critiques from peer-reviewers for each activity in order to eliminate weak components and to strengthen others
- Two months before submission, obtain additional feedback on specific components from established scientists
- Obtain and include appropriate reviews, approvals, and supporting documentation for use of human subjects, animal welfare, and biohazards in the application per instructions for the *Application for a Public Health Service Grant,* form PHS 398 (Rev. 04/2006)
- Submit the application by the deadline (See **Receipt, Review, and Award Cycles**, below)

<u>REVIEW CONSIDERATIONS</u>

REVIEW PROCEDURES

Upon receipt, applications will receive an independent, objective, administrative review by Program staff using current policies and procedures that apply to all PHS applications.

Applications considered to be incomplete or not responsive to RCMI policies will be returned without further review. All complete applications will be reviewed for scientific and technical merit by the NCRR Research Centers in Minority Institutions and IDEA Review Committee (RCMI/IDEARC). Second-level review will be conducted by NCRR's National Advisory Research Resources Council (NARRC).

REVIEW CRITERIA

The primary criterion for the evaluation of an RCMI grant application is the direct impact the proposed program will have on enhancement of the applicant institution's health-related research program, based on the assessment of the specific plan proposed for achieving the overall program goals identified by the institution. The value of each component will be determined by the extent to which that activity will contribute to the stated RCMI goals.

Major Factors

Major factors that will be considered in the overall evaluation of the application include:

- general Plan for Expanding the Biomedical Research Capabilities;
- organizational Structure and Administration of the Program;
- appropriateness of the RCMI Advisory Committee (RAC) and other consultative resources for guiding the RCMI Program;
- for competing continuation and supplemental applications, progress of the institution in achieving previous goals of its RCMI program; for new applications, institutional history that is relevant to the proposed RCMI program;
- pilot studies and developmental or collaborative research projects proposed;
- assessments of infrastructure components and feasibility of achieving what is proposed with the resources requested;
- appropriateness of the requested budget
- formative and summative evaluation plan
- explicit attention to use of animals and human subjects protection and appropriate inclusion of women, minorities and children as noted on page 38 of the Instructions for the *Application for a Public Health Service Grant*, form PHS 398 (Rev. 04/2006).

For competing continuation and supplemental applications, the institution's track record and success in carrying out previous institutional goals for its RCMI program is a critical and essential element of the review; specific measures to be used to evaluate progress are listed under **Evaluation Plan**, below.

General Plan for Expanding Biomedical Research Capabilities

All aspects of planning and goal setting for the RCMI program will be evaluated, including:

- Identification and prioritization of major research development areas
- Adequacy of the planning process and self-assessment of current biomedical research capabilities
- Appropriateness of future institutional RCMI goals, including plans for reasonable expansion

of biomedical research capacity within the time-frame proposed and for sustaining this enhanced capacity beyond the period of the grant support
- Adequacy of institutional commitment to biomedical research
- Appropriateness of an institutional evaluation plan
- Consistency of long-term goals with enhancement of biomedical research and how the evaluation component of the program is functioning

Organizational Structure and Administration of the Program

All aspects of organizational structure and administration of the program will be evaluated, including:

- Appropriateness of the organizational and administrative structure;
- Organizational changes, if any, designed to enhance biomedical research activities;
- Rationale and need for these resources to achieve institutional RCMI goals, including the potential for developing high-quality research programs;
- Adequacy and appropriateness of administrative leadership for implementing and managing the resources, including collaborative and consultative arrangements;
- Appropriateness of the plan for the resources, including objectives, implementation strategy and timetable, and involvement of the RAC;
- Appropriateness and effectiveness of the organizational and administrative structure and lines of authority within the Center;
- The qualifications and experience of the PD and his/her ability to provide effective leadership in implementing the institutional RCMI plan; and
- Institutional commitment to biomedical research and to the RCMI program.

RCMI Advisory Committee(s)

Appropriateness of the RCMI Advisory Committee (RAC) and other consultative resources for guiding the RCMI Program will be evaluated, including the following:

- The appropriateness of the composition of the RAC to provide the needed guidance for the RCMI program;
- For the external subcommittee of the RAC, the degree of involvement and appropriateness of the members' scientific and administrative expertise;
- The role of the internal subcommittee of the RAC in the review of the pilot research studies and developmental/collaborative research projects; and
- The role in developing the RCMI center grant application and other RCMI-related grant applications.

Description of the Institutional Progress in Achieving RCMI Program Goals (competing continuation applications only)

Progress of the institution in achieving previous goals of its RCMI program during the funding period (usually five years) will be evaluated. The following factors will be evaluated:

- Specific examples of how these goals were achieved and how they enhanced research-related activities and institutional development;
- If previous goals were not fully achieved, specific examples of the shortcomings and how they affected progress of institutional development;
- The quality and number of new biomedical/behavioral research faculty recruited;
- The strengthening and enhancing of institutional research support services;
- Institutional incentives and support for research development;
- Research productivity as measured by the number and quality of peer-reviewed publications, scientific presentations, and successful grant applications; and
- For amended applications, response of the present application to the previous critiques.

For **new applications**, history that is relevant to the proposed RCMI program, as well as a detailed and thorough description of the current status of the institution's research infrastructure, capabilities and activities, and a self-evaluation, will be expected. Baseline data must be included in new applications; data demonstrating program impact must be provided in all competing continuation applications. The following categories of data must be provided:

- **Institutional Development** as measured by
- number and quality of the biomedical/behavioral research faculty
- plans for further developing the biomedical/behavioral research faculty, including appropriate mentoring plans and time commitments for junior faculty
- number of graduate degrees awarded in the biomedical/behavioral sciences
- enhancement of institutional incentives and support for research development
- strengthening/enhancement of institutional research support services
- number of postdoctoral fellows and research associates at the institution

- **Organizational and Administrative Improvements** as measured by
- major organizational changes that enhanced biomedical and behavioral research
- increased proficiency for grants and contracts management

- **Improvement in the Research Environment** as measured by
- hiring of skilled technical personnel
- development of new or enhanced research and biotechnological capabilities (give examples)
- number and quality of scientific seminars and colloquia sponsored by the institution
- number of visiting scientists, nature of interactions, and benefits gained

- **Research Infrastructure Improvement** as measured by
- improvements and expansion of the facilities dedicated to biomedical/behavioral research
- acquisition and utilization of major instrumentation

- **Faculty Development and Achievement** as measured by
- scientific honors and awards to faculty
- number of grant applications submitted for peer-review and number funded
- participation in peer-review activities
- election to national and international professional societies
- participation of faculty members in peer-review activities outside of the institution

- involvement in planning national and international scientific meetings

- **Research Productivity** as measured by
- number of peer-reviewed faculty publications
- number of presentations at major scientific meetings
- number and dollar amount of research grants and contracts awarded
- number and nature of active collaborative research activities

Research/Research-Related Activities

Assessments of infrastructure components are not based solely on evaluations of individual scientific protocols, but rather on a broader analysis of the feasibility of achieving what is proposed with the resources requested. In addition, it must be recognized that for a developmental program such as this, a major initiative may be implemented at any time during a five-year project period; i.e., not only in the first year or two, as might be expected for a specific research project. Therefore, the inclusion of requests for facilities, major equipment, and/or additional faculty in year three or year four (for example) may be justifiable, provided that the application adequately describes unmet need and plans for the future use of the resource consonant with the institutional plan.

Infrastructure Components and Core Laboratories

Major factors to be considered in the evaluation of each infrastructure component and/or core laboratory include:

- Rationale and need for the resource to achieve institutional RCMI goals, including the potential for developing a high-quality research program;
- Importance of the facility to the research of the faculty, including RCMI-supported pilot projects and research by Center faculty that is supported from other sources;
- Number and qualifications of investigators utilizing the core facility;
- Number of projects or protocols that utilize the core facility, including the demonstrated need for current or requested equipment (the existence of a current and/or projected user community is critical);
- Adequacy and appropriateness of administrative and scientific leadership for implementing and managing the resources, including collaborative and consultative arrangements;
- Qualifications of the director of the core facility;
- Appropriateness of the plan for the resource, including objectives, implementation strategy and timetable, SOP for use and management of the facility; and involvement of the RAC;
- Reasonableness of plans to institutionalize support for this resource over time; and
- For competing continuation and supplemental requests, the assessment of progress toward original goals for the infrastructure component is an essential element in the review

Pilot and Developmental Projects

The review of pilot studies and developmental or collaborative research projects is not based solely on the traditional considerations used for peer evaluation of scientific merit (pilot data are

not required). Reviewers also take into account the preliminary nature of the proposed studies and, in a broader sense, the extent to which the research activity will contribute to the goals of the RCMI program. To the extent appropriate, all pilot research activities will be evaluated according to NIH review guidelines for scientific projects, i.e., the five criteria used for scientific merit review: significance, approach, innovation, investigator, and environment.

Major factors to be considered in the evaluation of pilot and developmental projects include:

- Significance and relevance of the proposed research problem
- Potential of the research to advance the concepts or methods that drive the field and scientific knowledge in general
- Approach, including appropriateness of research plan, specific aims, experimental design, methodology, consideration of alternatives, data analysis, scope, and timetable
- Innovation is a significant consideration in some, though not all, types of research projects; innovation is characterized by novel concepts, approaches, or methods, original and innovative aims, development of new methodologies, or paradigms challenged
- Investigator training and qualification, and the appropriateness of the research to the experience level of the Principal Investigator and other personnel
- Environment in which the research will be performed
- adequacy of resources
- availability of any specialized facilities needed
- institutional support for the protocol
- extent to which the research takes advantage of any unique features of the scientific environment or employs productive collaborative arrangements
- Relevance of proposed project to the institutional plan for expansion of biomedical research capacity and enhanced opportunities for collaboration
- As warranted, explicit attention to human subjects protection and appropriate inclusion of women, minorities and children as noted on page 38 of the Instructions for the *Application for a Public Health Service Grant*, form PHS 398 (Rev. 04/2006).
- As warranted, explicit attention to use of animals in research.

Budgets

Appropriateness of the requested budget and proposed project period will be evaluated. A complete and detailed budget and budget justification is necessary for each subsection of the application and must be in agreement with the Overall Summary Budget.

Formative and Summative Evaluation Plan

In addition to the measures of institutional infrastructure as indicated above, every proposed RCMI Program must include a formative and summative evaluation plan in the application. This plan must provide the details of how the institution will evaluate whether or not the program achieved its goals and objectives as well as a program's progress and effectiveness. The emphasis of the evaluation activities for the RCMI Program should be on improvement of the program and capacity-building at the institution. Improvement of the program is defined by the specific goals and measurable objectives the institutions set for themselves in the program

planning. The institution must identify an independent evaluator, not a part of the RCMI Program, who will perform the evaluation. The completed evaluation plan should be included as a major section of the proposal.

The plan will be evaluated based on the:
- Credentials of the evaluator and/or evaluation company;
- Adequacy of the evaluation planning process and methods for data collection and analysis; and
- Adequacy of the evaluation budget for the planned data collection and analysis.

AWARD CRITERIA

The Principal Investigator will be notified of the Council's recommendation shortly after it meets. Award decisions will be based on the technical merit of the application as determined by peer-review, amounts recommended through the peer-review process, other programmatic priorities to ensure a balance among the various types of programs, populations served, and/or geographic distribution. Grant awards are subject to availability of funds.

Support of an application for competing continuation of an RCMI program for an additional project period will be contingent upon the outcome of peer and Council review and the availability of funds.

REPORTING/MONITORING

The following material supplements the **General Information for DRI Applicants and Grantees** section of these Guidelines.

ANNUAL PROGRESS REPORT

Grantees are encouraged to utilize the categories for evaluation of the impact of RCMI support, listed under **Evaluation Plan**, above, in annual progress reports. This process will serve to document benchmark achievements on a regular basis, which should be helpful in compiling this required information when developing an application for competing continuation of the program.

OTHER EVALUATIVE MECHANISMS

Midway through the project period (at the end of the third year of a five-year RCMI project period, for example) or as deemed necessary by NIH staff, administrative staff visits with a team of external reviewers may be conducted to assess the progress of the grantee institution's RCMI program and to estimate the future impact that can be expected from continuing RCMI support.

Alternatively, grantees may benefit significantly by conducting their own mid-course assessment utilizing external advisory committee members and other reviewers appropriate for this type of evaluation. These analyses may lead to mid-course adjustments and a better-informed basis for future plans. The RCMI Program office must approve recommended changes prior to implementation.

In addition, administrative visits by NIH staff will be arranged when needed to facilitate achievement of both individual institutional as well as national RCMI goals.

INQUIRIES

Written and telephone inquiries concerning the RCMI Program are strongly encouraged, especially during the planning phase of the application. Please contact the NCRR staff listed in the **Inquiries** section of these Guidelines.

RCMI FACULTY DEVELOPMENT (FD) AWARD

PURPOSE

The FD award provides up to five years of career development support for faculty at Research Centers in Minority Institutions (RCMI) grantee institutions to enable them to become independent biomedical research investigators.

ELIGIBILITY REQUIREMENTS

Eligibility for this Program is limited to institutions with a funded RCMI grant.

A candidate for a Faculty Development award must have a Ph.D. or doctoral degree in the health professions and a full-time faculty appointment at an RCMI grantee institution. The candidate must be a U.S. citizen or hold a permanent immigration visa. The candidate may not have been the Principal Investigator on an independent peer-reviewed grant within five years prior to the funding of the application. The primary mentor and other participating scientists may be based at the applicant institution or at other performance sites.

MECHANISM OF SUPPORT

The application must be submitted as a competing supplement to a funded RCMI program grant. The requested budget may not go beyond the project period of the parent RCMI grant. The

award is not renewable.

ALLOWABLE COSTS

SALARY

For candidates who have completed sub-specialty (fellowship) or post-doctoral training, NCRR will provide a salary for the award recipient of up to $75,000 per year plus fringe benefits for a minimum of 75-percent effort. Although a greater effort may be proposed, the maximum allowable salary is $75,000. The institution may supplement the NCRR contribution with other funds up to a level that is consistent with the institution's salary schedule and the salary of comparable positions at the institution. For those with no sub-specialty or post-doctoral training, the maximum salary is $60,000. Institutional supplementation of salary must not require duties or responsibilities that would interfere with the purpose of the award.

The total salary requested must be based on a full-time, 12-month staff appointment. It must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the same department. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure.

RESEARCH DEVELOPMENT SUPPORT

NCRR will provide up to $25,000/year for:

- Tuition, fees, and books related to research career development
- Research expenses such as supplies, equipment, and technical personnel
- Travel to scientific meetings or training
- Other justified expenses related to the FD program

RESTRICTIONS ON USE

Funds may be used only for the specified candidate and may not be used for any other purpose. If a funded FD position is terminated earlier than expected, the RCMI Program must be notified in writing. These funds are to remain unexpended, unless prior approval is obtained from NCRR.

OBJECTIVES AND SCOPE

ENVIRONMENT

Faculty development activities must be conducted within a well-established research career development program with highly qualified mentors. These activities may occur totally, or in part, at the RCMI grantee institution or at other institutions, depending on the needs of the program, the availability of mentors, and other resources for a quality career development program.

MENTOR(S)

A primary mentor must be identified who, together with the applicant, is responsible for the planning, direction, and execution of the program. Candidates may nominate additional mentors as appropriate.

PROGRAM

Up to five years of didactic and research activities may be supported. The program must be designed and tailored to fit the specific needs of the applicant within the time-frame proposed. At least 75-percent full-time professional effort must be devoted to the goals of the program; the remainder may be devoted to other teaching or research pursuits consistent with the objectives of the FD award.

EVALUATION

In carrying out its stewardship of human resources-related programs, NCRR may request information essential to an assessment of the effectiveness of this program. Accordingly, recipients are hereby notified that they may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

SPECIAL LEAVE

Leave to another institution, including a laboratory in a foreign country, may be permitted if directly related to the purpose of the award. Only local, institutional approval is required if such leave does not exceed three months. For longer periods, prior written approval from NCRR is required. To obtain prior approval, the award recipient must submit a letter describing the plan to the Director, DRI, countersigned by her/his department head and the appropriate institutional official. A copy of a letter or other evidence from the institution where the leave is to be taken must be submitted to assure that satisfactory arrangements have been made. Support from the career-award will continue during such leaves.

Leave with or without award support may not exceed 12 months. Such leave requires the prior written approval of NCRR and will be granted only in unusual situations. Support from other sources is permissible during the period of leave. Such leave does not reduce the total number of months of program support for which an individual is eligible, provided sufficient time remains in the project period of the parent grant. Parental leave will be granted consistent with the policies of NIH and the grantee institution.

TERMINATION OR CHANGE OF INSTITUTION

When a grantee institution plans to terminate an award, NCRR must be notified in writing at the earliest possible time so that appropriate instructions can be given for termination. If the

individual is moving to another RCMI-eligible institution, career-award support may be continued provided:

- A new career-award application is submitted by the new institution
- All conditions of the award are met at the new institution
- The period of support requested is no more than the time remaining within the existing award period
- The new application is submitted far enough in advance of the requested effective date to allow the necessary time for review

A final progress report, invention statement, and Financial Status Report are required upon either termination of an award or relinquishment of an award in a change of institution situation.

UP-TO-DATE INFORMATION

All applicants and grantees must ensure they have the latest information about the RCMI FD Award and related policies and procedures by visiting the RCMI Web page at http://www.ncrr.nih.gov/resinfra/ri_rcmi.asp.

APPLICATION PROCEDURES

Applicants must use the *Application for a Public Health Service Grant*, form PHS 398 (Rev. 04/2006), following standard instructions except where modified according to the RCMI FD section of the Appendix to these Program Guidelines: *Supplemental Instructions for the PHS 398 Grant Application - RCMI*.

Applicants must also review the **General Information for DRI Applicants and Grantees** section of these Guidelines for other important information.

REVIEW CONSIDERATIONS

REVIEW PROCEDURES

Upon receipt, applications will receive an independent objective review using current policies and procedures that apply to all PHS applications. Incomplete applications will be considered unresponsive and will be returned for appropriate revisions. All complete applications will be reviewed for scientific and technical merit by the NCRR initial review group, Research Centers in Minority Institutions and IDEA Review Committee (RCMI/IDEARC). Second-level review will be conducted by NCRR's National Advisory Research Resources Council (NARRC).

REVIEW CRITERIA

The following review criteria will be used for RCMI FD applications:

Candidate Selection Process

- Appropriateness of the criteria used to identify and evaluate potential candidates
- Adequacy of participation by RCMI program governance (PI, PD and RAC)
- Effectiveness of the process

Candidate

Qualifications of the candidate, including:

- Quality of the candidate's academic record and relevant work experiences
- Potential to develop into an independent researcher
- Commitment to a biomedical research career

Career Development Plan

- Likelihood that the career development plan will contribute substantially to the scientific development of the candidate
- Appropriateness of the content and duration of the proposed didactic and research components of the program
- Consistency of the career development plan with the candidate's career goals and prior research experience
- Quality of the proposed training in the responsible conduct of research

Research Project

- Appropriateness of the research project
- to the stage of research development of the candidate
- as a vehicle for developing the research skills identified in the career development plan
- Relevance of the proposed research to the goal of the RCMI program
- Evaluation according to NIH review guidelines for scientific projects
- significance and relevance of proposed research problem
- potential of the research to advance the concepts or methods that drive the field and scientific knowledge in general
- approach, including appropriateness of research plan, specific aims, experimental design, methodology, consideration of alternatives, data analysis, scope, and timetable
- innovation is a significant consideration in some, although not all, types of research projects; innovation is characterized by novel concepts, approaches, or methods, original and innovative aims, development of new methodologies, or paradigms challenged
- investigator training and qualifications, and the appropriateness of the research to the experience level of the Principal Investigator and other personnel
- Environment in which the research will be performed
- adequacy of resources
- availability of any specialized facilities needed
- institutional support for the protocol
- degree to which the research takes advantage of any unique features of the scientific environment or employs useful collaborative arrangements

- Relevance of proposed project to the institutional plan for expansion of biomedical research capacity and enhanced opportunities for collaboration

Mentor(s)

For the primary mentor and other key investigators, the review committee will evaluate:

- Appropriateness of mentor's research qualifications in the area of the application
- Quality and extent of mentor's proposed role in providing guidance and advice to the candidate
- Previous experience in fostering the development of researchers
- History of research productivity and support

Research Environment

- Adequacy of research facilities
- Availability of appropriate educational opportunities
- Adequacy and availability of personnel and support services
- Quality and relevance of the environment for scientific and professional development of the candidate

Institutional Commitment

- Adequacy of the RCMI institution's commitment to the scientific development of the candidate to become an independent investigator
- Assurances that the institution intends for the candidate to be an integral part of its research program
- Appropriateness of institutional support and incentives available to the investigator after the FD experience

AWARD CRITERIA

The Principal Investigator will be notified of the Council's recommendation shortly after it meets. Award decisions will be based on the technical merit of the application as determined by peer-review, amounts recommended through the peer-review process, other programmatic priorities to ensure a balance among the various types of programs, populations served, and/or geographic distribution. Grant awards are subject to availability of funds.

REPORTING/MONITORING

Grantees must review and follow the instructions in the **General Information for DRI Applicants and Grantees** section of these Guidelines.

INQUIRIES

Written and telephone inquiries concerning the RCMI FD Program are strongly encouraged,

especially during the planning phase of the application. Please contact the NCRR staff listed in the **Inquiries** section of these Guidelines.

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RCMI CLINICAL RESEARCH INFRASTRUCTURE INITIATIVE (RCRII)

Major Factors

Major factors to be considered in the overall evaluation of the application include:

- Adequacy of the planning process, including self-assessment of current clinical research capabilities, concept development, and involvement of advisory resources
- Appropriateness of institutional RCRII goals, including plans for reasonable expansion of clinical research capacity within the time frame proposed and for sustaining this enhanced capacity beyond the period of grant support; an appreciation of the uniqueness of the institution and its current capacity to pursue clinical research is critical to this assessment
- Appropriateness of the organizational and administrative structure established to accomplish RCRII goals
- Qualifications, experience, and commitment of the PD, and his/her ability to provide effective leadership in implementing the institutional RCRII plan
- Appropriateness of the CRAC and other consultative resources for guiding the RCRII
- Adequacy of institutional commitment to clinical research
- Appropriateness and adequacy of the institution's evaluation plan
- Appropriateness of requested budget and proposed project period
- Scientific merit of pilot projects, qualifications of the investigators to conduct the research, and their potential for career development
- Diversity in staff – gender, race/ethnicity, academic rank
- Explicit attention to human subjects protection and appropriate inclusion of women, minorities and children as noted on pages 36-39 of the Instructions for the *Application for a Public Health Service Grant*, form PHS 398 (Rev. 04/2006).

The institution's track record and success in carrying out previous institutional goals for its RCRII is a critical and essential element of the review of competing continuation and supplemental applications. Specific measures to be used to evaluate progress are listed under **Evaluation Plan**, below.

Institutional and Administrative Plan

The adequacy of the planning process, including self-assessment of current biomedical research capabilities, budgeting, concept development, and involvement of advisory committees are major factors that will be considered in the overall evaluation of the application.

Description of the Institution

The progress of the institution in achieving the goals of its RCRII program during the funding period (usually five years) will be evaluated. For new applications, history that is relevant to the proposed RCRII, as well as a detailed and thorough description of the current status of the

institution's clinical research infrastructure, capabilities and activities, and a self-evaluation, will be expected. The following factors will be evaluated:

- Specific examples of how these goals were achieved and how they enhanced clinical research-related activities and institutional developments
- If previous goals were not fully achieved, specific examples of the shortcomings and how they affected progress of institutional development
- The quality and number of new clinical research faculty recruited
- The strengthening and enhancement of institutional research support services
- Institutional incentives and support for clinical research development
- Research productivity as measured by the number and quality of peer-reviewed publications, scientific presentations, and successful grant applications
- For amended applications, response of the submitted application to the previous critiques

General Plan for Expanding Clinical Research Capabilities

All aspects of planning and goal-setting for the RCRII will be evaluated, including:

- Identification and prioritization of major clinical research development areas
- Adequacy of the planning process and self-assessment of current clinical research capabilities
- Appropriateness of future institutional RCRII goals, including plans for reasonable expansion of clinical research capacity within the time-frame proposed and for sustaining this enhanced capacity beyond the period of the grant support
- Adequacy of institutional commitment to clinical research and appropriateness of an institutional evaluation plan
- Consistency of long-term goals with enhancement of clinical research and how the evaluation component of the program is functioning
- Organizational structure and administration of the program

Organizational and Administrative Structure

Appropriateness of the organizational and administrative structure; institutional commitment to clinical research and to the RCRII; and the qualifications, experience and commitment of the PD will be evaluated, using the following criteria:

- Organizational changes, if any, designed to enhance clinical research activities
- Rationale and need for these resources to achieve institutional RCRII goals, including the potential for developing high-quality research programs
- Adequacy and appropriateness of administrative leadership for implementing and managing the resources, including collaborative and consultative arrangements
- Appropriateness of the plan for the resources, including objectives, implementation strategy and timetable, and involvement of the CRAC
- Appropriateness and effectiveness of the organizational and administrative structure and lines of authority within the Center

- The qualifications and experience of the PD and his/her ability to provide effective leadership in implementing the institutional RCRII plan

Clinical Research Advisory Committee

Appropriateness of the Clinical Research Advisory Committee (CRAC) and other consultative resources for guiding the RCRII. As noted earlier, the CRAC must be composed of two subcommittees, external and internal. The CRAC will be evaluated using the following criteria:

- The appropriateness of the composition of the CRAC for providing the needed guidance for the RCRII
- The degree of involvement and appropriateness of the external subcommittee members' scientific and administrative expertise
- The role of the internal subcommittee in the review of the pilot research studies and developmental/collaborative research projects, including the involvement of women, minorities, and children in clinical studies
- The Committee's role in developing the RCRII center grant application and other RCRII-related grant applications

Budgets

Appropriateness of requested budget and proposed project period will be scrutinized. A complete and detailed budget and budget justification is necessary for each subsection of the application and must be in agreement with the Overall Summary Budget.

Evaluation Plan

Appropriateness and adequacy of the institution's plan for evaluation of both short-term and long-term goals of the RCRII and the relevance of these goals to the mission of the institution will be evaluated. The inclusion of adequate evaluation parameters, mechanisms, and timetables will be assessed.

Baseline data must be included in new applications. Data demonstrating program impact must be included in all subsequent applications. The application should address:

- **Plans for Institutional Development** measured by
- number and quality of clinical research faculty
- plans for further development of clinical research faculty, including appropriate mentoring plans and time commitments for junior faculty
- number of graduate degrees awarded in the health sciences
- enhancement of institutional incentives and support for clinical research development
- strengthening/enhancement of institutional clinical research support services
- number of postdoctoral fellows and research associates at the institution involved in clinical research

- **Organizational and Administrative Improvements** measured by
- major organizational changes that enhanced clinical research
- increased proficiency for grants and contracts management

- **Improvement of the Clinical Research Environment** measured by
- hiring of skilled technical personnel
- development of new or enhanced clinical research capabilities (give examples)
- number and quality of scientific seminars and colloquia sponsored by the institution
- number of visiting scientists, nature of interactions, and benefits gained

- **Improvement of the Clinical Research Infrastructure** measured by
- improvements and expansion of the facilities dedicated to clinical research
- acquisition and utilization of major instrumentation

- **Clinical Research Faculty Development and Achievement** measured by
- scientific honors and awards to faculty
- number of grant applications submitted for peer-review and number funded
- participation in peer-review activities
- election to national and international professional societies
- participation of faculty members in peer-review activities outside of the institution
- involvement in planning national and international scientific meetings

- **Clinical Research Productivity** measured by
- number of peer-reviewed faculty publications
- number of presentations at major scientific meetings
- number and amount of research grants and contracts received
- number and nature of active collaborative research activities

Clinical Research/Research-Related Activities

Assessments of infrastructure components are not based solely on specific evaluations of individual scientific protocols, but rather on a broader analysis of the feasibility of achieving what is proposed with the resources requested.

In addition, it must be recognized that for a developmental program, a major activity may be implemented at any time during a five-year project period, not only in the first year or two as might be expected for a specific research project. Therefore, the inclusion of requests for facilities, major equipment and/or additional faculty in year three or year four (for example) may be justifiable, provided that the application adequately describes unmet needs, and plans for the future use of the resource that are consistent with the institutional plan.

Infrastructure Components and Core Laboratories

Major factors to be considered in the evaluation of infrastructure components and core laboratories include:

- Rationale and need for these resources to achieve institutional RCRII goals, including the potential for developing high-quality clinical research programs
- The facility's importance to the clinical research of the faculty, both RCRII-supported pilot projects and other Center faculty
- The number and qualifications of investigators utilizing the core facility, and the number of projects or protocols that utilize the core facility, including the demonstrated need for current or requested equipment; the existence of a user community (current and/or projected) is critical
- Adequacy and appropriateness of administrative and scientific leadership for implementing and managing the resources, including collaborative and consultative arrangements
- The qualifications of the director of the core facility
- Appropriateness of the plan for the resource, including objectives, implementation strategy and timetable, and involvement of the CRAC
- Reasonableness of plans to institutionalize support for the resources over time
- For competing continuation and supplemental requests, the assessment of progress toward original goals for the infrastructure component is an essential element in the review

Pilot Protocols and Developmental Projects

Review of pilot protocols and developmental or collaborative clinical research projects is based not only on the traditional considerations necessary for peer evaluation of scientific merit, but also takes into account the preliminary nature of the proposed studies and, in a broader sense, the extent to which the research activity will contribute to the goals of the RCRII. Pilot clinical research activities will be evaluated according to NIH review guidelines for scientific projects, using the five criteria for scientific merit review: significance, approach, innovation, investigator, and environment.

Major factors to be considered in the evaluation of pilot and developmental projects include:

- Significance and relevance of proposed research problem
- Potential of the research to advance the concepts or methods that drive the field, and scientific knowledge in general
- Approach, including appropriateness of research plan, specific aims, experimental design, methodology, consideration of alternatives, data analysis, scope, and timetable
- Innovation is a significant consideration in some, although not all, types of research projects; innovation is characterized by novel concepts, approaches, or methods, original and innovative aims, development of new methodologies, or paradigms challenged
- Investigator training and qualifications, and the appropriateness of the clinical research to the experience level of the Principal Investigator and other personnel
- Environment in which the clinical research will be performed, adequacy of resources,

availability of any specialized facilities needed, institutional support for the protocol, and degree to which the clinical research takes advantage of any unique features of the scientific environment or employs useful collaborative arrangements

- Relevance of proposed project to the institutional plan for expansion of clinical research capacity and enhanced opportunities for collaboration
- Explicit attention to human subjects protection and appropriate inclusion of women, minorities and children as noted on pages 36-39 of the Instructions for the *Application for a Public Health Service Grant*, form PHS 398 (Rev. 04/2006).

AWARD CRITERIA

The Principal Investigator will be notified of the Council's recommendation shortly after it meets. Award decisions will be based on the technical merit of the application as determined by peer-review, amounts recommended through the peer-review process, other programmatic priorities to ensure a balance among the various types of programs, populations served, and/or geographic distribution. Grant awards are subject to availability of funds.

Support of an application for competing continuation of an RCRII for an additional project period will be contingent upon the outcome of peer and Council review, and the availability of funds.

REPORTING/MONITORING

The following material supplements the **General Information for DRI Applicants and Grantees** section of these Guidelines.

ANNUAL PROGRESS REPORT

Grantees are encouraged to use in their annual progress reports the categories for evaluation of the impact of RCRII support listed under **Review Criteria**, above. This process will serve to document benchmark achievements on a regular basis, which should be helpful in compiling this required information when developing an application for competing continuation of the program.

OTHER EVALUATIVE MECHANISMS

Midway through the project period (at the end of the third year of a five-year RCRII project period, for example), or as deemed necessary by NIH staff, site visits may be conducted to assess the progress of the grantee institution's RCRII and to estimate the future impact that can be expected from continuing RCRII support.

Alternatively, grantees may benefit significantly by conducting their own mid-course assessment, utilizing CRAC external members and other reviewers appropriate for this type of evaluation. These analyses may lead to mid-course adjustments and a better informed basis for future plans. DRI must approve any changes recommended.

In addition, administrative visits by NIH staff will be arranged when indicated to facilitate achievement of both institutional and national RCRII goals.

INQUIRIES

Written and telephone inquiries concerning the RCRII Program are strongly encouraged, especially during the planning phase of the application. Please contact the NCRR staff listed in the **Inquiries** section of these Guidelines.

DRI Guidelines: May 2007-

RCRII CLINICAL RESEARCH FACULTY DEVELOPMENT (CRFD) AWARD

PURPOSE

The Research Centers in Minority Institutions (RCMI) Clinical Research Faculty Development (CRFD) Award provides up to five years of career development support to a physician or dentist dedicated to becoming an independent clinical investigator.

ELIGIBILITY REQUIREMENTS

Eligibility for this Program is limited to institutions with a funded RCMI Clinical Research Infrastructure Initiative (RCRII) grant.

A candidate for a Clinical Research Faculty Development award must have an M.D., D.D.S., or an equivalent degree and have completed residency; completion of subspecialty (fellowship) training for two years is preferred but not required. The candidate must be a U.S. citizen or hold a permanent immigration visa. Candidates may not hold independent peer-reviewed grant support, as the PI, prior to the funding of this application. The candidate must have a faculty appointment at the RCRII grantee institution.

The primary mentor and other participating scientists may be based at the applicant institution or at other institutions with clinical research centers (such as NCRR's General Clinical Research Centers and Clinical and Translational Science Awards (CTSA) Centers).

MECHANISM OF SUPPORT

The application must be submitted as a competing supplement to a funded RCMI Clinical Research Infrastructure Initiative (RCRII) grant. The requested budget may not go beyond the project period of the parent RCRII grant award. The award is not renewable. No more than three CRFDs will be supported for a given RCRII.

ALLOWABLE COSTS

SALARY

NIH will provide salary for the award recipient of up to $85,950 per year plus commensurate fringe benefits for up to 50-percent effort. At least 25-percent effort is required. The institution may supplement NIH contribution up to a level that is consistent with the institution's salary scale. Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the award.

Recipients of this award may derive additional compensation from other Federal sources or awards, provided the total salary derived from all Federal sources does not exceed $171,900 per

year and the total effort does not exceed 100 percent. Direct salary is exclusive of fringe benefits and Facilities and Administration (F&A) costs.

The total salary requested must be based on a full-time, 12-month staff appointment. It must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure.

RESEARCH DEVELOPMENT SUPPORT

NIH will provide generally up to $25,000 per year for the following expenses:
- Research expenses, such as supplies, equipment, and technical personnel, for the PI and his/her mentored clinical investigators
- Travel to research meetings or training
- Statistical services, including personnel and computer time

ANCILLARY PERSONNEL SUPPORT

Salary for secretarial and administrative assistance, for example, is not allowed.

OBJECTIVES AND SCOPE

ENVIRONMENT

The institution must have a well-established clinical research and clinical career-development program. The institution must be able to demonstrate a commitment to the candidate as a productive, independent investigator. The candidate and institution must be able to describe a career program that will utilize the relevant research and educational resources, and the institution must certify that the candidate will be released from other duties and be able to devote up to a 25- to 50-percent effort to a clinical research program. The institution must demonstrate the availability of beginning clinical investigators to be mentored.

PROGRAM

The Program provides up to five consecutive 12-month awards. Up to 50 percent of the investigator's effort (at least 25 percent) must be devoted to the clinical research program and mentoring. The remainder may be devoted to other clinical, teaching, or research pursuits consonant with the objectives of the award. The research phase of an award period must be devoted to clinical research in scientific areas relevant to the career goals of the candidate.

EVALUATION

In carrying out its stewardship of human resource-related programs, NCRR may request information essential to an assessment of the effectiveness of this program. Accordingly, recipients are hereby notified that they may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

SPECIAL LEAVE

Leave to another institution, including a laboratory in a foreign country, may be permitted if directly related to the purpose of the award. Only local, institutional approval is required if such leave does not exceed three months. For longer periods, prior written approval from NCRR is required. To obtain prior approval, the award recipient must submit a letter describing the plan to the Director, DRI, countersigned by her/his department head and the appropriate institutional official. A copy of a letter or other evidence from the institution where the leave is to be taken must be submitted to assure that satisfactory arrangements have been made. Support from the career-award will continue during such leaves.

Leave with or without award support may not exceed 12 months. Such leave requires the prior written approval of NCRR and will be granted only in unusual situations. Support from other sources is permissible during the period of leave. Such leave does not reduce the total number of months of program support for which an individual is eligible, provided sufficient time remains in the project period of the parent grant. Parental leave will be granted consistent with the policies of NIH and the grantee institution.

TERMINATION OR CHANGE OF INSTITUTION

When a grantee institution plans to terminate an award, NCRR must be notified in writing at the earliest possible time so that appropriate instructions can be given for termination. If the individual is moving to another eligible institution, career-award support may be continued provided:

- A new career-award application is submitted by the new institution
- All conditions of the award are met at the new institution
- The period of support requested is no more than the time remaining within the existing award period
- The new application is submitted far enough in advance of the requested effective date to allow the necessary time for review

A final progress report, invention statement, and Financial Status Report are required upon either termination of an award or relinquishment of an award in a change of institution situation.

UP-TO-DATE INFORMATION

All applicants and grantees must ensure they have the latest information about the CRFD Award and related policies and procedures by visiting the RCRII Web page at http://www.ncrr.nih.gov/resinfra/ri_rcrii.asp.

APPLICATION PROCEDURES

Applicants must use the *Application for a Public Health Service Grant*, form PHS 398 (Rev. 04/2006), following standard instructions except where modified according to the CRFD section of the Appendix to these Program Guidelines: *Supplemental Instructions for the PHS 398 Grant Application - RCMI*.

Applicants must also review the **General Information for DRI Applicants and Grantees** section of these Guidelines for other important information.

REVIEW CONSIDERATIONS

REVIEW PROCEDURES

Upon receipt, applications will receive an independent, objective review using current policies and procedures that apply to all PHS applications. Incomplete applications will be considered unresponsive and will be returned for appropriate revisions. All complete applications will be reviewed for scientific and technical merit by the NCRR Research Centers in Minority Institutions Review Committee (RCMIRC). Second-level review will be conducted by NCRR's National Advisory Research Resources Council (NARRC).

REVIEW CRITERIA

The following review criteria will be used for CRFD applications:

Candidate

- Quality of the candidate's academic and clinical record
- Evidence of ongoing, high-quality clinical research and the relevance of that research to this program
- Potential to conduct quality clinical research
- Commitment to a clinical research career
- Appropriateness of the content and duration of the proposed research program
- Evidence of monetary support for clinical research

Research Plan

A fundamentally sound research plan must be provided. In general, less detail is expected with regard to research planned for the later years of the award, but the application should outline the general goals for these years.

- Appropriateness of the research plan as a vehicle for demonstrating skills and capabilities in clinical research
- Scientific and technical merit of the proposed research
- Relevance of the proposed research to the candidate's career objectives
- Availability of adequate resources to conduct the research program
- Demonstration that the proposed program will relieve the candidate from other patient care or administrative duties and allow him/her to devote time to clinical research
- Adequacy of the plan's attention to gender and minority issues associated with projects involving human subjects
- Adequacy of plans for including children as appropriate for the scientific goals of the research, or justification for exclusion

Mentoring Plan

- Experience and potential to serve as a mentor
- Adequacy of the plans for mentoring or supervising beginning clinicians in clinical research

Environment and Institutional Commitment

- Applicant institution's commitment to the scientific development of the candidate and assurances that the institution intends for the candidate to be an integral part of its research program
- Adequacy of research facilities and the availability of appropriate educational opportunities
- Quality and relevance of the environment for scientific and professional development of the candidate and others pursuing clinical research
- Applicant institution's commitment to provide adequate time for conduct of the research program

AWARD CRITERIA

The Principal Investigator will be notified of the Council's recommendation shortly after it meets. Award decisions will be based on the technical merit of the application as determined by peer-review, amounts recommended through the peer-review process, other programmatic priorities to ensure a balance among the various types of programs, populations served, and/or geographic distribution. Grant awards are subject to availability of funds.

REPORTING/MONITORING

Grantees must review and follow the instructions in the **General Information for DRI Applicants and Grantees** section of these Guidelines.

INQUIRIES

Written and telephone inquiries concerning the CRFD Program are strongly encouraged, especially during the planning phase of the application. Please contact the NCRR staff listed in the **Inquiries** section of these Guidelines.

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DRI Guidelines: May 2007-

RCMI PLANNING GRANT (PG)

PURPOSE

The purpose of the RCMI Planning Grant is to provide RCMI-eligible institutions – with or without a funded RCMI grant – the resources needed to plan new programmatic thrusts and compete for biomedical or behavioral research support from the RCMI Program or other components of the Public Health Service (PHS).

The RCMI Program is designed to expand the national capability for research in the health sciences by providing grant support to predominantly underrepresented minority institutions that offer the doctorate degree in the health professions or in a health-related science. The Program assists eligible institutions in strengthening their research environment by improving their human and physical resources for the conduct of biomedical and/or behavioral research. RCMI grants also provide limited support for developmental and pilot projects and for collaborative research projects.

The primary goal of the RCMI Program is to enable predominantly underrepresented minority health professional schools and graduate institutions to become more successful in obtaining competitive extramural support for the conduct of biomedical and/or behavioral research. The Program also expands the capacity for clinical research at doctorate-granting minority institutions that have affiliated medical schools by providing resources to develop the appropriate infrastructure.

As a part of the application development process, potential RCMI Planning Grant applicants are required to (1) select a Program Director (PD), and (2) establish a Planning Committee composed of institutional officials and external members. The external members must be biomedical and/or behavioral research scientists who can assure the quality of submitted applications.

ELIGIBILITY REQUIREMENTS

Eligibility for this Program is limited to academic institutions within the United States and its territories that have an underrepresented (50 percent or more) enrollment of students underrepresented in biomedical sciences (African American, Hispanic, Native American, Alaskan Native, Native Hawaiian, and Pacific Islander) and that award doctorates in the health or health-related sciences.

MECHANISM OF SUPPORT

The P20 exploratory mechanism will be used for these planning grants.

Responsibility for the planning, direction, and execution of the grant will be solely that of the

applicant. The total requested project period may not exceed 12 months. Requested direct costs may not exceed $75,000 for the 12-month period. Facilities and Administration (F&A) costs will be provided.

ALLOWABLE COSTS

Funds may be requested for personnel, such as faculty release time and support for a Program Director and staff, and consultant services, including external advisors and collaborators. Requests for office equipment, office supplies, travel, and other expenses should be limited to those necessary for program development and should be carefully and specifically justified. Support will not be provided for pilot research projects, research infrastructure, or students. All requested items must be related to needs of a 12-month planning activity.

PROGRAM CHARACTERISTICS

The purpose of the RCMI Planning Grant is to provide currently unsupported RCMI-eligible institutions the resources needed to plan and apply for RCMI support, and to provide currently supported RCMI institutions the resources needed to plan and apply for support through new RCMI initiatives.

PRINCIPAL INVESTIGATOR

The Principal Investigator (PI) should be the President of the applicant institution or his/her designated representative for RCMI planning purposes. In addition, the governance structure must include a Program Director (PD), and an RCMI Advisory Committee.

PROGRAM DIRECTOR

The Program Director (PD) is nominated by and responsible to the PI. The PD must be willing and able to devote the time and effort necessary for effective management and implementation of the planning process. S/he should be a knowledgeable and experienced biomedical scientist and an effective administrator.

PLANNING COMMITTEE

The Planning Committee must be advisory to the PI and PD. It should consist of eight to twelve members and must include a cross-section of qualified faculty and appropriate members external to the institution. It is essential that the Committee be knowledgeable about the institution's strengths and weaknesses in biomedical research, capabilities and needs, and overall goals. It should possess among its members the experience and knowledge needed to identify and recommend expert consultation from the biomedical community at large and to facilitate the development and/or strengthening of necessary collaborative relationships between institutions and faculty. The Committee will oversee the overall institutional planning and application development. The Committee must make recommendations throughout the process.

PROGRAM PLANS

Program plans for the enhancement of biomedical research capacity must be consistent with the long-range goals of the applicant institution.

UP-TO-DATE INFORMATION

All applicants and grantees must ensure they have the latest information about the RCMI Planning Grant and related policies and procedures by visiting the RCMI Web page at http://www.ncrr.nih.gov/resinfra/ri_rcmi.asp.

APPLICATION PROCEDURES

Prospective applicants are advised to communicate as early as possible in the planning phase of application development with the NCRR Program and grants management staff listed in the **Inquiries** section of these Guidelines.

Applicants must use the *Application for a Public Health Service Grant*, form PHS 398 (Rev. 04/2006), following standard instructions except where modified according to the RCMI PG section of the Appendix to these Program Guidelines: *Supplemental Instructions for the PHS 398 Grant Application - PG*.

Applicants must also review the **General Information for DRI Applicants and Grantees** section of these Guidelines for other important information.

REVIEW CONSIDERATIONS

REVIEW PROCEDURES

Upon receipt, applications will receive an independent, objective, administrative review using current policies and procedures that apply to all PHS applications. Applications that are incomplete, nonresponsive to these Guidelines, or exceed the 12-month budget limit of $75,000 in direct costs will be returned to the applicant.

Applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific and technical merit by the NCRR Research Centers in Minority Institutions and IDEA Review Committee (RCMI/IDEARC). Second-level review will be provided by NCRR's National Advisory Research Resources Council (NARRC).

REVIEW CRITERIA

Major factors to be considered in the evaluation of applications include:

- Feasibility and timeliness of the proposed plan, based on the mission, five-year history, and current biomedical research capability, of the applicant institution
- Adequacy of the planning process, including concept development and involvement of advisory resources
- Appropriateness of the organizational and administrative structure established to accomplish planning grant goals
- Qualifications, experience, and commitment of the PD, and his/her ability to provide effective leadership in developing the proposed plan
- Appropriateness of the Planning Committee
- Adequacy of institutional commitment to biomedical research
- Merit of the applicant's institutional plan for developing an enhanced biomedical research infrastructure
- Diversity in staff – gender, race/ethnicity, academic rank
- Explicit attention to human subjects protection and appropriate inclusion of women, minorities and children as noted on pages 36-39 of the Instructions for the *Application for a Public Health Service Grant*, Form PHS 398 (Rev. 04/2006).

AWARD CRITERIA

The Principal Investigator will be notified of the Council's recommendation shortly after it meets. Award decisions will be based on the technical merit of the application as determined by peer-review, amounts recommended through the peer-review process, other programmatic priorities to ensure a balance among the various types of programs, populations served, and/or geographic distribution. Grant awards are subject to availability of funds.

REPORTING/MONITORING

Grantees must review and follow the instructions in the **General Information for DRI Applicants and Grantees** section of these Guidelines.

INQUIRIES

Written and telephone inquiries concerning RCMI Planning Grants are strongly encouraged, especially during the planning phase of the application. Please contact the NCRR staff listed in the **Inquiries** section of these Guidelines.

INQUIRIES

	NCRR CONTACTS FOR INFORMATION		
	Program and its Policies	**Fiscal Matters, Grants Management policies, Regulations**	**Review of Applications**
RCMI **RCMI FD** **RCMI PG**	Shelia A. McClure, Ph.D. Health Scientist Administrator, DRI Tel: 301-451-6536 McClurSh@mail.nih.gov	Irene Grissom Grants Management Officer Tel: 301-435-0844 GrissomI@mail.nih.gov	Mahadev Murthy, Ph.D. Scientific Review Administrator RCMI Review Committee Tel: 301-435-0813 mmurthy@mail.nih.gov
RCRII **CRFD**	Maureen Beanan, Ph.D. Health Scientist Administrator, DRI Tel: 301-435-0961 beananm@mail.nih.gov		
Common Address Elements	Division of Research Infrastructure National Center for Research Resources National Institutes of Health One Democracy Plaza, Ninth Floor 6701 Democracy Boulevard Bethesda, Maryland 20892-4874 Fax: 301-480-3770	Office of Grants Management National Center for Research Resources National Institutes of Health One Democracy Plaza, Room 1043 6701 Democracy Boulevard Bethesda, Maryland 20892-4874 Fax: 301-480-3777	Office of Review National Center for Research Resources National Institutes of Health One Democracy Plaza, Room 1068 6701 Democracy Boulevard Bethesda, Maryland 20892-4874 Fax: 301-480-3660

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DRI Guidelines: May 2007-

RECEIPT, REVIEW, AND AWARD CYCLES

Programs	**Cycle I**	**Cycle II**	**Cycle III**
Application Receipt Dates			
RCMI	January 25	May 25	September 25
RCMI FD	January 25	May 25	September 25
RCRII	January 25	May 25	September 25
CRFD	January 25	May 25	September 25
RCMI PG	January 25	May 25	September 25
Review and Award Schedule			
Scientific Merit Review	June/July	October/ November	February/March
NARRC Review	September	January/February	May/June
Earliest Project Start Date	December	April	July

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GENERAL INFORMATION FOR DRI APPLICANTS AND GRANTEES

ELIGIBILITY

In general, NIH grants may be awarded to public and private non-profit organizations and institutions (including institutions of higher education, hospitals, and non-profit research institutes), both domestic and foreign, and, in rare cases, to individuals. For-profit organizations are eligible to receive awards under all NIH programs unless specifically excluded by legislation. In addition, special eligibility requirements in these Program Guidelines apply.

UP-TO-DATE INFORMATION

Before applying to a DRI program, you must ensure you have the latest information by visiting the program's Web page at the internet address (URL) given for it in these Guidelines, or through the DRI Homepage at http://www.ncrr.nih.gov/research_infra.asp.

CONTACT WITH DRI PROGRAM STAFF

After reviewing the information on DRI program(s), interested applicants should contact DRI program staff, who can provide clearer understanding of program policies and guidelines, and up-to-date information on program priorities. The applicant should also discuss a competing continuation application with staff to determine whether future plans for the project conform with current policies.

ACCEPTANCE FOR REVIEW OF UNSOLICITED APPLICATIONS THAT REQUEST $500,000 OR MORE IN DIRECT COSTS

NIH policy requires that applicants seek agreement to accept assignment from DRI staff at least six weeks prior to the anticipated submission of any application requesting $500,000 or more in direct costs for any year. This policy does not apply to applications submitted in response to Requests for Applications (RFAs) or in response to other announcements that include specific budgetary limits. However, such applications must be responsive to any budgetary limits specified, or they will be returned to applicants without review. (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html).

An applicant planning to submit a grant application with $500,000 or more in direct costs for any year is required to contact DRI program staff in writing or by telephone during the development process of the application, no later than six weeks before the anticipated submission date. If NCRR is willing to accept assignment of the application for consideration of funding, the staff will notify the Center for Scientific Review before the application is submitted.

The Principal Investigator must include with the application a cover letter that indicates prior staff concurrence and identification of program staff contacted, or the application will be returned to the applicant without review. Therefore, NIH strongly encourages applicants to contact program staff at the earliest possible time.

AMENDED GRANT APPLICATIONS

All revised and supplemental applications must include an Introduction. A revised application will be returned without review if it does not comply with all of these requirements:

- Before a revised application can be submitted, the Principal Investigator must have received the summary statement from the previous review
- There must be substantial changes in the content of the application
- The application must include an Introduction of not more than three pages that summarizes the substantial additions, deletions, and changes
- The Introduction must also include responses to the criticisms and issues raised in the summary statement
- The changes in the Research Plan must be clearly marked by appropriate bracketing, indenting, or changing of typography, unless the changes are so extensive as to include most of the text (this exception should be explained in the Introduction); do not underline or shade changes
- The Preliminary Studies/Progress Report section should incorporate any work done since the prior version was submitted
- Acceptance of a revised application automatically withdraws the prior version, since two versions of the same application cannot simultaneously be pending.

Note: NIH will consider no more than two amendments to a grant application [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-041.html]

APPLICATION PREPARATION

GENERAL INFORMATION

An application MUST be submitted by the receipt deadline, MUST be complete, and MUST give thorough coverage of all aspects of the program. DO NOT rely on sending additional material or making corrections after the deadline. No supplemental materials may be submitted after formal submission without approval from the Scientific Review Administrator (SRA).

Submission Instructions

Submit the original and three copies of your application to:

Center for Scientific Review
National Institutes of Health
Two Rockledge Centre, Room 1040
6701 Rockledge Drive, MSC 7710
Bethesda, Maryland 20892-7710
Bethesda, Maryland 20817 (For Express/Courier Service)
Tel: 301-435-0715

Mail Security: NIH No Longer Accepts "In Person" or "Hand-delivered" Applications

All United States Postal Service (USPS) mail addressed to the National Institutes of Health must use the unique NIH Zip Code 20892 to ensure that special procedures and precautions will be used for the safety of all individuals who must handle mail. The Zip Code for courier delivery (e.g., FEDEX, UPS) of grant applications addressed to the Center for Scientific Review (CSR) is 20817. All applications and other deliveries to CSR must either come via courier delivery or the USPS. Until further notice, **CSR will no longer accept applications delivered by individuals**. http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-012.html

The cooperation of applicant and grantee organizations is greatly appreciated and allowances should be made for the extra time needed to process properly incoming USPS mail and other deliveries.

Timely Submission

An application will be considered on time if it is received by, or mailed on or before, the published receipt date, and a proof of mailing – a legibly-dated U.S. Postal Service postmark, or a dated receipt from a commercial carrier or the U.S. Postal Service – is provided. Private-metered postmarks are not acceptable as proof. If a receipt date falls on a weekend, it will be extended to the following Monday; if the date falls on a holiday, it will be extended to the following work day.

Applications must be received by the specified dates. However, an application received after the deadline may be acceptable if it carries a legible proof-of-mailing date, assigned by the carrier, and the proof-of-mailing date is not later than one week prior to the deadline date.

Waiver of Receipt Date

The receipt date will be waived only in extenuating circumstances, at the discretion of the Center for Scientific Review (CSR). To request a waiver, include an explanatory letter with the signed, completed application. No request for a waiver will be considered prior to receipt of the application, and there is no guarantee that the waiver will be granted.

Completeness and Responsiveness

Submit a complete application. An application will be returned if it is illegible, if the instructions were not followed, or if the material presented is insufficient to permit an adequate review.

Applications considered to be incomplete or not responsive to program guidelines or policies will be returned without further review. Special attention should be given to all budget justifications, review of protocols for use of human subjects and vertebrate animals, and the application instructions for detailed information in these areas. It is crucial that the applicant refer to and carefully follow the instructions for the *Application for a Public Health Service Grant*, form PHS 398 (Rev. 04/2006); *Guidance for Preparing the Human Subjects Research Section*, pages 36-39; and *Vertebrate Animals*, page 39 of the Instructions) along with any additional instructions contained or mentioned in these Guidelines.

Required Formats for Applications Submitted to NIH

The scale of the NIH effort to identify and support the best possible biomedical and behavioral research -- approximately 80,000 competing applications were received in fiscal year 2006 -- requires standards for application submission.

See *FAQs: Revised PHS 398 and PHS 2590 Forms and Instructions* for detailed information on using the new fillable PDF forms and other important information.
[http://grants1.nih.gov/grants/forms_faq.pdf]

Supplementary Material

Do not send supplementary or corrective material – unless specifically required, e.g., human subjects certification, vertebrate animals verification, changes in other support – after the receipt date, unless the SRA solicits or agrees to accept this information. The application must be complete and accurate at the time of submission, as there is no guarantee that late material will be considered.

Duplicate Applications

The Center for Scientific Review (CSR) will not accept an application that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application.

The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

FORMS AND INSTRUCTIONS

Applications

Additional Information and FAQs about Forms PHS 398 (Rev. 04/2006) and PHS 2590 (rev. 04/2006)

" \14 NIH will continue to inform the public of notable changes to the documents and forms through the NIH Guide for Grants and Contracts http://grants1.nih.gov/grants/guide/index.html and the NIH Forms and Applications page http://grants1.nih.gov/grants/forms.htm. Applicants must download the most current versions of instructions and forms prior to applying to NIH.

Appendices

Given the slightly contradictory requirements to be both concise and complete, it is tempting to rely heavily upon appendices to provide the required details. However, you should be aware that only the two primary reviewers of your application receive both the main body and the appendices. The remaining members of the review group receive only the main text. Thus, you should not place essential information in an appendix, since most of the reviewers will not receive it and will be forced to rely solely on the comments of the primary reviewers. A possible compromise is to provide some information in the main body, but then provide the full details in the appendix. This gives the secondary reviewers some sense of the information, and provides the primary reviewers with adequate information. Be sure to follow the instructions regarding the permissible content and length of appendices, **IF** appendices are allowed.

URLs in Grant Applications or Appendices

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review, because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

Public Access to Research Data

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment (consult NIH-provided guidance at http://grants1.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm).

Applicants may wish to place collected data in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under such an award.

AFTER APPLICATION SUBMISSION

REVIEW PROCEDURES

Once your proposal is submitted, it undergoes a two-level process of peer-review before becoming eligible for funding. For the typical research grant, It takes at least nine months from the time an application is received until the time a grant award can be made.

Upon receipt, applications will receive an independent objective review using current policies and procedures that apply to all PHS applications. Incomplete applications will be considered unresponsive and will be returned. All complete applications will be reviewed for scientific and technical merit by an NCRR initial review group. Second-level review will be conducted by NCRR's National Advisory Research Resources Council (NARRC).

APPLICATION NUMBER

A unique application number is assigned to each application. An example of an application number is 1 R25 RR12345-01A1, which is made up of the following components:

Application Type	Activity Code	Awarding Unit	Serial Number	Suffixes	
				Year	Other
1	R25	RR	12345	01	A1

PEER REVIEW

Applications for support from the NIH are evaluated initially by peer review groups composed of scientists from the extramural research community. The objective of the initial peer review is to evaluate and rate the scientific and technical merit of the proposed research or research training.

The second level of peer review is carried out by NIH's National Advisory Councils. These Councils (e.g., NCRR's National Advisory Research Resources Council) are composed of scientists from the extramural research community and public representatives to ensure that the NIH receives advice from a cross-section of the US population in the process of its deliberation and decisions.

The NIH Office of Extramural Research (OER) (http://grants1.nih.gov/grants/peer/peer.htm) manages the development and implementation of policies and procedures that pertain to peer review conducted in all components of the NIH. The Center for Scientific Review (CSR) also makes available information regarding the Peer Review process (http://www.csr.nih.gov/review/peerrev.htm).

FUNDING DECISIONS

Once Council has approved an application, it becomes eligible for funding. Funding decisions

are made by NCRR staff, taking into account many factors, including the scientific merit of the application, its program relevance, and the NCRR budget.

NONCOMPETING CONTINUATION APPLICATION

For funded applications, DRI Program Officials will provide to grantees any special instructions to be used in preparing the *Non-Competing Grant Progress Report*, form PHS 2590 (Rev. 4/2006) available at http://grants1.nih.gov/grants/funding/2590/2590.htm.

RESEARCH INVOLVING HUMAN SUBJECTS

REQUIRED EDUCATION FOR ALL INVESTIGATORS

Policy

NIH requires education in the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html).

Before funds are awarded for competing applications or contract proposals involving human subjects, investigators must provide a description of education completed in the protection of human subjects for each individual identified as "key personnel" in the proposed research. Key personnel include all individuals responsible for the design and conduct of the study. The description of education is to be submitted in a cover letter that accompanies the description of Other Support, IRB approval, and other information in accordance with Just-in-Time procedures.

Investigators must also include a description of such education in their annual progress reports.

Educational Resources

Many institutions have developed educational programs on the protection of research participants and made participation in such programs a requirement for their investigators. NIH does not plan to issue a list of "endorsed" programs. Rather, NIH points out that a number of curricula are readily available to investigators and institutions. For example, all NIH intramural investigators and research administrators who oversee clinical projects are required to complete an on-line tutorial on the protection of human research subjects, which can be used by other institutions seeking to meet training requirements in this area. It is available at http://206.102.88.10/ohsrsite/researcherCBT/intro.html

Additional Information

See Frequently Asked Questions for the Requirement for Education on the Protection of Human Subjects at http://grants1.nih.gov/grants/policy/hs_educ_faq.htm.

INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN CLINICAL RESEARCH

All NIH-supported biomedical or behavioral research projects involving human subjects must consider appropriate inclusion of women, minorities and children as noted on pages 36-39 of the Instructions for the *Application for a Public Health Service Grant,* form PHS 398 (Rev. 04/2006).

For research involving human subjects, it is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establish to the satisfaction of the relevant IC Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an IC Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion, except when the study would duplicate data from other sources. Women of child-bearing potential should not be routinely excluded from participation in clinical research. All NIH-supported biomedical and behavioral research involving human subjects is defined as clinical research. This policy applies to research subjects of all ages.

Reference

All investigators proposing research involving human subjects should read the *NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001* and the NIH *Inclusion of Children Policy Implementation*, available at http://grants1.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm and http://grants1.nih.gov/grants/funding/children/children.htm.

As part of the scientific and technical merit evaluation of the research plan, reviewers will be instructed to address "the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification for exclusion."

Application Research Plans

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. The research plan should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan should contain a description of the proposed outreach programs for recruiting women and minorities as participants. To comply with this policy, DRI recommends that applicants use the following "three-table" approach – with interpretive text between tables two and three – developed by NCRR's Division of Clinical Research:

Three-Table Format – The first table should give the national demographics of the disease under study. For example, if rheumatoid arthritis were being studied, the first table would be as follows:

National Demographics for Citizens Afflicted with Rheumatoid Arthritis (%)							
	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female	0.3	0.7	15.3	1.9	51.3	4.1	73.6
Male	0.1	0.2	3.0	0.4	21.0	1.7	26.4

The numbers presented in the first table should represent percentages of the total number of rheumatoid arthritis patients in the United States who fall into the listed demographic categories. For example, of those with rheumatoid arthritis in the United States, 51.3 percent are white females and 3.0 percent are black males. Following the table, a reference listing the source of the information should be identified in full.

The second table should indicate the patient distribution that would be anticipated in the protocol if no special recruiting efforts were to be made. These data can reflect either numbers of research subjects or percentages thereof and represent: a) the patients recruited into this protocol to date, b) the recruitment into a forerunner of this protocol, c) the demographic distribution of all rheumatoid arthritis patients seen at the hospital, or d) the demographic distribution of all rheumatoid arthritis patients in the city or state. It should be indicated whether the data are characterized as a, b, c or d.

Table 2 should then be compared to Table 1. If the numbers listed in Table 2 are substantially lower in minorities overall or in women, then a plan should be described that will appropriately increase the participation of the relevant groups.

Table 3 should present numbers of research subjects, not percentages. The total number should be that which the investigator's power calculation indicated as the final number of subjects to be recruited into this protocol. The numbers within Table 3 should reflect the anticipated result of the plan for gender and minority recruitment and, when totaled, equal the final number of subjects. If Table 2 for this protocol is close to or surpasses the national demographics in terms of overall minorities and women, then the Table 3 data can be adapted from Table 2. However, if the data in Table 2 are far below the national demographics in terms of minorities overall and women, then the Table 3 should reflect the outreach plan to recruit the appropriate patients. Protocols specifically designed and approved to study only one minority group or one gender are exempt from this guideline.

NIH POLICY ON REPORTING RACE AND ETHNICITY DATA

Policy

NIH has adopted the 1997 Office of Management and Budget (OMB) revised minimum standards for maintaining, collecting, and presenting data on race and ethnicity for all grant applications and active research (http://www.whitehouse.gov/omb/fedreg/ombdir15.html).

Collection of this information and use of these categories is required for all research that meets the NIH definition of clinical research. This policy applies to all new applications and proposals, annual progress reports, competing continuation applications, competing supplement applications for research grants, contracts, and intramural projects as of January 10, 2002.

NIH has published additional guidance and instruction for using the revised minimum standards for maintaining, collecting, and presenting data on race and ethnicity found in the PHS 398 (rev. 4/2006) and PHS 2590 (rev.4/2006) that should be used in conjunction with the instructions in the PHS 398 and 2590 (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html).

The 1997 OMB revised minimum standards include two ethnic categories

- Hispanic or Latino
- Not Hispanic or Latino

and five racial categories

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

The categories in this classification are social-political constructs, not anthropological in nature.

Ethnic and Racial Definitions

The following are the ethnic and racial definitions for the minimum standards categories

- Ethnic Categories
- Hispanic or Latino – a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race; the term "Spanish origin" can also be used in addition to "Hispanic or Latino"
- Not Hispanic or Latino
- Racial Categories
- American Indian or Alaska Native – a person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment
- Asian – a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)
- Black or African American – a person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American"
- Native Hawaiian or Other Pacific Islander – a person having origins in any of the original

peoples of Hawaii, Guam, Samoa, or other Pacific Islands
- White – a person having origins in any of the original peoples of Europe, the Middle East, or North Africa

Data Collection Procedures and Display Requirements

When using respondent self-report or self-identification to collect an individual's data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first, followed by the option to select more than one racial designation.

When reporting these data in the aggregate, investigators should report the number of respondents

- In each ethnic category
- Who selected only one category for each of the five racial categories
- Who selected multiple racial categories reported as the "number selecting more than one race"
- In each racial category who are Hispanic or Latino

Investigators may provide the detailed distributions, including all possible combinations, of multiple responses to the racial designations as additional information. However, more detailed items should be designed so they can be aggregated into the required categories for reporting purposes. NIH is required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases. Federal agencies will not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

Guidance on Reporting Ethnicity/Race and Sex/Gender in Clinical Research

NIH policy (http://grants1.nih.gov/grants/funding/women_min/women_min.htm) requires all grants, contracts, and intramural projects conducting clinical research to address the Inclusion of Women and Minorities.

NIH defines clinical research as

- 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
- mechanisms of human disease
- therapeutic interventions
- clinical trials
- development of new technologies

- Epidemiologic and behavioral studies
- Outcomes research and health services research

New Applications (type 1) and Competing Continuations (type 2)

When submitting type 1 and type 2 applications

- Involving the collection of new/additional data in clinical research
- provide plans for the total number of subjects proposed for the study
- provide the distribution by ethnic/racial categories and sex/gender

  This information must be reported using the newly revised categories and according to the format provided in the new Targeted/Planned Enrollment Table http://grants1.nih.gov/grants/funding/phs398/enrollment.pdf

- Using existing data in clinical research with no plans for collecting new/additional data
- provide plans for the total number of subjects proposed for the study
- provide the distribution by ethnic/racial categories and sex/gender

  Investigators are not required to re-contact subjects solely to comply with the newly revised categories. If the existing data on ethnicity and race allows accurate correspondence with the new categories, the investigator can use the format in the Targeted/Planned Enrollment table. However, if the existing data do not allow accurate correspondence with the new categories, information may be reported using the former categories and according to the format in the 4/98 version of the Inclusion Table http://grants1.nih.gov/grants/funding/women_min/InclusionOld_Form.pdf.

Non-Competing Grant Progress Reports (type 5) and Competing Supplements (type 3)

In annual progress reports (type 5) and competing supplement applications (type 3)
- Provide the cumulative total enrollment of subjects to date (as well as any proposed additions to the Targeted/Planned enrollment in the case of Competing Supplement Applications)
- Present the distribution by ethnic/racial categories and sex/gender
- If data collection is ongoing, such that new subjects will be enrolled and/or additional data will be collected from human subjects
- report ethnicity/race and sex/gender sample composition using
- the format in the former 4/98 Version of the Inclusion Table, OR
- the new Inclusion Enrollment Report Table [Note: If investigators with on-going data collection choose to report information using the new Inclusion Enrollment Report, they must continue to use this format for the remaining years of the project.]
- If data collection is complete, such that no new/additional subject contact is planned
- continue to report using the former categories and according to the 4/98 Version of the Inclusion Table, OR
- if data allow accurate correspondence with the new categories, use the format in the new Inclusion Enrollment Report

Additional Information and NIH Contacts

Additional information on NIH policy regarding the Inclusion of Women and Minorities in Clinical Research is available online at http://grants1.nih.gov/grants/funding/women_min/women_min.htm. The NCRR contact for further information about the policy and relevant Center programs is:

Shelia McClure, Ph.D.
National Center for Research Resources
National Institutes of Health
One Democracy Plaza, Room932
6701 Democracy Boulevard, MSC 4874
Bethesda, Maryland 20892-4874
Tel: 301-435-0788
mcclursh@mail.nih.gov

VERTEBRATE ANIMALS

Research dealing with vertebrate animals must be accompanied by appropriate documentation as described on pages 39 of the Instructions for the *Application for a Public Health Service Grant*, form PHS 398 (Rev. 04/2006).

GRANTS POLICY

NIH GRANTS POLICY STATEMENT

The NIH Grants Policy Statement (NIHGPS) *(rev. 03/01)* is effective for all NIH grants and cooperative agreements with budget periods beginning on or after March 1, 2001, and supersedes, in its entirety, *NIH Grants Policy Statement (10/98)* as a standard term and condition of award (http://grants1.nih.gov/grants/policy/nihgps_2001/). The NIHGPS published in October, 1998, remains the standard term and condition for all grants and cooperative agreements with budget periods that began between October 1, 1998 and February 28, 2001.

The NIHGPS makes available to NIH grantees, in a single document, up-to-date policy guidance that will serve as the terms and conditions of NIH awards. This document is also designed to be useful to those interested in NIH grants by providing information about NIH.

Part I provides a glossary of commonly used terms; describes NIH and its relationship to other organizations within the Department of Health and Human Services (DHHS); specifies grantee, NIH, and other DHHS staff responsibilities; outlines the application and review processes; and explains the various resources available to those interested in NIH grants processes.

Part II serves as the terms and conditions that are incorporated by reference in all NIH grant awards. It also specifies, in separate sections, requirements that pertain to construction grants; training grants and fellowships; conference grants; consortium agreements; grants to foreign and international organizations (and domestic grants with substantial foreign components); grants to Federal institutions and payments to (or on behalf of) Federal employees; grants to for-profit

organizations; modular grants; and research patient-care activities.

Part III contains general contact information to aid the reader. This format allows general information, application information, and other types of reference material to be separated from legally binding terms and conditions that are contained in Part II.

Interim changes to NIH grants policies will be published in the NIH Guide for Grants and Contracts (http://grants1.nih.gov/grants/guide/index.html).

Additional questions about the NIHGPS may be directed to NIH's Division of Grants Policy at 301-435-0949, the Grants Management Specialist/Officer identified on an NIH Notice of Grant Award, or the grants management staff listed in the **Inquiries** section of these Guidelines.

NIH GUIDE FOR GRANTS AND CONTRACTS

The NIH Guide for Grants and Contracts (NIH Guide) is the official publication of NIH policies, procedures, and availability of funds (http://grants1.nih.gov/grants/guide/index.html). Occasionally, unofficial notices of interest to the scientific research community are published. Weekly updates to the NIH Guide Table of Contents are available via a LISTSERV (http://grants1.nih.gov/grants/guide/listserv.htm).

NIH REGIONAL SEMINARS ON FUNDING AND GRANTS ADMINISTRATION

The Office of Extramural Research (OER) sponsors semiannual Regional Seminars on Program Funding and Grants Administration, appropriate for grants administrators, new researchers, and graduate students. These seminars are intended to help demystify the application and review process, clarify Federal regulations and policies, and highlight current areas of special interest or concern. The seminars serve the NIH mission of providing education and training for the next generation of biomedical and behavioral scientists. NIH policy, grants management, review, and program staff provide a broad array of expertise and encourage personal interaction between themselves and seminar participants http://grants1.nih.gov/grants/seminars.htm.

GRANTSINFO

GrantsInfo (http://grants2.nih.gov/grants/guide/notice-files/not98-150.html) provides general information about the NIH extramural research and research training programs. Application kits and other forms can be obtained from GrantsInfo. Inquiries and requests for materials may be submitted by telephone or e-mail. The GrantsInfo staff is trained to handle inquiries and to ensure that GrantsInfo can provide the most up-to-date information possible. To use the GrantsInfo services, contact:

GrantsInfo
Division of Extramural Outreach and Information Resources
National Institutes of Health
6701 Rockledge Drive, Suite 6095

Bethesda, Maryland 20892-7910
Telephone: (301) 435-0714
E-mail: GrantsInfo@nih.gov

NIH "WELCOME WAGON" LETTER

The NIH "Welcome Wagon" Letter (http://grants1.nih.gov/grants/funding/welcomewagon.htm) covers many of the items discussed above, as well as other information of particular importance to officials of organizations planning to submit an application or receiving an award from NIH for the first time: key requirements are highlighted, and referrals to important sources of information are provided.

USEFUL NIH WEB SITES

About NIH - http://www.nih.gov/about/
Getting Started at NIH - http://grants1.nih.gov/grants/useful_links.htm
NIH Grants and Funding Opportunities - http://grants1.nih.gov/grants/index.cfm
Welcome to Extramural Research at NIH - http://grants2.nih.gov/grants/welcome.htm
Grants - Office of Extramural Research Home Page - http://grants1.nih.gov/grants/oer.htm

REQUIRED ACKNOWLEDGMENTS

Grantees are REQUIRED to place an acknowledgment of NIH grant support and a disclaimer, as appropriate, on any publication (including audiovisual materials and other products) written or published with such support and, if feasible, on any publication reporting the results of, or describing, a grant-supported activity. A suggested acknowledgment and disclaimer follow:

> "This publication was made possible by NIH Grant Number RR-[insert grant number] from the [insert name of DRI program] Program of the National Center for Research Resources." or "The project described was supported by NIH Grant Number RR-[insert grant number] from the [insert name of DRI program] Program of the National Center for Research Resources." and, as appropriate, "Its contents are solely the responsibility of the authors and do not necessarily represent the official views of NIH."

ADMINISTRATIVE AND COST STANDARDS

All awards are subject to the DHHS regulations on the administration of grants found at 45 Code of Federal Regulations 74 (http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr74_01.html) or 92 (http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr92_01.html), the applicable cost principles (*Cost Principles for Educational Institutions, for State, Local, and Indian Tribal Governments and for Non-Profit Organizations*, http://www.whitehouse.gov/omb/fedreg/cost_principle_nprm_preamble.html), the NIH Grants Policy Statement (http://grants1.nih.gov/grants/policy/nihgps_2001/), and supplemental guidelines published for specific programs.

PROGRAM INCOME

Program income is gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the award (e.g., user fees for core laboratories or for analyses performed by core facilities). An estimate of the amount and source of program income expected to be generated as a result of an award must be included on the Checklist Page of all competing and non-competing continuation applications. Net program income earned during a budget period must be reported on the long-form Financial Status Report (except for program income earned as a result of inventions, to which special rules apply). Costs incident to the generation of program income may be deducted from gross income to determine the net amount to be reported, provided these costs have not been charged to the award. For grants subject to the expanded authorities, program income may be used by the grant recipient to advance eligible project or program objectives (http://grants2.nih.gov/grants/policy/nihgps_2001/part_iia_5.htm#_Toc504811854). For grants excluded from the expanded authorities (e.g., resource grants), the first $25,000 of net program income earned during a budget period may be used by the grant recipient to further eligible project or program objectives. These grantees must obtain approval from NCRR program and grants management staff for the use of program income over and above $25,000 per budget period.

REPORTING/MONITORING

ANNUAL PROGRESS REPORTS

A Non-Competing Grant Progress Report (NIH form 2590) is required annually as part of the non-competing continuation award process, as described in the NIH Grants Policy Statement, http://grants1.nih.gov/grants/policy/nihgps_2003/index.htm. Instructions for the NIH form 2590 can be found at: http://grants.nih.gov/grants/funding/2590/2590.htm. For NCRR-supported Center and Resource grants, the PHS form 2590 incorporates an Annual Progress Report (APR), which provides information in greater detail than the standard NIH form 2590. The NCRR uses the information contained in the APR to facilitate programmatic stewardship of the grant and to respond to inquiries from other governmental agencies and the public. Specific instructions for completing an APR and including it with the NIH form 2590 can be found at http://aprsis.ncrr.nih.gov.

Additional information or non-technical questions either about the PHS 2590 or the APR should be directed to Dr. Shelia McClure (mcclursh@mail.nih.gov) or 301-435-0788.

Investigators in their final year of funding that submitted or intend to submit a competitive continuation application need only submit the APR.

FINAL PROGRESS REPORT

When the grant ends, the final progress report is due 90 days after the end of the project period. This final report should cover the entire project period.

FINANCIAL STATUS REPORT (FSR)

The FSR is submitted on Standard Form 269 (Long Form) or Standard Form 269A (Short Form) as the report of expenditures documenting the financial status of the award, according to the official accounting records of the grantee organization.
(http://grants1.nih.gov/grants/fsr_sf269_long.pdf or
http://grants1.nih.gov/grants/fsr_sf269a_short.pdf)

The FSR for each budget period must be submitted within 90 days after the close of the budget period, unless the grant was awarded under the streamlined, non-competing award process (SNAP - http://grants2.nih.gov/grants/funding/2590/section_2.html#snap). FSRs for grants subject to SNAP are due 90 days after the close of the competitive segment. When reporting grant-related program income, the long-form FSR (SF 269) must be used.

FSRs submitted to the NIH are submitted to the NIH Office of Financial Management for review and acceptance. They are then forwarded to the awarding office for review and inclusion in the official grant file.

FSRs for NIH awards should be sent to:

Government Accounting Branch
Office of Financial Management
National Institutes of Health
31 Center Drive, Room B1B05A, MSC 2050
Bethesda, Maryland 20892-2050
Tel: 301- 402-9123

NIH has a system for the electronic transmittal of Financial Status Reports that allows participants to list currently due and late FSRs, as well as to submit FSRs electronically (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-03-008.html).

GLOSSARY

Activity Code - A three-digit code identifying the type of award mechanism (e.g., R01 is a research project grant). Major series are: F - fellowship, K - research career, N - research contracts, P - research programs and centers, R - research projects, S - research-related programs, T - training, U - cooperative agreements, and Y - interagency agreements.

Allowable Cost - A cost incurred by a recipient that is: (1) reasonable for the performance of the award; (2) allocable; (3) in conformance with any limitations or exclusions set forth in the Federal cost principles applicable to the organization incurring the cost or in the Notice of Grant Award as to types or amount of cost items; (4) consistent with internal regulations, policies and procedures that apply uniformly to both Federally financed and other activities of the organization; (5) accorded consistent treatment; (6) determined in accordance with generally accepted accounting principles; and (7) not included as a cost in any other Federally-financed grant (unless specifically authorized).

Alteration and Renovation (A&R) - The work required to change the interior arrangements or other physical characteristics of an existing facility or installed equipment so that it may be more effectively used for the project. Alteration and renovation may include work referred to as improvements, conversion, rehabilitation, remodeling, or modernization, but is distinguished from construction and large-scale permanent improvements.

Amended Application - A revised application submitted by an applicant.

Application - Generally, a request for financial support of a project or activity submitted to DHHS on specified forms and in accordance with instructions provided by the DHHS awarding office.

Appeal - A procedure for contesting the peer review of a grant application. Synonymous with rebuttal.

Application Identification Number - Consists of application type, activity code, administering organization (IC), serial number, and suffix (year, amendment, supplement):

1 R01 RR 83723 -01 A1 S1

The application number identifies the type of application (new is Type 1), activity code (research project grant - R01), organization to which it is assigned (NCRR - RR), serial number assigned by the Center for Scientific Review, and a suffix showing the support year for the grant and other information identifying a supplement, amendment, or a fellowship's institutional allowance. For contracts, the suffix is replaced by a modification number.

Application Types -

Type l - New
Type 2 -Competing continuation (a.k.a. renewal or recompeting application)
Type 3 -Application for additional (supplemental) support
Type 4 -Application for additional support beyond that previously recommended
Type 5 -Noncompeting continuation
Type 7 -Change of grantee institution
Type 9 -Change of NIH awarding institute or division (competing continuation) Amended - see Resubmission

Approval or Authorization of the Awarding or Cognizant Federal Agency - The documentation evidencing written consent for a recipient to incur a specific cost, or take other actions that require prior approval. If costs or other actions are specifically identified in a grant application, approval of the application constitutes such authorization. If the costs are covered by a state-wide or local cost, allocation plan or an indirect cost proposal, approval of the plan or the indirect cost rate constitutes the approval.

Approved Budget - The recipient's financial expenditure plan, including any revisions approved by the awarding office, for carrying out a grant-supported project or activity. The approved budget includes Federal funds and may require non-Federal participation, the amount of which is specified on the initial award document and on any subsequent revised or amended award notice.

Assignment - See receipt, referral, and assignment of applications.

Assurance - A certification by an applicant, normally included with the application or State plan, that it will abide by a particular requirement if awarded a Federal grant.

Authorized Institutional Official - The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards.

Automatic Carryover - Under expanded authorities for research grants, the authority that is delegated to the recipient to move unobligated balances remaining at the end of any budget period to a subsequent budget period which thereby increases authorized expenditures. (See "Expanded Authorities.")

Award - Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements in the form of money or property in lieu of money, by the Federal Government to an eligible recipient. The term does not include the following: technical assistance, which provides services instead of money; other assistance in the form of loans, loan guarantees, interest subsidies, or insurance; direct payments of any kind to individuals; and contracts which are required to be entered into and administered under procurement laws and regulations.

Awarding Office - NIH Institute or Center responsible for the award, administration, and

monitoring of grant-supported activities.

Budget Period - The intervals of time into which a multi-year period of assistance (project period) is divided for budgetary and funding purposes. Budget periods are usually 12 months long but may be shorter or longer, if appropriate.

Capital Expenditure - The cost of an asset, including the cost to put it in place. Capital expenditure for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it was acquired. Ancillary charges, such as taxes, duty, protective in-transit insurance, freight, and installation may be included in, or excluded from, capital expenditure cost in accordance with the recipient organization's regular accounting practices.

Carryover - The ability of grantees to use grant funds from one budget period (typically, one year) in the next period for grants covered by new a grant regulation, 45 CFR Part 74 (known as the expanded authorities), which applies to most R (but not R41 or 43), P, K, and T series grants.

Carryover Balance - Unobligated funds of the recipient from a previous funding period under a grant that are authorized for use to cover allowable costs in a current funding period.

Catalog of Federal Domestic Assistance - A catalog published twice a year that describes domestic assistance programs administered by the Federal Government. This government-wide compendium of Federal programs lists projects, services, and activities that provide assistance or benefits to the American public.

Categorical Grant - A grant having a specifically defined purpose.

Centers - Center grants are awarded to institutions on behalf of Program Directors and groups of collaborating investigators. They provide support for long-term, multidisciplinary programs of research and development.

Centers of Excellence (COEs) - Recipients of a “Center of Excellence” award from the Centers of Excellence (COE) Program of the Division of Disadvantaged Assistance, Bureau of Health Professions, Health Resources and Services Administration, DHHS. The telephone number for the COE Program Office is 301-443-2100. A list of Centers of Excellence, and further information about the COE Program, can be found at http://bhpr.hrsa.gov/diversity/coe/default.htm.

Change of Recipient Institution - A process whereby the legal and administrative responsibility for a grant-supported project or activity is transferred from one legal entity to another before the expiration date of the approved project period. (See "Replacement Recipient.")

Change of Principal Investigator - A process, usually initiated by the grantee, whereby the approved principal investigator is replaced, usually requiring approval by the Awarding Office.

Change of Scope - A process, usually initiated by the grantee, whereby the objectives or specific aims identified in the approved grant application are significantly changed, and requiring approval by the Awarding Office.

Closeout - The process by which the awarding office determines whether all applicable administrative actions and all work required by the grant have been completed by the recipient and the awarding agency for a project or other specified period.

Co-Funding - An agreement by two or more awarding agencies (usually ICs) to participate jointly in the support of a grant.

Cognizant Agency - The Federal agency which, on behalf of all Federal agencies, is responsible for: reviewing, negotiating, and approving cost allocation plans, indirect cost rate and similar rates; monitoring non-Federal audit reports; conducting Federal audits as necessary; and resolving cross-cutting audit findings.

Competing Applications - Applications that are either new or recompeting that must undergo initial peer-review.

Competing Continuation Application - A request for a grant to extend for one or more additional budget periods a project period that would otherwise expire. Competing continuation applications compete with other competing continuation, competing supplemental, and new applications for funds.

Competing Continuation Award - An award that adds funds to a grant and extends one or more budget periods beyond the currently established project period.

Competitive Segment - The initial project period recommended for support (up to five years) or each extension of a project period resulting from the award of a competing continuation grant.

Competition or Competitive Review Process - The process whereby applications are reviewed by an independent/objective review panel and evaluated against established review criteria and scored and rated accordingly. As a result, usually the applications with the highest scores and rating receive grants.

Completion Date - The date on which all work under an award is completed or the date on the award document, or any supplement or amendment thereto, on which Federal sponsorship ends (i.e., the end of a project period).

Conflict of Interest - Any action by a reviewer in the grants review or awarding process which would affect, or could appear to affect, the reviewer's financial interest, or would cause the reviewer's impartiality in the grants process to be questioned. Specific situations include, but are not limited to, the following: a reviewer may not participate in the review or award of a specific grant application in which any of the following has a financial interest: (1) the reviewer, the reviewer's spouse, parent, child, or partner; (2) any organization in which the reviewer, the reviewer's spouse, parent, child, or partner serves as officer, director, trustee, partner or is otherwise similarly associated; (3) any organization in which the reviewer, the reviewer's spouse, parent, child, or partner is negotiating for or has an arrangement concerning prospective employment or other similar association; or (4) any organization in which the reviewer, the reviewer's spouse, parent, child, or partner has an interest with respect to any pending grant application competing under the same program as any other grant application to be reviewed by the same committee or group of field researchers.

Consortium Grant - A grant to one institution in support of a project in which any programmatic activity is carried out through a collaborative arrangement between or among the recipient institution and one or more other institutions or organizations which are separate legal entities, administratively independent of the recipient. The involvement of the non-recipient (collaborating) institutions is that of actually performing a portion of the programmatic activity.

Construction - A project, supported through a discretionary grant or a cooperative agreement, to support the initial building or large-scale modernization or permanent improvement of a facility.

Cooperative Agreement - An award instrument of financial assistance where “substantial involvement” is anticipated between the DHHS awarding agency and the recipient during performance of the contemplated project or activity. “Substantial involvement” means that the recipient can expect Federal programmatic collaboration or participation in managing the award.

Cost Center - An identifiable department or area within a recipient's organization that has been assigned an account number in the recipient's accounting system for the purpose of accumulating costs.

Cost Principles - The principles as set out in applicable statutes, regulations, grantor instructions, Office of Management and Budget Circulars and generally accepted accounting rules used for determining allowability, reasonableness, and allocability of costs applicable to grants, contracts, and other agreements.

Cost Sharing or Matching - The value of allowable third party in-kind contributions and the allowable costs of a Federally assisted project or program not borne by the Federal Government.

Currently Effective Indirect Cost Rate - The rate authorized by the cognizant Federal agency for reimbursing F&A costs under DHHS grants.

Deferral - a term that indicates that applications are approved but not funded, or are held for a later review cycle.

Deferred - Refers to the delay in the review of an application by a scientific review group, usually to the next review cycle, due to insufficient information.

DHHS - Department of Health and Human Services.

Direct Costs - Costs that can be identified with a particular project or program. Allowable direct costs may include:

Salaries and fringe benefits of Principal Investigators and supporting staff
Expenditures for project-related equipment and supplies
Fees and supporting costs for consultant services
Expenses for travel
Inpatient and outpatient costs for research subjects
Alterations and renovations
Publications and other miscellaneous expenses
Contract services
Costs for consortium participants

Direct Operations - Funds for salary and other administrative costs.

Disallowance Letter - The formal letter issued to a recipient by an authorized official advising of specific costs that have been determined to be unallowable. Where appropriate, the letter also informs the recipient of its appeal rights.

Disallowed Cost or Disallowance - A charge to a grant that the Federal awarding agency determines to be unallowable, in accordance with the applicable Federal cost principles or other terms and conditions contained in the award.

Dual Assignments - Applications simultaneously assigned to two ICs. The primary IC has complete responsibility for administering and funding the application; the secondary assumes this responsibility only if the primary is unable or unwilling to support it.

Dual Review System - Peer-review process used by NIH. The first level of review provides a judgment of scientific merit. The second-level of review, conducted by an IC's advisory council or board, assesses the quality of the first review, sets program priorities, and makes funding recommendations.

Eligibility - The status an entity must possess in order to be considered for a grant.

Equipment - The tangible, non-expendable personal property (including exempt property) charged directly to an award having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. However, consistent with recipient policy, lower limits may be established.

Executive Order - An order issued by the President of the United States which has the full force and effect of law on the Executive Branch of the Federal Government.

Executive Order 12372 (Intergovernmental Review of Federal Programs) - The process under which state and local officials review certain proposed Federal financial assistance (usually in the form of grant applications). The objectives of the process are to increase state flexibility to design a consultation process and select programs for review, increase the ability of state and local elected officials to influence Federal decisions, and compel Federal officials to be more responsive to state concerns. For those states that participate in the process, a single state official or organization is designated for coordination of the review process and to send official state process comments and recommendations to Federal agencies. These state officials or organizations are referred to as State Single Points of Contact (SPOCs). [45 CFR Part 100, *Intergovernmental Review of Department of Health and Human Services Programs and Activities,* is DHHS's implementation of the Executive Order.]

Exempt Property - The tangible personal property acquired, in whole or part, with Federal funds, where the awarding agency has statutory authority to vest title in the recipient without further obligation to the Federal Government.

Expanded Authorities - The operating authorities provided to grantees under certain research grant mechanisms that waive the requirement for NIH prior approval for specified actions. [http://grants2.nih.gov/grants/policy/nihgps_2001/part_iia_5.htm#_Toc504811854 and http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-070.html]

Extramural Research - Research supported by NIH through a grant, contract, or cooperative agreement.

Expiration Date - The date signifying the end of the current budget period, after which the grantee is not authorized to obligate grant funds regardless of the ending date of the project period or "completion date."

Expenditure Report - (1) for non-construction grants, the Financial Status Report; (2) for construction grants, the Outlay Report and Request for Reimbursement for Construction Programs; and (3) all other OMB-approved program-specific expenditure reports.

Extension - The prolonging of a project period.

F&A (Facilities and Administration) Costs - Costs that are incurred by a grantee for common or joint objectives and that, therefore, cannot be specifically identified with a particular project or program. These costs were previously known as "indirect costs."

Federal Funds Authorized - The total amount of Federal funds obligated by the Federal Government for use by the recipient. This amount may include any authorized carryover of recipient unobligated funds from prior funding periods when permitted by agency regulations or agency implementing instructions.

Federal Share - The amount, generally expressed as a percentage of total project costs, of financial, property, or other direct assistance provided by the Federal Government to an eligible recipient to accomplish a public purpose of support or stimulation authorized by statute. The Federal and non-Federal share are so noted on the Notice of Grant Award.

Field Reader - A person selected to review grant applications during a competitive review process. Field readers may function the same as independent review group members, except that they do not meet to discuss applications and their evaluations are submitted by mail.

Final Indirect Cost Rate - A permanent rate established after the actual direct costs for a given fiscal year of the organization are known and the actual amount of F&A costs applicable to federally-sponsored programs have been determined. This type of rate is not subject to subsequent adjustment.

Financial Status Report (FSR) - A financial report due 90 days after the end of each budget period showing the status of awarded funds for that period. The report is mandatory for continued funding of the grant.

Fixed Indirect Cost Rate - A permanent rate that has the same characteristics as a predetermined rate. However, unlike a predetermined rate, the difference between the estimated costs used to establish the fixed rate, and the actual costs of the period covered by the rate, is "carried forward" as an adjustment to the rate computation of a subsequent period.

Funding Period - The period of time when Federal funding is available for obligation by the recipient.

Grant - A financial assistance mechanism between NIH and a recipient for approved activities. Performance responsibility rests primarily with the recipient, and there is little or no Federal involvement or participation in the work involved.

Grant-approved Project/Activities - Those activities specified or described in a grant application, plan, or other document that are approved by NIH awarding office for funding, or changes which may be proposed by the grantee and subsequently approved by NIH awarding office Grants Management Officer. For purposes of this definition, it does not matter whether Federal funding constitutes all or only a portion of the financial support necessary to carry out such activities.

Grant Appeals - A DHHS policy that provides for an appeal by the grantee institution of post-award administrative decisions made by awarding offices. There are two levels of appeal available – an informal NIH procedure and a formal DHHS procedure. The grantee must first exhaust the informal procedures before appealing to the DHHS Appeals Board.

Grant Budget Period - The interval (usually 12 months) into which the grant project period is divided for funding and reporting purposes.

Grants Management Officer (GMO) - NIH official who is responsible for the business

management of grants and cooperative agreements, including ensuring that both the granting agency and grantees meet all requirements of laws, regulations, and policies.

Grants Management Specialist - An NIH staff member who is the focal point for all business activities associated with the negotiation, award, and administration of a grant or cooperative agreement. He or she also interprets grant administration policy and provisions.

Health Scientist Administrator (HSA) - At NIH, the awarding office official who is responsible for the technical, scientific, or programmatic aspects of a grant. This official may also be referred to as the Program Officer or Project Officer. Such individuals deal with recipient organization staff to assure programmatic progress and work closely with the Grants Management Officer and the grants management staff in the overall administration of grants.

HHS - See DHHS

Human Subjects - Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under Federal regulations, human subjects are defined as living individuals about whom an investigator conducting research obtains data through intervention or interaction with the individuals or identifiable private information.

IC - See Institute/Center.

Incremental Funding - The process by which an awarding agency funds multi-year projects in budget periods. For example, a three-year project would normally be funded in three budget periods.

Independent or Objective Review - An advisory competitive review of discretionary grant applications usually conducted by peer/expert review groups.

Indirect Costs - Those costs that are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular sponsored project, program, or activity but are nevertheless necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries are generally treated as indirect costs. For institutions subject to OMB Circular A-21, the term "facilities and administration" is used to denote indirect costs.

Indirect Cost Base - The accumulated direct costs (normally either total direct salaries and wages or total direct costs exclusive of any extraordinary or distorting expenditures) that are used to distribute indirect costs to individual Federal grant awards and programs.

Indirect Cost Pool - The accumulated costs that jointly benefit two or more programs or other cost objectives.

Indirect Cost Proposal - The documentation prepared by a recipient to substantiate its claim for the reimbursement of indirect costs. This proposal provides the basis for review, audit, and negotiation leading to the establishment of the organization's indirect cost rate(s).

Indirect Cost Rate - The ratio, expressed as a percentage, of an organization's total indirect costs to its direct cost base (commonly direct salaries and wages or total direct costs exclusive of any extraordinary or distorting expenditures). When a rate is established for a specific activity or program, the rate represents the ratio of the total indirect costs allocated to the activity or program to the direct base costs of the activity or program. (See "Indirect Cost Base.")

Indirect Cost Rate Agreement - The document that formalizes the establishment of indirect cost rates and provides information on the proper application of the rates.

Initial Peer-Review Criteria -

Significance -	Is the topic important? Will it advance scientific knowledge?
Approach -	Are the hypothesis, design, and methods well developed and appropriate? Are potential problems addressed?
Innovation -	Does the proposal involve new ideas or methods? Does it challenge existing paradigms?
Investigator -	Do the investigator and collaborators have the training and experience to do the work?
Environment -	Will the scientific environment contribute to success? Is there institutional support for the project? Does the work take advantage of existing opportunities including collaborations?

Initial Review Group (IRG) - In PHS, a group composed of primarily non-Federal scientific experts who conduct the initial scientific and technical merit review of grant applications. (See "Scientific Review Group.")

Institute/Center (IC) - Major NIH organizational component responsible for a particular grant program(s) or set of activities.

Institutional Review Board (IRB) - IRBs are set up by research institutions to ensure the protection of rights and welfare of human research subjects participating in research conducted under their auspices. IRBs make an independent determination to approve, require modifications in, or disapprove research protocols based on whether human subjects are adequately protected, as required by Federal regulations and local institutional policy.

Institutions of Emerging Excellence - Recipients of a "Center of Excellence" award – in the fiscal year preceding the fiscal year in which an application is submitted for an RFIP award – from the Centers of Excellence (COE) Program of the Division of Disadvantaged Assistance, Bureau of Health Professions, Health Resources and Services Administration, DHHS. (See "Centers of Excellence.")

Intramural Research - Research conducted by government-run NIH laboratories.

Investigator-Initiated Research - Research funded as a result of an investigator, on his or her own, submitting a research application.

Invention - Any discovery which is or may be patentable or otherwise protectable. The term "subject invention" means any invention of an awardee conceived or first actually reduced to practice in the performance of work under a funding agreement, i.e., contract, grant, or cooperative agreement.

Invention Reporting - The requirement that recipients of contracts, grants, or cooperative agreements fully disclose any subject inventions made during the performance of work under a funding agreement in order to protect the government's rights.

Just In Time - A reinvention innovation in which applicants send some information to NIH only if an award is likely, streamlining the application process.

Key Personnel - Individuals who contribute in a substantive way to the scientific development or execution of a project, whether or not they receive compensation from the grant supporting that project. The principal investigator is included in this category.

Low-Cost Extension - An extension of time to a project period and/or budget period to complete the work under a grant, with minimal amount of further Federal support.

Mechanism - See Activity code.

Monitoring - A process whereby the programmatic and business management performance aspects of a grant are reviewed by collecting and assessing information from reports, audits, site visits, and other sources.

National Advisory Council/Board - An administrative body in the Public Health Service (PHS) composed of both scientists and lay members that has a broader responsibility than initial review groups. As authorities knowledgeable in specific areas, Council/Board members perform the final advisory review of grant applications and also offer advice and make recommendations on matters of significance to the policies, missions, and goals of the awarding unit they advise.

No-Cost Extension - An extension of time to a project period and/or budget period to complete the work of the grant under that period, without additional Federal funds or competition.

Non-competing Application - Those applications which will be reviewed noncompetitively, rather than through the usual competitive review process.

Non-competing Continuation Award - A grant award for a subsequent budget period within a previously approved project period for which a recipient does not have to compete with other applicants.

Non-competing Grant - An ongoing grant whose award is contingent on the completion of a progress report as the condition for the release of money for the following year.

Non-Federal Share - The portion of allowable project costs not borne by the Federal

Government.

Not Recommended for Further Consideration (NRFC) - A judgment made by a scientific review group for applications when the merit of the proposed research is not significant and substantial enough to warrant a further review by a council/board. The study section does not recommend funding; the application cannot be funded by an IC.

Notice of Award (NOA; formerly NOGA or NGA) - Official notification to the applicant that the project is being funded. The official award document, signed by the Grants Management Officer, or his or her delegate, that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and, (3) provides the documentary basis for recording the obligation of Federal funds in the Department's accounting system.

OMB - The United States Office of Management and Budget.

OMB Circular A-21 - The OMB Circular establishing the cost principles for allowability of costs incurred by institutions of higher education under federally-sponsored agreements.

OMB Circular A-87 - The OMB Circular establishing the cost principles for allowability of costs incurred by state, local and federally-recognized Indian tribal governments under federally-sponsored agreements.

OMB Circular A-102 - The OMB Circular establishing the administrative standards for grants (except for some block grants and entitlement grants) and cooperative agreements to state and local governments and federally-recognized Indian tribal governments.

OMB Circular A-110 - The OMB Circular establishing the administrative standards for grants and cooperative agreements to non-governmental organizations.

OMB Circular A-122 - The OMB Circular establishing the cost principles for allowability of costs incurred by non-profit organizations under federally-sponsored agreements, except institutions of higher education subject to Circular A-21 and hospitals which are covered under 45 CFR Part 74, Appendix E, *Principles For Determining Costs Applicable to Research and Development Under Grants and Contracts With Hospitals*. Note that the allowability of costs incurred by commercial organizations is determined in accordance with the provisions of the Federal Acquisition Regulation (FAR), Part 31.

OMB Circular A-133 - The OMB Circular establishing audit requirements for states, local governments, Indian tribes and non-profit organizations.

Outlays or Expenditures - The charges made to the Federally-sponsored project or program. They may be reported on a cash or accrual basis. For reports prepared on a cash basis, outlays are the sum of actual cash disbursements for direct charges for goods and services, the amount of indirect expense incurred, the value of in-kind contributions applied, and the amount of cash advances and payments made to contractors and subrecipients. For reports prepared on an accrued expenditure basis, outlays are the sum of actual cash disbursements, the amount of indirect expense incurred, the value of in-kind contributions applied, and the net increase (or decrease) in the amounts owed by the recipient for the goods and other property received, for services performed by employees, contractors, subrecipients, subcontractors, and other payees, and other amounts becoming owed under programs for which no current services or performance is required, such as annuities, insurance claims, and other benefit payments.

PA - See Program Announcement.

PAR - See Program Announcement.

Payline - A funding cut-off point determined by balancing the number of applications with the amount of funds available.

Peer Review - A form of independent review utilizing reviewers who are the professional equivalents of the applicant's Project Director or Principal Investigator.

PHS - Public Health Service.

PI - See "Principal Investigator."

Pre-award Cost - The cost incurred prior to the effective date of the award and in anticipation of the award, where incurrence is necessary to comply with the proposed delivery schedule or period of performance.

Predetermined Indirect Cost Rate - An indirect cost rate, applicable to a specified current or future period, usually the recipient's fiscal year. This rate is based on an estimate of the costs to be incurred during the period. Except under very unusual circumstances, a predetermined rate is not subject to adjustment.

Principal Investigator (PI) - A qualified person designated by the applicant institution to direct the project or program defined in the grant application. Principal Investigators are responsible and accountable to the grantee for the proper conduct of the project activity. The grantee is, in turn, legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity.

Prior Approval - The written permission provided by the authorized granting official from the DHHS awarding office before the recipient may undertake certain activities (such as performance or modification of an activity), expend funds, or exceed a certain dollar level.

Priority Score - An average of the individual ratings given by voting members of the scientific

review group. Ratings range from 1.0 (or 100 – outstanding) to 5.0 (or 500 – acceptable), reflecting a judgment of scientific merit. While the study sections work with the 1.0 to 5.0 range, the listed priority score on a summary statement is given in the 100 to 500 range.

Program - A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, whose purpose is to implement an organization's mission or some specific program-related aspect of that mission. In these Guidelines, "program" refers to those NIH programs that carry-out their mission through the award of grants or cooperative agreements to other organizations.

Program Announcement (PA or PAR) - one of NIH's formal published announcements of the availability of federal funding through one of its assistance programs. The announcement invites applications and provides such information as eligibility and evaluation criteria, funding preferences/priorities, how to obtain application kits, and the submission deadline.

Program Balance - The need to balance an IC's support of research in all its programmatic areas with its high-quality applications eligible for funding.

Program Income - The gross income received by the grant recipient and/or sub-recipient that was directly generated by the supported activity, or earned as a result of the award. Program income includes (but is not limited to) income from fees for services performed, the use or rental of real or personal property acquired under the grant, the sale of commodities or items fabricated under an award, license fees and royalties on patents and copyrights, and payments of interest on loans made with grant funds. Except as otherwise provided in statute, regulation, or the terms and conditions of the award, program income does not include interest earned on advances of grant or subgrant funds, or rebates, credits, discounts, refunds, etc., or interest earned on any of them.

Program Official - An IC staff member responsible for overseeing and monitoring a scientific program and progress of grants in his or her portfolio. S/he serves as the counterpart to the Grants Management Officer who is responsible for all business management aspects of a grant.

Programmatic Reduction - The dollar amount a grant award is reduced from the amount recommended by the study section (Scientific Review Group). This is done so ICs can maintain a sufficient number of grants in their portfolio and to combat inflation of grant costs.

Progress Report - A recipient report which contains for each grant information on the comparison of actual accomplishments to objectives established for the period.

Project Costs - The total allowable costs incurred by a recipient (and the value of the in-kind contributions made by third parties) in accomplishing the objectives of the award during the project period.

Project Director/Principal Investigator/Program Director - An individual designated by the recipient to direct the project or program being supported by a grant. S/he is responsible and accountable to officials of the recipient organization for the proper conduct of the project, program, or activity.

Project Period - The total time for which support of a project has been approved – consisting of one or more budget periods – including any extensions. The total project period comprises the initial competitive segment, subsequent competitive segment(s) resulting from a competing continuation award(s), and noncompeting extensions. Competing extensions of a project period are subject to peer-review, reevaluation of the activity, and recompetition for available funds. It does not constitute a commitment by the Federal Government to fund the entire period.

Property - The term, unless otherwise stated, includes real property, equipment, intangible property, and debt instruments.

Provisional Indirect Cost Rate - A temporary rate established for a given period to permit interim reimbursement of indirect costs pending the establishment of a permanent rate for the period. When a permanent rate is established, the indirect costs reimbursed based on the provisional rate are adjusted upward or downward to reflect the costs based on the permanent rate.

Real Property - Land, including land improvements, structures and appurtenances thereto, but excluding movable machinery and equipment.

Reasonable Cost - A cost is reasonable if, in its nature or amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost.

Rebuttal - A procedure for contesting the peer-review of a grant application. Synonymous with appeal.

Recipient or Grantee - The entity receiving financial assistance directly, in the form of a grant or cooperative agreement, from a Federal agency to carry out a project or program. Although grant funding and benefits may be limited to a particular site or component of a larger entity, the entire legal entity that received the award is legally responsible for carrying out a program or project, even if the grant award document refers only to the particular site or component.

Recommended - Designation given by a study section advising that an application be funded. The application gets a priority score and summary statement. Roughly the top half of applications being reviewed are recommended for funding.

Recommended Levels of Future Support - Funding level recommended for each future year approved by the scientific review group, subject to availability of funds and scientific progress.

Recompeting ("Type 2 ") - A competing continuation application or renewal; a grant whose project period is over and for which the applicant is again seeking NIH support.

Replacement Recipient - An organization which assumes responsibility, upon approval of the awarding agency, for an existing financial assistance award. In order for there to be a replacement recipient, the bona fide need for the project must continue, the purpose of the grant from the government's perspective must be the same, and the revised grant must have the same scope. An example of a replacement grant would be an instance when a Principal Investigator transfers to a new organization and the original recipient relinquishes the grant to that organization.

Request For Applications (RFA) - one of NIH's formal published announcements of the availability of Federal funding through one of its assistance programs. The announcement invites applications and provides such information as eligibility and evaluation criteria, funding preferences/priorities, how to obtain application kits, and the submission deadline.

Research Portfolio - The cohort of grants supported by a given NIH organization.

Research Project Grants (RPG) - A budget term referring in NCRR to the following mechanisms: R01, R03, R21, R33, R35, R37, R41, R42, R43, R44, P01, U01, U19, U43, U44.

Resubmission - Sending NIH an application for initial peer-review after it has been reviewed by a study section and revised by the applicant. Each resubmission is given a code, e.g., A1, A2. NIH limits you to two resubmissions.

Reversionary Interest - The interest of the government in real property acquired with Federal grant funds. To protect that interest, real property acquired with grant funds may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the recipient, except as expressly authorized in writing by the awarding component.

Review Cycle - Refers to the Center for Scientific Review's thrice yearly initial peer-review cycle, from the receipt of applications to the date of the review.

RFA - See Request for Applications.

Scientific Review Administrator (SRA) - A Health Science Administrator who manages the activities of a scientific review group, including CSR study sections, and is responsible for coordinating and reporting the review of each application assigned to it. The SRA serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications reviewed. The SRA performs an initial review of applications for completeness and conformity to requirements, ensures that adequate numbers of reviewers with appropriate expertise are available for application review, assigns applications to individual reviewers as discussion leaders and for preparation of written critiques, and serves as the overall point of contact with applicants during the initial phase of the peer-review process (i.e., until the conclusion of the scientific review group meeting).

Scientific Review Group (SRG) - Formerly called initial review group; a.k.a. study section - A chartered committee that performs the first level of peer-review; now generally called a scientific

review group. (See also “Dual Review System.”)

SEPs - Special Emphasis Panels, formerly known as (SRCs) Scientific Review Committees have been established to cover all scientific peer-review activities formerly provided by *ad hoc* groups. A SEP may include a variety of scientific review activities such as responses to Requests for Applications, program projects, centers, and project concepts. SEPs will be used for project site visits in institutions where the site visit team is also the scientific review group, initial review of applications from members of chartered advisory committees with appointed membership, and overflow of applications where previously done by *ad hoc* groups.

Small Business Concern - A business, including its affiliates, which is independently- owned and operated, is not dominant in the field of operation, and can further qualify under the criteria concerning number of employees, average annual receipts, or other criteria, as prescribed by the Small Business Administration (Title 13 CFR 121, "Small Business Concern").

Special-Purpose Equipment - That equipment which is usable only for research, medical, scientific, or other technical activities. This includes such items as microscopes, X-ray machines, and surgical instruments. The governing criterion for distinguishing general-purpose equipment from special-purpose equipment is the potential use of the equipment, not its actual use. General-purpose equipment does not become special-purpose equipment merely because it is used only on research, medical, scientific or other technical activities, or because it is used in a scientific or technical location or environment.

Streamlined Review (formerly triage) - A practice, expanded under NIH's reinvention efforts, through which applications judged by reviewers to be in the bottom tier (roughly 50-100 percentile) are not given a priority score.

Success Rate - Roughly, the number of applications funded by an IC divided by the number of applications referred to it that were reviewed (applications resubmitted during the fiscal year are counted only once).

Summary Statement - An official document showing the outcome of initial peer-review, containing priority score and percentile, codes for various areas of concern (e.g., human subject research), and recommended budget. Summary statements generally have a short synopsis of the project prepared by the scientific review administrator and reviewer critiques. When special review criteria are used, the critiques are synthesized by the scientific review administrator.

Supplemental Application - A request for an increase in support during a current budget period to expand a project's scope or to meet unforeseen increased costs.

Supplemental Award - The award of additional funds to: (1) support new or additional activities which are not identified in the current grant or which significantly expand the project's scope beyond the purpose(s) for which the current grant was awarded; (2) support an expansion of the grant approved activities; or (3) provide for an increase in costs due to unforeseen circumstances.

Suspension - Temporary withdrawal of a grantee's authority to obligate grant funds, pending

either corrective action by the grantee, as specified by NIH, or a decision by NIH to terminate the award.

Termination - The permanent cancellation of the recipient's authority to obligate all or part of the funds which have been awarded to it. It also means the recipient's voluntary relinquishment of that authority. Termination is distinct from NIH's refusal to provide additional funds through a non-competing continuation award (denial of refunding/witholding of support).

Terms and Conditions - All requirements imposed on a recipient by the Federal awarding agency, whether by statute, regulation, or within the grant award document itself. The terms of award may include both standard and special provisions, appearing on each Notice of Grant Award, that are considered necessary to attain the objectives of the grant, facilitate post-award administration of the grant, conserve grant funds, or otherwise protect the Federal Government's interests.

Total Project Costs - The total allowable direct and F&A costs incurred by the recipient to carry out an approved grant-supported project or activity, including costs charged to NIH grant, costs paid by the recipient from non-federal sources, and the value of third-party in-kind contributions.

Triage - Not Used: See "Streamlined Review."

Unallowable Cost - A cost determined to be unallowable in accordance with the applicable federal cost principles or other terms and conditions contained in a grant award.

Unliquidated Obligation - (1) For reports prepared on a cash basis, the amount of obligations incurred by the recipient that has not been paid; and (2) for reports prepared on an accrued expenditure basis, the amount of obligations incurred by the recipient for which an outlay has not been recorded.

Unobligated Balance - The portion of the funds authorized by the Federal agency that has not been obligated by the recipient.

Unscored - A designation given by a study section indicating that it judges an application to be in the bottom half of applications being reviewed and therefore unlikely to be funded. The application does not receive a priority score but is reviewed, and the applicant receives the reviewers' critiques. Occasionally, an unscored application is funded by a special action of an IC's advisory council.

Vertebrate Animals - Any live animal having a backbone or spinal column used or intended for use in research, research training, experimentation, biological testing, or for related purposes.

Withholding of Support - A decision by NIH not to make a noncompeting continuation award within the current competitive segment.