

MIDCAREER INVESTIGATOR AWARD IN PATIENT-ORIENTED RESEARCH
(K24)

RELEASE DATE: June 8, 2004

PA NUMBER: PA-04-107

EXPIRATION DATE: April 1, 2007, unless reissued.

Department of Health and Human Services (DHHS)

NOTE TO APPLICANTS: Applicants submitting competing renewals or amended applications for the July 1, 2004 receipt date should follow the guidelines in PA-00-005 <http://grants.nih.gov/grants/guide/pa-files/PA-00-005.html>

This program announcement, PA-04-107, will supersede PA-00-005 and apply to all K24 applications submitted on or after the October 1, 2004 deadline.

PARTICIPATING ORGANIZATION:

National Institutes of Health (NIH)

(<http://www.nih.gov>)

COMPONENTS OF PARTICIPATING ORGANIZATION:

National Institute on Aging (NIA)

(<http://www.nia.nih.gov>)

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

(<http://www.niaaa.nih.gov>)

National Institute of Allergy and Infectious Diseases (NIAID)

(<http://www.niaid.nih.gov>)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

(<http://www.niams.nih.gov>)

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

(<http://www.nibib.nih.gov>)

National Cancer Institute (NCI)

(<http://www.nci.nih.gov>)

National Institute of Child Health and Human Development (NICHD)

(<http://www.nichd.nih.gov>)

National Institute on Deafness and Other Communication Disorders (NIDCD)

(<http://www.nidcd.nih.gov>)

National Institute of Dental and Craniofacial Research (NIDCR)

(<http://www.nidcr.nih.gov>)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

(<http://www.niddk.nih.gov>)

National Institute on Drug Abuse (NIDA)

(<http://www.nida.nih.gov>)

National Institute of Environmental Health Sciences (NIEHS)

(<http://www.niehs.nih.gov>)

National Institute of Nursing Research (NINR)

(<http://ninr.nih.gov/ninr/>)

National Eye Institute (NEI)

(<http://www.nei.nih.gov>)

National Heart, Lung, and Blood Institute (NHLBI)

(<http://www.nhlbi.nih.gov>)

National Institute of Mental Health (NIMH)

(<http://www.nimh.nih.gov>)

National Institute of Neurological Disorders and Stroke (NINDS)

(<http://www.ninds.nih.gov>)

National Center for Complementary and Alternative Medicine (NCCAM)

(<http://www.nccam.nih.gov>)

National Center for Research Resources (NCRR)

(<http://www.ncrr.nih.gov>)

The following NIH Institutes and Centers do not participate in this program:

National Institute of General Medical Sciences (NIGMS); National Human Genome Research Institute (NHGRI); National Library of Medicine (NLM); National Center on Minority Health, Health Disparities (NCMHD); and the Fogarty International Center (FIC).

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: 93.866; 93.271; 93.855, 93.856; 93.846; 93.286; 93.398; 93.865; 93.173; 93.121; 93.847, 93.848, 93.849; 93.279; 93.113, 93.114, 93.115; 93.361; 93.867; 93.233, 93.837, 93.838, 93.839; 93.281; 93.853; 93.213; 93.389

THIS PA CONTAINS THE FOLLOWING INFORMATION

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SPECIAL NOTE: The participating NIH institutes and centers may have distinctive guidelines and requirements for this announcement in order to accommodate the career needs of researchers working in fields related to their specific research missions.

Candidates are therefore encouraged to contact the staff person in the relevant institute or center listed under INQUIRIES prior to preparing an application to discuss issues of eligibility and review the specific provisions of this award.

PURPOSE OF THIS PA

The purpose of the Midcareer Investigator Award in Patient-Oriented Research is to provide support for clinician investigators to allow them protected time to devote to patient-oriented research (POR) and to act as research mentors primarily for clinical residents, clinical fellows and/or junior clinical faculty. This award is primarily intended for clinician investigators who are at the Associate Professor level or are functioning at that rank in an academic setting or equivalent non-academic setting, and who have an established record of independent, peer-reviewed Federal or private research grant funding in POR. This award is intended to advance both the research and the mentoring endeavors of outstanding patient-oriented investigators. It is expected, for example, that investigators will obtain new or additional independent peer-reviewed funding as the PI for POR and establish and assume leadership roles in collaborative POR programs; and that there will be an increased effort and commitment to mentor beginning clinician investigators in POR to enhance the research productivity of the investigator and increase the pool of well-trained clinical researchers of the future. With a view to achieving these objectives, the maximum level of allowable Research Development Costs has been increased in this announcement from \$25,000 to \$50,000 per year.

For the purposes of this award, and in agreement with the recommendations of the NIH Director's Panel on Clinical Research, (<http://www.nih.gov/news/crp/97report/index.htm>), patient-oriented research is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator directly interacts with human subjects. This area of research includes 1) mechanisms of human disease; 2) therapeutic interventions; 3) clinical trials, and; 4) the development of new technologies. Studies falling under Exemption 4 for human subjects research are not included in this definition.

RESEARCH OBJECTIVES

Background

In 1995, the NIH Director's Panel on Clinical Research was convened by the former Director of NIH, Dr. Harold Varmus, to review the status of clinical research in the United States and to make recommendations about how to ensure its effective continuance. The Panel first developed a three-part working definition of Clinical Research, breaking down Clinical Research into three categories: patient-oriented research (POR), epidemiologic and behavioral studies, outcomes research and health services research. The Panel then formulated 10 recommendations that were presented to the Advisory Council to the Director NIH in December, 1996. In the area of training, the

Panel recommended the initiation of new support mechanisms for mid-career clinical investigators, providing protected time to stabilize their clinical research laboratories, continue mentoring of junior clinical researchers, and to enhance their clinical research careers.

In response to the recommendations of the Advisory Council in the area of training, NIH in 1998 issued two program announcements (PA). The first PA entitled Mentored Career Development Award in Patient-Oriented Research used the NIH K23 funding mechanism and was intended to provide junior clinical investigators protected time to initiate a research career in POR. The second PA entitled Midcareer Investigator Award in Patient-Oriented Research used the NIH K24 funding mechanism and was primarily intended to provide protected time to investigators with their own independent research support, i.e. PI's, to mentor junior clinical investigators, particularly K23 grantees, in POR and to stabilize the careers of these investigators so that they could continue to be available as mentors in POR. This award has formed an important part of the NIH initiative to attract and retain talented individuals to the challenges of patient-oriented research.

Objectives

The specific objectives of the Midcareer Investigator Award in Patient-Oriented Research are to:

- o encourage established, mid-career clinician scientists who are experienced in POR to devote more time to POR and enhance their clinical research skills in order to mentor new clinical investigators and to conduct meritorious patient-oriented research.
- o increase the pool of clinical researchers who can conduct patient-oriented research, who will be able to successfully compete for peer-reviewed grants, and mentor the next generation of clinical investigators.

MECHANISM OF SUPPORT

This Program Announcement will use the NIH K24 award mechanism. Planning, direction, and execution of the proposed project and program will be the responsibility of the applicant.

Applicants may request three to five years of support (at least three years are required). This award may be renewed one-time if the K24 recipient continues to have independent peer-reviewed patient-oriented research support at the time of submission of the competing renewal application. Applicants requesting renewals must also meet all the remaining requirements of the original award.

Funding beyond the first year is contingent upon satisfactory progress during the preceding year, as documented in the required progress report (refer to "Special

Requirements G. Reporting Requirements"). The terms of the NIH Grants Policy Statement and the requirements of this PA apply to these awards.

This PA uses just-in-time procedures. However, since this PA requires that the applicant have a track record of research support, independent or otherwise, current and past research support must be documented in the application as a part of the research support section of the biosketch.

The modular budget format does not apply to the K24.

ELIGIBLE INSTITUTIONS

You may submit an application if your institution has any of the following characteristics:

- o For-profit or non-profit organizations;
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories;
- o Domestic institutions/organizations;
- o Foreign institutions are not eligible to apply

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Only U.S. citizens or noncitizen nationals, or an individual lawfully admitted for permanent residence who possesses an Alien Registration Receipt Card (I-151 or I-551), or some other verification of legal admission as a permanent resident, are eligible to receive this award. Candidates must meet this criterion prior to the time of award. Noncitizen nationals, although not U.S. citizens, owe permanent allegiance to the U.S. They are usually born in lands that are not states but are under U.S. sovereignty, jurisdiction, or administration. Individuals on temporary or student visas are not eligible.

Candidates for this award must have a health-professional doctoral degree or its equivalent. Such degrees include but are not limited to the M.D., D.O., D.D.S., D.M.D., O.D., D.C., Pharm.D., N.D. (Doctor of Naturopathy), as well as a doctoral degree in nursing. Candidates with Ph.D. degrees are eligible for this award if the degree is in a clinical field and they usually perform clinical duties. This may include clinical psychologists, clinical geneticists, speech and language pathologists. Applicants should be at the Associate Professor level, or are functioning at that rank in an academic setting or equivalent non-academic setting and must have an established record of independent, peer-reviewed patient-oriented research grant funding and record of publications. This award is intended for individuals who are at a mid-career stage and have a record of supervising and mentoring patient oriented researchers. Candidates are advised to discuss their eligibility with the institute contacts listed in the INQUIRIES section of this program announcement.

Candidates must be able to demonstrate the need for a period of intensive research focus as a means of enhancing their clinical research career and a need for protected time to enhance their mentoring activities.

Candidates must commit 25 to 50 percent effort to conducting patient-oriented research and mentoring.

Candidates for the K24 award may not have pending or concurrently apply for any other PHS career award.

(Please note that NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: www.lrp.nih.gov)

SPECIAL REQUIREMENTS

A. Program

The K24 award provides three to five years of support. Twenty-five to fifty percent of full-time professional effort must be devoted to the patient-oriented research program and mentoring that are part of the award. The remainder may be devoted to other clinical, teaching, or research pursuits consonant with the objectives of the award.

B. Research Support

o Candidates are expected to continue to hold independent peer-reviewed support during the period of this award. Candidates losing this support during the award period must document in their annual Progress Reports efforts to replace this support and demonstrate that they continue to meet all other requirements of the K24 award.

o Candidates may not receive additional compensation from another HHS award (specifically, AHRQ or SAMHSA) that exceeds the maximum allowable salary compensation (See details on current salary limitations at http://grants.nih.gov/grants/policy/salcap_summary.htm).

C. Environment

The institution must be able to demonstrate a commitment to the applicant as a productive, independent investigator. The application must describe a program that will use the relevant research and educational resources available and the institution must certify that the candidate will be released from other duties and be able to devote 25 to 50 percent effort (at least 25 percent effort) to a patient-oriented research program.

The applicant institution must document the availability of beginning clinical investigators (including junior clinical faculty) to be mentored.

If there is an NIH (K30) Clinical Research Curriculum Award at the sponsoring institution, a plan should be described for integrating the proposed mentoring activities with the K30 curriculum.

D. Allowable Costs

Salary: The NIH Midcareer Investigator Award in Patient-Oriented Research (K24) will provide salary for levels of effort between 25 and 50 percent. The actual salary provided by the award is based on a full-time, 12-month institutional salary and the level of effort requested up to the maximum legislated salary rate in effect at the time of award. In all cases, the salary requested 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. The award will also provide fringe benefits on the calculated base salary at the established institutional rate.

The institution may supplement the NIH salary 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 K24 award.

In addition, the candidate may derive additional compensation for effort associated with other Federal sources or awards provided the total salary derived from all Federal sources does not exceed the maximum legislated salary rate and the total percent effort does not exceed 100 percent.

Research Development Support: The NIH will provide up to \$50,000 per year for the following expenses: (a) research expenses, such as supplies, equipment and technical personnel for the PI and the mentees; (b) travel to research meetings or training; (c) statistical services including personnel and computer time.

Ancillary Personnel Support: Salary for secretarial and administrative assistance, etc. is not allowed.

Facilities and Administrative Costs: These costs will be reimbursed at 8 percent of modified total direct costs.

E. Evaluation

In carrying out its stewardship of human resource related programs, the NIH 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.

F. Other Income

Awardees may retain royalties and fees for activities such as scholarly writing, service on advisory groups, honoraria from other institutions for lectures or seminars, fees resulting from clinical practice, professional consultation or other comparable activities, provided these activities remain incidental, are not required by the research and research-related activities of this award, and provided that the retention of such pay is consistent with the policies and practices of the grantee institution.

All other income and fees, not included in the preceding paragraph as retainable, may not be retained by the career award recipient. Such fees must be assigned to the grantee institution for disposition by any of the following methods:

- o The funds may be expended by the grantee institution in accordance with the NIH policy on supplementation of career award salaries and to provide fringe benefits in proportion to such supplementation. Such salary supplementation and fringe benefit payments must be within the established policies of the grantee institution.
- o The funds may be used for health-related research purposes.
- o The funds may be paid to miscellaneous receipts of the U.S. Treasury. Checks should be made payable to the Department of Health and Human Services, NIH and forwarded to the Director, Office of Financial Management, NIH, Bethesda, Maryland 20892. Checks must identify the relevant award account and reason for the payment.

Usually, funds budgeted in an NIH supported research or research training grant for the salaries or fringe benefits of individuals, but freed as a result of a career award, may not be rebudgeted. The awarding component will give consideration to approval for the use

of released funds only under unusual circumstances. Any proposed retention of funds released as a result of a career award must receive prior written approval of the NIH awarding component.

G. Special Leave

Leave to another institution, including a foreign laboratory, may be permitted if the proposed experience is 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 of the NIH awarding institute is required. Details on the process for submission of prior approval requests can be found in the NIHGPS (rev. 12/03), Requests for Prior Approval, at http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600130.” Due to the special nature of the K24, this letter must include a description of the plans to continue meeting the effort commitments of both the research and mentoring components of the K24 award. 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 K24 award will continue during such leave.

Leave without award support may not exceed 12 months. Such leave requires the prior written approval of the NIH funding institute and may 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.

H. Termination or Change of Institution

When a grantee institution plans to terminate an award, the NIH awarding institute must be notified in writing at the earliest possible time so that appropriate instructions can be given for termination. The Director of the NIH may terminate an award upon determination that the purpose or terms of the award are not being fulfilled. In the event an award is terminated, NIH shall notify the grantee institution in writing of this determination, the reasons therefore, the effective date, and the right to appeal the decision.

If the grantee is moving to another eligible institution, career award support may be continued provided:

- o A relinquishing statement is submitted by the original institution and a transfer application is submitted by the new institution at least three months prior to the transfer in order to allow the necessary time for administrative review by the NIH awarding institute.
- o All conditions of the award are met at the new institution.

- o The period of support requested is no more than the time remaining within the existing award period.

- o A change of grantee request normally will be permitted only when all of the benefits attributable to the original grant can be transferred, including equipment purchased in whole or in part with grant funds. In reviewing a request to transfer a grant, NIH will consider whether there is a continued need for the grant-supported project or activity and the impact of any proposed changes in the scope of the project. A change may be made without peer review, provided the PI plans no significant change in research and career development objectives and the facilities and resources at the new organization will allow for successful performance of the project. If these conditions or other programmatic or administrative requirements are not met, the NIH awarding office may require peer review or may disapprove the request and, if appropriate, terminate the award.

If an applicant is planning to move to a new eligible institution prior to or immediately after the issuance of an award, the contacts listed in the INQUIRIES section of this program announcement should be contacted prior to the preparation of an application to discuss this situation.

A final progress report, invention statement, and Financial Status Report are required upon either termination of an award or when an award is relinquished as a recipient changes institutions.

I. Additional reporting requirements:
(for non-competing and competing renewal applications)

If the application is funded, additional reporting requirements for NON-COMPETING Grant Progress Report (PHS Form 2590) and for competitive renewal applications are as follows:

- o A description of how the K24 award has contributed to the recipient's immediate and long-term career objectives.

- o Updated listing of active and pending research support using the OTHER SUPPORT pages from PHS Form 398. Clearly denote the recipient's role in each of these grants or projects. Asterisk those active/pending sources of support that are a result of the protected time provided by the K24 award. Describe plans for obtaining patient-oriented research support during the next funding period.

- o A description of the research activities conducted during the reporting period. This description should clearly distinguish research activities utilizing the protected time provided by the K24 award from other research activities.

- o A description of the mentoring activities during the prior award period directly resulting from the protected time provided by the K24 award. Include the names of

the individuals mentored; degree(s), professional specialty(ies) and staff positions; publications resulting directly from the K24-supported mentoring; current positions; and mentoring activities for each of these individuals. Describe plans for mentoring during the next funding period.

WHERE TO SEND INQUIRIES

Refer to INQUIRIES AND NIH STAFF CONTACTS

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dunandbradstreet.com/>. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format.

For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

The title and number of this program announcement must be typed on line 2 of the face page of the application form and the YES box must be checked.

SUPPLEMENTARY INSTRUCTIONS: The instructions in the Form PHS 398 do not fully apply to the special needs of this grant application. Letters of Reference, information about the Career Development/Training Activities During Award Period, and Statements by Sponsor(s) are NOT REQUIRED. Therefore, in addition to the required information listed in the instructions for Research Career Awards in the PHS 398, all applications MUST include the following information in the respective sections:

BIOGRAPHICAL SKETCH: A biographical sketch should be provided for the candidate only using the Biographical Sketch Format Page. Candidates must list both current and pending research support following the format of the BIOGRAPHICAL SKETCH Format Page in the PHS Form 398 format and clearly define their specific role on each of the listed research projects/ grants. For competing renewal applications, identify those research projects resulting directly from the support provided by the prior K24 award.

CANDIDATE

- o The candidate's immediate and long-term career objectives in POR and in mentoring beginning clinician investigators.

- o A summary of the research career of the candidate, documenting the ability of the candidate to conduct high quality POR and commitment to a career in POR.

o Documentation of the ability to provide mentoring to beginning clinician investigators. Provide the number of years of mentoring experience, mentoring role (i.e., research advisor, clinical mentor, etc.), the number of clinicians mentored, the specialties of the individual mentees and the stages in their professional career. In addition, describe the types of research that were conducted by the individuals mentored, and the proportion of mentored individuals currently in academic medicine and/or directly participating in POR.

o An explanation as to how the relief from patient care or administrative responsibilities through the protected time provided by this award will contribute to the development or expansion of the candidate's POR program and increased level of commitment to mentoring beginning clinician investigators. It is important to convey to the reviewers the reasons for needing protected time to continue a vital research program and continue to engage in the mentoring of new scientists. It should be clear that this award will permit the candidate to spend more time on research and mentoring and less time on administrative and clinical responsibilities for the institution.

ENVIRONMENT AND INSTITUTIONAL COMMITMENT TO THE CANDIDATE

o A description of the facilities and other resources that will be provided to the candidate.

o Letter of commitment from the institution. This letter should provide statements concerning the amount of protected time the candidate will receive (25 to 50% required); the duties from which he/she will be relieved (if clinical duties the institution should describe specific steps that will be taken to cover these duties, such as hiring clinical staff); and the institutional commitment to enhancing the candidate's ability to be a productive, independent investigator. Descriptions of the institution should be sufficiently detailed so that reviewers can determine if the environment is conducive to performing high quality POR. This information will be evaluated very carefully by the peer reviewers and carry substantial weight in the evaluation of an application.

RESEARCH PLAN

A Research Plan that establishes goals both for the individual's research career and for mentoring. These goals should be appropriate to the experience level of the candidate, and to the research and training environment. The Research Plan should be presented in two separate parts.

o Currently supported research: There is no need to provide extensive detail with regard to ongoing, funded research. Enough information should, however, be provided in the areas of Hypotheses and Specific Aims; Background, Significance and Rationale; Preliminary Studies and Results; and Research Design and Methods to permit the peer reviewers to evaluate the extent, special features and general quality of the candidate's research activities and opportunities for mentoring.

o New research to be specifically supported by this grant: Describe how this award will be used to help refine the candidate's research skills and/or develop new directions in

POR. This description should include a Statement of Hypothesis and Specific Aims; Background, Preliminary Studies and Aims; Significance and Rationale; and Research Design and Methods. Although it is not expected that this description should be as detailed as an application for an investigator-initiated research grant (e.g., R01), it is expected that sufficient detail be provided to permit an evaluation of the scientific merit of the research, and to clearly show research opportunities for mentoring. Documentation must be provided that appropriate and adequate resources, both in terms of support and facilities, are available to the candidate to conduct the research program(s). This is an important part of the application because it will provide the main rationale and justification needing protected time for research. The candidate must ensure that the inclusion of women, members of minority groups and their subpopulations, and children, has been addressed in the development of the design for all proposed patient-oriented research. The candidate must provide for each new research project proposed the information described in the General Instructions in Form PHS 398 on Human Subjects and Vertebrate Animals. Candidates must provide plans for ensuring continuing support of their POR programs preferably as the PI.

- o Percent effort committed to the research plan.

MENTORING PLAN

- o The Mentoring Plan is a required component of the application.

- o The plan should include a description of the availability of beginning clinician investigators for mentoring; their previous training and specialization; plans for recruitment, selection and supervision; the types of educational and research experiences that will be provided; and the capacity in which the candidate for the K24 award will serve as a mentor. If there is an existing clinical research curriculum, e.g. an NIH K30, describe how the mentoring plan will be integrated with the curriculum. Candidates must also describe a plan for supporting the research of their mentees during the period of the K24 award. This plan should include active support for POR at the time of application for a K24 Award, and may include the K24 Research Development Support.

- o The proposed percent effort committed to the mentoring plan.

APPLICATION RECEIPT DATES: Applications submitted in response to this program announcement will be accepted at the standard application deadlines, which are available at <http://grants.nih.gov/grants/dates.htm>. Application deadlines are also indicated in the PHS 398 application kit.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, five signed photocopies in one package to:

Center for Scientific Review (CSR)
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710

Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

APPLICATION PROCESSING: Applications must be mailed on or before the receipt dates described at <http://grants.nih.gov/grants/funding/submissionschedule.htm>. The CSR will not accept any application in response to this PA 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 a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. An appropriate scientific review group convened in accordance with the standard NIH peer review procedures (<http://www.csr.nih.gov/refrev.htm>) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

- o Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
- o Receive a written critique
- o Receive a second level review by the appropriate national advisory council or board.

REVIEW CRITERIA

In the written comments, reviewers will be asked to evaluate the following aspects of the application:

- o Candidate
- o Research Plan
- o Mentoring Plan
- o Progress Assessment (competing renewal applications only)
- o Environment and Institutional Commitment to the Candidate

The scientific review group will address and consider each of these criteria in assigning the application's overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to deserve a high priority score. The review criteria are listed in logical order, not in order of priority.

CANDIDATE

- o Evidence of ongoing high quality patient-oriented research and the relationship of that research to this program.
- o Evidence of the candidate's capabilities and commitment to serve as a mentor for patient-oriented research.
- o Demonstration that the proposed program and protected time will relieve the candidate from non-research patient care and administrative duties and allow him/her to devote additional time to patient-oriented research.
- o Record of financial support for patient-oriented research.

RESEARCH PLAN

Although it is understood that currently funded research described in K24 applications do not require the level of detail necessary in regular research grant applications, a fundamentally sound research plan must be provided. New research proposed in the K24 application that is not currently funded by a peer-reviewed grant should include a Statement of Hypothesis and Specific Aims; Background, Preliminary Studies and Aims. The application should outline the general goals for the later years and sufficient detail should be provided to permit evaluation of the scientific merit of the plan.

- o Appropriateness of the research plan as a vehicle for demonstrating and developing skills and capabilities in patient-oriented research to prospective mentees.
- o Scientific and technical merit of the proposed research.
- o Relevance of the proposed research to the candidate's career objectives.
- o Availability of adequate resources to conduct the research program. This includes adequacy of plans for continued support of the research during the funding period of the grant.
- o Adequacy of the plan's attention to gender and minority issues associated with projects involving human subjects.
- o Adequacy of plans for including children as appropriate for the scientific goals of the research, or justification for exclusion.

MENTORING PLAN

- o Adequacy of the plans for mentoring or supervising beginning clinicians in patient oriented research.

- o Adequacy of plans to integrate appropriate clinical research curricula, such as those offered by available K30 programs at the institution, into the mentoring plans.
- o Appropriateness of the proposed level of effort committed to the mentoring component.

PROGRESS ASSESSMENT(Additional criteria for competing renewal applications)

- o Extent to which the career, research and mentoring objectives of the previous award have been achieved.
- o Justification of the need for an additional 3 to 5 years of support.
- o Evidence of leadership in patient-oriented research such as through being principal investigator on independent peer-reviewed research grants and providing high quality mentorship.

ENVIRONMENT AND INSTITUTIONAL COMMITMENT

- o Applicant institution's commitment to the scientific development of the candidate and assurances that the institution intends the candidate to be an integral part of its research program.
- o Adequacy of research facilities and the availability of appropriate educational opportunities;
- o Quality and relevance of the environment for continuing the scientific and professional development of the candidate and for others pursuing patient-oriented research;
- o Applicant institution's commitment to provide adequate protected time for the candidate to conduct the research and mentoring program.
- o Applicant institution's commitment to the career development in patient-oriented research of individuals mentored by the candidate.

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score:

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in the section on Federal Citations, below).

INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH: The adequacy of plans to include subjects from both genders, all racial and ethnic groups

(and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria in the sections on Federal Citations, below).

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

ADDITIONAL CONSIDERATIONS

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the career development plan and proposed research.

AWARD CRITERIA

Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- o Scientific merit of the proposed project as determined by peer review
- o Availability of funds
- o Relevance to program priorities

REQUIRED FEDERAL CITATIONS

ANIMAL WELFARE PROTECTION: Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>), as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>), as applicable.

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

DATA AND SAFETY MONITORING PLAN: Data and safety monitoring is required for all types of clinical trials, including physiologic, toxicity, and dose-finding studies (phase I); efficacy studies (phase II), efficacy, effectiveness and comparative trials (phase III). The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998:

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>);

a complete copy of the updated Guidelines are available at

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at

<http://grants.nih.gov/grants/funding/children/children.htm>.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>. A continuing education program in the protection of human participants in research is available online at: <http://cme.nci.nih.gov/>

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see <http://escr.nih.gov>). It is the responsibility of the applicant to provide, in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: 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. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA 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 this award.

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION: The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

URLs IN NIH 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. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance No. 93.398 at <http://www.cfda.gov/>, and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies described at <http://grants.nih.gov/grants/policy/policy.htm> and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

INQUIRIES AND NIH STAFF CONTACTS

Applicants are encouraged to contact the individuals designated below, in advance of preparing an application, for additional information concerning the areas of research, receipt dates, and other types of pre-application instructions.

National Institute on Aging (NIA)
Dr. Robin Barr
Telephone: 301-496-9322
Email: rb42h@nih.gov

National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Dr. Robert B. Huebner
Telephone: 301-443-4344
E-mail: bhuebner@mail.nih.gov

National Institute of Allergy and Infectious Diseases (NIAID)
Dr. Milton Hernandez
Telephone: 301-496-3775

Email: mh35c@nih.gov

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Dr. Richard Lymn

Telephone: 301-594-5128

Email: rl28b@nih.gov

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Note: Please refer to the NIBIB website for specific guidance on NIBIB policies and procedures for K-awards (<http://www.nibib.nih.gov/training/training.html>)

Dr. Meredith Temple-O'Connor

Telephone: 301-451-4792

E-mail: templem@mail.nih.gov

National Cancer Institute (NCI)

Note: The NCI has special policies and requirements for their K24 grants.

Refer to the following URL for this information:

<http://grants.nih.gov/grants/guide/notice-files/NOT-CA-00-020.html>

Dr. Lester Gorelic

Telephone: 301-496-8580

Email: lg2h@nih.gov

National Institute of Child Health and Human Development (NICHD)

Dr. Steven Klein

Telephone: 301-496-5541

Email: sk56d@nih.gov

National Institute on Deafness and Other Communication Disorders (NIDCD)

Dr. Daniel Sklare

Telephone: 301-496-1804

Email: ds104i@nih.gov

National Institute of Dental and Craniofacial Research (NIDCR)

Dr. Sharon M. Gordon

Telephone: 301-402-0799

Email: NIDCRtraining@mail.nih.gov

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Division of Diabetes, Endocrinology, and Metabolic Diseases

Dr. James Hyde

Telephone: 301- 594-7692

Email: jh486z@nih.gov

Division of Digestive Diseases and Nutrition
Dr. Judith Podskalny
Telephone: 301-594-8876
Email: jp53s@nih.gov

Division of Kidney, Urologic, and Hematologic Diseases
Dr. Terry Rogers Bishop
Telephone: 301-594-7717
Email: tb232j@nih.gov

National Institute on Drug Abuse (NIDA)
Office of Science Policy and Communications
Dr. Lucinda L. Miner
Telephone: (301) 443-6071
Email: CM171W@NIH.GOV

Division of Neuroscience and Behavioral Research
Dr. Charles Sharp
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Email: cs107m@nih.gov

Division of Epidemiology, Services and Prevention Research
Dr. Kathy Etz
Telephone: 301-443-1514887
Email: ke25p@nih.gov

Division of Treatment Research and Development
Dr. Jamie Biswas
Telephone: 301-443-5280
Email: jb168r@nih.gov

National Institute of Environmental Health Sciences (NIEHS)
Dr. Carol Shreffler
Telephone: 919 - 541- 1445
Email: shreffl1@niehs.nih.gov

National Eye Institute (NEI)
Dr. Chyren Hunter
Telephone: 301-496-2020
Email: CLH@nei.nih.gov
<http://www.nei.nih.gov/funding/t32.htm>

National Heart, Lung, and Blood Institute (NHLBI)
Dr. Ellen M. Werner
Telephone: 301-435-0061
Email: wernere@nhlbi.nih.gov
<http://www.nhlbi.nih.gov/funding/training/redbook/estk24.htm>

National Institute of Mental Health (NIMH)
Dr. Mark Chavez
Division of Mental Disorders, Behavioral Research, and AIDS
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National Institute of Nursing Research (NINR)
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Email: armstrongn@nih.gov

National Center for Complementary and Alternative Medicine (NCCAM)
Dr. Nancy J. Pearson
Telephone: 301-594-0519
Email: pearsonn@mail.nih.gov

National Center for Research Resources (NCRR)

Note: To be eligible for K24 support from the NCRR, an applicant must be affiliated with an institution that hosts a General Clinical Research Center (GCRC) and must include with their application a letter of commitment from the GCRC Program Director or the Principal Investigator to use GCRC resources.

Dr. David Wilde
Telephone: 301-435-0799
Email: wilded@mail.nih.gov

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Department of Health
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