GUIDELINES
for
Minority Supplements to the NCI Institutional Clinical Oncology Research Career Development Award Program (K12S)

INTRODUCTION

The Comprehensive Minority Biomedical Branch (CMBB) of the National Cancer Institute (NCI) has initiated a new strategy for increasing the number of underrepresented populations engaged in basic, clinical and population-based biomedical cancer research. This strategy is called the **C**ontinuing **U**mbrella of **R**esearch **E**xperiences CURE Program for Underrepresented populations. This program begins with introductory science experiences at the high school student level and continues progressively and selectively to the production of well-trained scientists conducting independent cancer research (http://deainfo.nci.nih.gov/cmbs/index.htm). It is clear that the success of research designed to reduce the disproportionate burden of cancer incidence and mortality in many ethnic and racial groups will depend substantially on the presence of a cadre of culturally sensitive, well-trained scientists from these underrepresented populations.

The NCI invites NCI-supported Institutional Clinical Oncology Research Career grantees (K12) to participate in the initial stages of the CURE Program by submitting administrative supplements to place promising underrepresented minority board eligible/certified clinical oncologists in patient-oriented cancer research settings.

PURPOSE

The purpose of the K12 CURE supplement is to increase the number of medical doctors and doctorally degreed Oncology Registered Nurses from underrepresented populations who are motivated and properly trained to: (1) communicate and collaborate with basic/behavioral research scientists in order to expedite the translation of basic/behavioral information into patient-oriented research; (2) perform independent clinical research that develops and tests rational scientific hypotheses based on fundamental and clinical research findings with the potential for improving the medical care of cancer patients; and (3) design and test innovative clinical protocols and manage all phases (i.e., pilot/Phase I, Phase II, Phase III) of clinical trials research.

For the purposes of this award, 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.

By providing research opportunities for underrepresented minorities through supplements to ongoing Institutional Clinical Oncology Research Career Development (K12) Awards, it is anticipated that the numbers of underrepresented individuals in the clinical oncology field will increase significantly.

NIH recognizes the need to increase the number of underrepresented minority scientists participating in biomedical and behavioral research. The NCI is emphasizing the use of the administrative supplement process to reach individuals from underrepresented populations interested in cancer clinical research and interested in participating more effectively in patient-oriented research. Using supplements to K12s (PAR-00-063) rather than R01s will provide a far more efficient way to place larger numbers of minority clinical oncologists in these research environments.

ELIGIBILITY

Program

Any NCI-supported Institutional Clinical Oncology Research Development Award (K12) grantee is eligible to apply for this supplement. These supplements must be used for the sole purpose of including an individual from an underrepresented population in the K12 program.

The CURE supplement must meet all of the eligibility requirements and must describe a program that provides all of the training and research career development opportunities for appointments to the NCI Clinical Oncology Career Development Program stated in RFA or PAR (RFA-CA-97-008, PAR- 99- 077 and PAR-00- 063) governing the current K12 award.

The CURE supplement is not intended to provide an alternative means of supporting minority individuals who already receive support from a research grant, a research training grant, a career development award, or any other DHHS funding mechanism essentially duplicating the provisions of the CURE supplement.

Individuals supported directly by the K12 program may not be concurrently supported by a CURE Supplement and may not be transferred to a CURE Supplement in order to increase the availability of funds to the parent grant for other uses.

Clinician Candidates

Candidates must belong to a particular ethnic or racial group that has been determined by the applicant institution to be underrepresented in biomedical or behavioral research. These populations, although not inclusive, are commonly identified as underrepresented: African American or Black, Hispanic or Latino, American Indian or Alaska Native, and Native Hawaiian or other Pacific Islander.

All candidates must be physicians holding the M.D. or D.O. degrees, or be doctorally prepared oncology registered nurses and must have completed residency and must be board eligible. Candidates must be able to spend a minimum of 75 percent of a full-time professional effort conducting research and research career development activities including taking courses during the period of the award.

All clinician candidates must be U.S. citizens or non-citizen nationals, or must be lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-551) or some verification of legal admission as a permanent resident of the U.S. Non-citizen nationals, although not U.S. citizens, owe permanent allegiance to the U.S.; they usually are born in the lands that are not states, but under U.S. sovereignty, jurisdiction or administration. Foreign nationals and individuals on temporary or student visas are NOT ELIGIBLE.

Individuals NOT eligible for a CURE supplement include former principal investigators on NIH research project grants (R01), FIRST Awards (R29), sub-leaders of program project (P01) or cancer center (P30) grants, and the equivalent. Former principal investigators of NIH Small Grants (R03) or Exploratory/Developmental Grants (R21) remain eligible.

MECHANISM OF SUPPORT AND SPECIAL CONSIDERATIONS

The K12 CURE program uses administrative supplements to the K12 and provides up to five years of support per supplement. In all cases, at the time of a K12 CURE Supplement, the parent K12 grant must have support remaining for at least two years. Planning, direction and execution of the CURE supplement is the responsibility of the Principal Investigator and the Advisory Committee on behalf of the appointee. K12 CURE Supplements are not renewable.

K12 CURE supplements are administered under NIH Grants Policy Statement (Rev. 03/01). The competing supplements are not subject to the Just-in-Time or the modular grant procedures. In future years, the non-competing application process is not subject to the Streamlines Noncompeting Application Process (SNAP). Expanding Authorities are in place, except that carry over of funds from one fiscal year to the next requires NCI approval.

Support under the K12 CURE supplement program is not transferable to another individual or transportable to another institution.

Allowable Costs

Clinician trainees may be provided salary up to $75,000 each year, plus fringe benefits. The total salary requested must be based on a full time, 12 month staff appointment. The actual salary must be consistent both with the established salary structure at the applicant

institution and with salaries actually provided by the institution from its own funds to other members with equivalent qualifications, rank and responsibilities in the department concerned. Supplementation of the NIH salary contribution up to a level that is consistent with the institution=s salary scale are subject to the same rules as for appointments directly to the K12 grant as described in PAR -00-063. Candidates cannot receive concurrent salary support from any other PHS award while being supported by the K12 program. Salaries for principal investigators, mentors, secretaries, administrative assistants and other ancillary personnel are NOT allowed.

Up to $30,000 in direct costs per trainee per year can be provided for the following types of expenses: (a) research-related expenses, such as supplies, equipment and technical personnel; (b) tuition, fees and books related to career development; (c) travel to research meetings or training; and (d) statistical services including personnel and computer time. These costs must be specifically and directly related to an individual trainee=s research activities. They cannot be pooled and used for advertising, recruiting or other purposes unrelated or indirectly related to the research activities of individual trainees.

Facilities and Administrative Costs (formerly called indirect costs) will be reimbursed at 8 percent of modified total direct costs or the actual cost rate, which ever is less.

SPECIFIC APPLICATION INSTRUCTIONS

The PHS 398 research grant application instructions and forms (rev. 5/2001) at http://grants.nih.gov/grants/funding/phs398/phs398.html are to be used in applying for these supplements. This version of the PHS 398 is available in an interactive, searchable PDF format. NIH will return applications that are not submitted on the 5/2001 version. For further assistance contact GrantsInfo, Telephone 301/435-0714, Email: GrantsInfo@nih.gov.

A request for a minority supplement to an Institutional Clinical Oncology Research Career Development Award may be submitted at any time. In making requests, the grantee institution, on behalf of the principal investigator of the parent grant, must submit the request for supplemental funds to the NCI. Please note that this procedure is different from the instructions in the PHS 398 application package.

The original and three (3) legible copies of the supplemental application should be sent to:

Referral Officer
Division of Extramural Activities
National Cancer Institute
6116 Executive Blvd., Room 8109, MSC-8329
Rockville, MD 20852 (express courier)

Bethesda MD 20892-8329

All applications should follow the format provided below:

1. A completed face page with appropriate signatures using page AA of PHS Form 398. Include the title and grant number of the parent grant on line 1 and in line 2 write "K12 CURE Supplement."

2. PHS Form 398 budget pages for the current and future years.

3. A biographical sketch of the candidate including background and achievements to date. Include all licensures/board certifications of the candidate.

4. A biographical sketch of the laboratory and the clinical research mentor(s) who will be responsible for the candidate. This sketch should include a listing of current and pending research support, preferably using the format of the OTHER SUPPORT pages in the PHS Form 398.

5. A brief (no more than two pages) description of the planned training program for the candidate. The plans must demonstrate that the candidate will be fully incorporated into the K12 program, provided the same didactic, laboratory and clinical research training opportunities as all other K12 trainees, and able to meet all the requirements of the parent K12 grant.

   Specifically:

   a. The program must provide the candidate with the patient-oriented research skills that deal directly with aspects of cancer detection, diagnosis, prognosis, or treatment of cancer patients. It should also provide the skills necessary for translating basic/ behavioral cancer research results into clinical experiments, procedures, and trials directly involving cancer patients in a clinical environment. It will not be sufficient within the scope of this initiative to use human cells and other clinical materials or animals in an isolated basic laboratory setting as the total research development program. Basic laboratory/behavioral research experience is essential, but it must be properly integrated with patient-oriented clinical research, thereby affording the trainee actual experience in the application of their own basic research to clinical research.

   b. The Program should include Core Requirements that the candidate is expected to complete before meeting the Program's training objectives. These requirements should include the following:

i. A didactic core component (e.g., formal courses in clinical trial design, biostatistics, informed consent, Institutional Review Boards; lecture series, seminars, and journal clubs) based on the experience and needs of each candidate. In those institutions with a Clinical Research Curriculum (K30) Award, the didactic component should link with and incorporate the new didactic programs developed through the K30 award.

ii A clinical research core component that provides "hands on" experience (e.g., protocol development; preparation of IRB applications; clinical trials management including patient accrual and analysis of outcomes) in all aspects of clinical trials.

iii A basic research core component that adequately prepares the trainee for communication, coordination, and collaboration with basic scientists of clinical research activities; ideally this would be linked to the core clinical research component.

The expectation of the NCI is that candidates will satisfy many of the Core Requirements and that they will be provided with the additional didactic and research experience over different periods of time in order to fully meet the objectives of the Program.

REVIEW CONSIDERATIONS

The review of these supplemental applications will be conducted by the Comprehensive Minority Biomedical Branch and the Cancer Training Branch of the NCI using the following review criteria:

1. The quality of the candidate's background and achievements at his/her current level of career development.

2. The experience and qualifications of the laboratory and the clinical research mentor(s).

3. The quality and breadth of the overall training and education plan for the candidate, and appropriateness of the plan for the stage of career development of the candidate.

4. The ability of the proposed training plan to fully incorporate the candidate into the K12 program, providing the candidate with the same opportunities for training and for meeting the requirements of the K12 program as all the other K12 trainees.

FUNDING

Applications will compete for available funds with all other approved applications. The applications will be rated and the one's ranked the highest will be funded by the NCI. Funding decisions may take approximately 3-4 months from receipt of a complete application. It is expected that three to six positions will be funded each fiscal year. Funding will be provided as an administrative supplement to the parent grant; however continued funding for the supplement is contingent upon successful progress of the minority investigator and continued funding of the parent grant. Requests for future years of support cannot exceed the parent grant project period.

NOTE: Candidates should be informed that their selection for this supplement will automatically make them Members of the CURE program of the National Cancer Institute. This will entitle them to receive the CURE Newsletter and have access to the multiple activities aimed at facilitating the next steps of a career in cancer research. Information about the CURE program of the NCI is published on the web at http://deainfo.nci.nih.gov/cmbs/index/htm.

CONTINUATION OF SUPPORT

A progress report on the supplement must be submitted in the non-competitive Institutional Clinical Oncology Research Career Development Award (K12) application under a separate section entitled "K12 CURE" using the Non-Competing Continuation for Minority Supplements to Institutional Clinical Oncology Research Career Development Award (K12) form attached.

FINAL REPORT

At the end of the supplemental period, the Principal Investigator must provide a final progress report which includes 1) name and ethnicity of the appointee, 2) narrative description of the specific appointee's research accomplishments, including all publications and clinical protocols and 3) future career plans of the trainee. The final progress report should be sent to Dr. Sanya Springfield at the address listed below under the Inquiries section.

INQUIRIES

Direct inquiries regarding programmatic issues to:

Ms. Bobby Rosenfeld
Senior Program Analyst

E-mail: rr63v@nih.gov
OR
Sanya A. Springfield, Ph.D.
Chief
E-mail: ss165i@nih.gov
Comprehensive Minority
Biomedical Branch
Office of Centers, Training and Resources
National Cancer Institute
6116 Executive Boulevard
Suite 7013, MSC 8347
Bethesda, MD 20892
Rockville, MD 20852 (express/courier service)
Telephone: 301-496-7344
Fax: 301-402-4551

Direct inquiries regarding fiscal matters to:

Ms. Barbara A. Fisher
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
6120 Executive Boulevard
Bethesda, MD 20892
Telephone: 301-846-1015
FAX: 301-846-5720
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