

Guidance and Advice
K12
Institutional Clinical Oncology Research Career Development Program

I. IMPORTANT ANNOUNCEMENTS:

The guidance and advice provided below are derived from the National Cancer Institute (NCI) Program Announcement (title: Clinical Oncology Research Career Development Program; number: PAR-04-096) issued in the NIH Guide on April 23, 2004. You can access this announcement directly by "clicking on" the following NIH website address: <http://grants.nih.gov/grants/guide/pa-files/PAR-04-096.html>. After consulting the official announcement, the information and clarifications provided below together with the Form PHS 398 application found on <http://grants.nih.gov/grants/funding/phs398/phs398.html> should be all that you need to prepare an application for the Institutional Clinical Oncology Research Career Development Program or **K12**.

II. BACKGROUND:

The purpose of the National Cancer Institute (NCI) Clinical Oncology Career Development Program is to increase the number of medical doctors and doctorally degreed Oncology Registered Nurses who are motivated and properly trained to: 1) perform clinical oncology research that develops and tests scientific hypotheses based on fundamental findings; 2) design and test hypothesis-based clinical protocols and manage all phases (i.e., pilot/Phase I, Phase II, and Phase III) of cancer therapeutic clinical trials, and (3) communicate and collaborate with basic research scientists in order to expedite the translation of basic/behavioral research discoveries into patient-oriented therapeutic cancer research. The National Cancer Institute (NCI) Institutional Clinical Oncology Career Development Program is intended to train clinical researchers whose career focus will be on patient-oriented therapeutic research and not on laboratory-based 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.**

In 1991 the National Cancer Institute (NCI) recognized the need for establishing formal training programs that would prepare the next generation of clinical scientists to participate more effectively in translational research. The NCI embarked on a pilot program initiative that would prepare clinical oncologists to be effective scientific partners with basic/behavioral scientists in the movement of discoveries in the laboratory into patient research settings or the reverse process of taking observations in the clinic back into a laboratory research setting. These well-trained clinical oncologist scientists would be expected to communicate, interact and collaborate with basic/behavioral scientists in the design and implementation of clinical trials that were hypothesis driven and based on an understanding of biological mechanisms. This pilot program initiative, announced in 1991 through RFA CA-91-32 and again in 1997 through RFA CA-97-008, was implemented through two successive RFAs in 1992 and 1997 and was founded on the following principles : (1) unlike career awards to individuals, these would be awards to institutions and the institution would appoint individuals to a formal training program; (2) rather than having a single mentor, the individuals on the program would likely have more than one mentor as they are exposed to the basic sciences and to the many disciplines critical to the clinical sciences; (3) the program would provide individuals with all of the information and training needed to design, implement and manage all phases of clinical trials research. The success of these pilot initiatives resulted in the NCI converting this Program from one that was driven by dollar set-asides and RFAs to one that is investigator-initiated and regularly available to the clinical oncology research community. Additionally, due to the critical role of nursing in general and oncology nursing in particular, in clinical cancer research and care, eligibility was extended to include doctorally prepared Oncology Registered Nurses.

The NCI anticipates that the availability of "multidisciplinary" research environments during the formative years of clinical research training will promote the team approaches that will be necessary for optimizing patient-oriented translational research. This Program focuses strictly on the preparation of clinical oncologists for research careers and relies on the institution to select and train candidates. "Click on" *Clinical Scientists, Patient-Oriented Research* in the margin of this page to explore other opportunities for those who are clinically educated to pursue careers in clinical research.

III. ELIGIBILITY:

1. **Institution:** Applications may be submitted by domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories.
2. **Program Leader/Principal Investigator:** The Program Leader is the Principal Investigator, **must** be an established investigator in patient-oriented research and able to provide both administrative and scientific leadership to the Program. Minorities, women and individuals with disabilities are encouraged to apply.
3. **Clinician Candidates:** All candidates **must** currently be physicians holding the M.D. or D.O. degrees, or be doctorally prepared oncology registered nurses **must** have completed the necessary clinical training (i.e., completed residency and are board eligible) to engage in clinical oncology research. Candidates **must be able to** spend a minimum of 75 percent of a full-time professional effort conducting research and research career development which includes all relevant didactic activities 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-151 or 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.**

Clinician candidates who were former principal investigators on NIH Small Grants (i.e., R03s) or Exploratory/Developmental Grants (i.e., R21s) remain ELIGIBLE. However, former or current principal investigators on NIH research project grants (i.e., R01s), FIRST Awards (i.e., R29s), comparable career development awards (e.g., K01, K07, K08, K23), sub-projects on Program Projects (i.e., P01s) or center grants (i.e., P50s) and equivalent are **NOT ELIGIBLE** for appointment to a K12 grant.

IV. MECHANISM OF SUPPORT:

Clinical Oncology Research Career Development Programs use the **K12** grant mechanism and provide up to **five years** of support. Planning, direction and execution of the Program is the responsibility of the Program Leader and the Advisory Committee on behalf of the institution. **K12s are renewable.** K12 awards are administered under NIH grants policy. However, K12s are not subject to "just-in-time" application procedures or to the Streamlined Noncompeting Application Process (SNAP). Expanded Authorities are in place, except that carry over of funds from one fiscal year to the next requires NCI approval.

V. ALLOWABLE COSTS:

The NCI Clinical Oncology Research Career Development Program or **K12** provides for the following costs:

1. **Direct cost cap:** No application may exceed \$700,000 in direct costs per annum. Applicants do not need to request prior permission to submit the K12 application unless the application is in addition to another K12 application submitted by the same institution; in addition to another NCI K12 grant at the same institution; or the requested direct costs per annum in any year exceeds the current cap on NCI K12 grants.

- 2- **Salary:** Clinician research candidates may be provided salary up to \$75,000 each year, based on a full-time, 12 month staff appointment; plus fringe benefits commensurate with the applicant institution's salary structure for persons of equivalent qualifications, experience, and rank. The institution may supplement the NCI contribution; however, supplementation may not be from Federal funds unless specifically authorized by the Federal program from which such funds are derived. In no case, may NIH funds be used for salary supplementation. Institutional supplementation of salary may not require extra duties or responsibilities that would interfere with the purpose of this award. The total salary requested must be based on a full-time, 12 month staff appointment. Salary support for the Program Leader/Principal Investigator and participating faculty is **NOT** allowed.
3. **Research and Development Support:** No more than \$30,000 in direct costs per individual candidate year can be provided for the following types of expenses: (a) research 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 documented for each individual candidate and must be **specifically and directly** related to the candidate'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. It is anticipated that the K12 trainees will be working in a funded research environment. It will therefore be allowable to use the research and development support provided by the K12 grant to augment this support in order to be able to include the trainee in this research, but it will not be allowable to use this to pay substantially for funded basic research studies or clinical trials.
4. **Ancillary Personnel Support:** Salaries for mentors, secretaries, administrative assistants and other ancillary personnel are **NOT** allowed.
5. **Facilities and Administrative Costs (formerly called indirect costs) :** These will be reimbursed at 8 percent of modified total direct costs or the actual cost rate, whichever is less.
6. The K12 grant, as administered by the NCI is not subject to the Streamlined Noncompeting Application Process (SNAP). In general, this means that all reporting of budgetary information and program progress are provided in greater detail in an annual progress report. While the K12 is subject to Expanded Authorities, the one exception to this is that carry over of funds from one fiscal year to the next must receive approval by NCI Grants Administration Staff (see XI. INQUIRIES).
7. **Other General Policies Related to Costs:**
 - a. The NCI does not allow **grant related income** (i.e., fees) from clinical practice, professional consultation, or other comparable activities required by the research provisions of this award to be retained by the principal investigator or the candidate. These fees must be assigned to the grantee institution for the disposition by one of several approved NIH methods described in PAR-03-083.
 - b. **Carryover of unobligated balances** into a future year of the grant may be permitted under exceptional circumstances. Requests for approval of carryover must be made directly to NCI program staff. The unobligated balance that can be carried over is subject to the current NIH limit.
 - c. **Funds** for the salaries and/or fringe benefits of individuals **freed up** from other NCI-supported research or training grants as a result of a K12 award may not be rebudgeted by the institution and may not be used for any other purpose without prior NIH approval.
 - d. Prior approval for candidates to **travel to a foreign research environment** as part of the training is required only if the stay exceeds three months.
 - e. A trainee may have up to a 12 month **leave of absence** without award support with prior written approval from the NCI.

- f. A **K12** grant **cannot** be transferred to another institution.

For appropriate advice and specific instruction regarding the above and other budgetary and administrative policies that you must follow in managing this award, please refer to section **XI. INQUIRIES**.

VI. SPECIAL PROVISIONS AND REQUIREMENTS:

1. Where there already exists an active Ruth L. Kirchstein (T32) National Research Service Award (NRSA) supporting a surgical or other clinical oncology research training program, the applicant **must** address the relationship between the existing T32 and proposed K12 programs. If there is significant overlap in the programs, the T32 award can be merged into the K12 program or modified to remove areas of substantial overlap. In those institutions with a Clinical Research Curriculum (K30) Award, the didactic component of this proposal should be linked with the K30 award.
2. The institution must have substantial peer-reviewed basic and clinical research support and faculty qualified in patient-oriented therapeutic cancer research to serve as mentors in the proposed Program.
3. The research environment should be one in which there are active basic/clinical research collaborations that exemplify a dynamic two-way exchange of information and ideas between basic and clinical scientists.
4. The PI **must use an Advisory Committee** to provide an oversight function and annual evaluation of the clinical research development program as a whole. The committee's **responsibilities might include:** selecting physician and oncology nurse candidates, assigning preceptors, approving each trainee's research development plan, evaluating each trainee's progress, monitoring the overall effectiveness of the program and recommending mid-course changes when needed. A detailed description should be provided of the committee's composition, function, and frequency of meetings. Plans for an annual evaluation of the program by the Advisory Committee should be described.
5. The Program must involve staff and clinical candidates representing at least two clinical oncology disciplines such as medical oncology, surgical oncology, radiation oncology, pediatric oncology, gynecologic oncology and oncology nursing. Clinical candidates from non-oncology medical subspecialties may also be represented in the Programs. However, these subspecialties should have direct relevance to cancer (e.g., thoracic surgery, pulmonology) and the individualized career development plans developed for these candidates must be focused on clinical oncology research.
6. . The Program must motivate and train candidates to: 1) perform clinical oncology research that develops and tests scientific hypotheses based on fundamental and clinical research findings; 2) design and test hypothesis-based clinical protocols and manage all phases (i.e., pilot/Phase I, Phase II, and Phase III) of cancer therapeutic clinical trials, and (3) communicate and collaborate with basic research scientists in order to expedite the translation of basic research discoveries into patient-oriented therapeutic cancer research.
7. The proposed program should have the flexibility to accommodate clinical candidates with different levels of basic and clinical research competence.
8. All competing applications for an Institutional Oncology Career Development Program (K12) Grant are now required to include a specific plan to recruit and retain underrepresented minorities in the Program. In addition, all future Non-competing Grant Progress Reports must include a

report on the recruitment and retention of underrepresented minorities during the previous award period.

9. Appointments of clinical candidates to the program should be for a **minimum of two years**. As long as a **K12** grant has been renewed, individual candidates **can be supported for up to seven years**. Clinical candidates must commit a minimum of 75 percent effort to the Program. The remaining 25 percent can be divided among other clinical and teaching activities only if they are consistent with the Program goals (i.e. the candidate's development into an independent clinical oncology researcher).
10. The Program should include Core Requirements that each candidate is expected to complete before meeting the Program's training objectives. All candidates graduating from the program must complete all of these requirements either directly or through combination with their past training experience. These requirements should include the following:
 - 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.
 - A *clinical research* core component that provides "hands on" experience (e.g., protocol development; preparation of IRB applications; clinical trials management including patient accrual, analysis of outcomes) in all aspects of Phase I, Phase II and where possible Phase III clinical trials.
 - A *basic research* core component that provides a hands-on research experience that adequately prepares the trainee for communication, coordination and collaboration of clinical research activities with basic scientists. This experience should be linked to the core clinical research component.

The expectation of the NCI is that candidates entering the Program with different backgrounds initially 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.

11. The institution must demonstrate a commitment to the development of trainees as productive, independent clinician investigators.
12. **Evaluation:** In carrying out its stewardship of human resources-related programs, the NCI or the NIH may request information essential to an assessment of the effectiveness of this program. Accordingly, recipients of support from this grant may be contacted after completion of the 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 this program.

VII. APPLICATION PROCEDURES:

SUBMISSION, REVIEW AND AWARD OF COMPETING APPLICATIONS

A. Application Receipt, Review and Award Dates:

There is one receipt date per year for K12 applications. This is June 1 for all new, renewal, supplemental and amended applications. Initial peer review of the application for scientific merit by an NCI initial review group is usually completed in October. Review by the National Cancer Advisory Board is usually completed in January. The earliest possible award date is April 1.

B. Where to send the application:

An **original and three copies** of the application should be submitted to the Center for Scientific Review (CSR), NIH, according to the instructions in the PHS Form 398 (rev. 4/98 and subsequent revisions) to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040-MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (For express/courier service)

To expedite review the review process, **two additional copies** should be sent to:

Referral Officer
Division of Extramural Activities
National Cancer Institute
6116 Executive Boulevard, Room 8062
MSC/8329
Bethesda, MD 20892-8329
Rockville, MD 20852 (express/courier service);

C. Format for Submitting the Application:

Applications for the Clinical Oncology Research Career Development Program or K12 are to be submitted on the grant application Form PHS 398 (last revised 4/98) **using the modified instructions below**. You can obtain the application forms in an interactive format by "clicking on" the following NIH website address: <http://grants.nih.gov/grants/funding/phs398/phs398.html>. For further assistance contact Grants Info, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Note of caution:

Type density and size for the entire application must conform to the instructions under Item I. Preparing Your Application. B. General Instructions. Format Specifications of the general instructions for the Form PHS 398. If they do not, the application could be returned to you by CSR without review.

General advice in Preparing a K12:

It is highly recommended that you make regular reference to the Review Criteria and Additional Review Criteria in PAR-03-083 and under section **VIII. REVIEW PROCEDURE AND CRITERIA** during the preparation of your application. The success of your application in addressing these criteria will determine its competitiveness for funding.

Modified Instructions for Preparation of a K12 Application:

The instructions in the Form PHS 398 application **do not fully apply** to the special needs of this grant application. This includes the "Just-In-Time" instructions for the submission of detailed budgets. **Detailed budgets must be provided**. Therefore, **please follow the modified instructions below** in preparing an application for the Clinical Oncology Research Career Development Program (**K12**). These instructions have been adapted to accommodate the Form PHS 398 and the special needs of the K12 grant:

1. **Face Page:** Use Form Page 1 of the Form PHS 398. On Line 1 include the title that best represents the nature of your training program. On line 2, provide the number starting with PAR, and title, "Institutional Clinical Oncology Research Career Development Program," of the NCI Program Announcement. The Program Leader will be the principal investigator (P.I.) of the grant application.
2. **The Description/Performance Site(s)/Key personnel** (Form Page 2 of the Form PHS 398): Complete as directed in the PHS 398. The information provided should include the P.I., Advisory

Committee members, mentors and other faculty participating in the program. Please make sure that you denote each individuals degree and department affiliation (or equivalent).

3. **Table of Contents** to be organized as follows:
 - a. Face Page
 - b. Description/Key personnel
 - c. Table of Contents
 - d. Statement of Commitment
 - e. Detailed Budget Page for First Year
 - f. Budget for Entire Proposed Period of Support
 - g. Biographical Sketches (not to exceed 2 pages per individual)
 - Principal Investigator
 - Advisory Committee Members
 - Mentors
 - Other Faculty
 - Trainees (if available)
 - h. Other Support of the Principal Investigator and the Mentors that is specifically relevant to the purpose and objectives of this Career Development Program. This should include support from other training programs that relate to this application (e.g. other K12 grants, K30 Awards, T32 Awards, R25T Awards)
 - i. Career Development/Training Plan (**May exceed 25 pages; tables should be included in the text, not as appendices**):
 - i. Introduction to **Revised Application** (not to exceed 3 pages)
 - ii. Purpose and Objectives
 - iii. Description of Core Requirements
 - iv. Research Base/Resources and Facilities (Suggested tabular formats for this information can be found under Item j. below)
 - v. Program Management
 - Principal Investigator
 - Recruitment Strategies (Including a separate plan for recruitment of underrepresented minorities)
 - Advisory Committee
 - Individual Training Plans
 - j. Summary Information on Program (We have created suggested tabular formats for your convenience. "Click on" [TABLES \(Word for Windows\)](#) or [TABLES \(Adobe for Acrobat Files\)](#),, which ever you prefer to download this information.
 - k. Human Subjects (Refer to the following hotlink for the required "Special Statement Regarding Human Subjects Research Under K12 Support" to be provided at the time an award is offered: _____)
 - l. Vertebrate Animals
 - m. Checklist
 - n. Appendices
 - a. Summary Information on Program (We have created suggested tabular formats for your convenience. "Click on" [TABLES \(Word for Windows\)](#) or which ever you prefer, to download this information.
4. **Statement of Commitment:** This statement should guarantee that all candidates participating in this Program will commit 75% of a full-time professional effort to research and research career development.
5. **Detailed Budget for the First Year:** Use Form Page 4 of the Form PHS 398 and provide the salary and fringe benefits, supplies, travel, etc., specified for each trainee, either by name or by position (i.e., position 1, position 2 etc.) if the position is not filled. Note that there is an upper level

of salary of \$75,000 plus fringe benefits and an upper limit for other costs of \$30,000 per trainee; and a required minimum 75% effort.

6. **Budget for the Entire Proposed Period of Support:** Follow directions as provided in the Form PHS 398 for Form Page 5.
7. **Biographical Sketches:** Provide biographical sketches using the Biographical Sketch Format Page of the Form provided in Form PHS 398. Group the biosketches into the following five sections: (1) Principal Investigator; (2) Advisory Committee Members ; (3) Mentors; (4) Other Faculty; and (5) Trainees (when available)
8. **Career Development/Training Plan:**
 - a. Purpose and Objectives: Briefly describe the background, purpose, and objectives of this career development program. This description should include **two or more oncology disciplines** being represented in the Program and a discussion of the strategies to be used to ensure that the representation in each discipline in the mentor population and the trainee population will satisfy the intent of this NCI **requirement**. The description should clearly show how the purpose and objectives of the Program will meet the broader objectives and intent of the NCI to prepare candidates who can design and implement all phases of clinical trials research and who can effectively with basic scientists on projects in patient-oriented therapeutic cancer research.
 - b. Description of the **Core Requirements** of the Program: Describe separately the core didactic, core clinical research and core basic research experiences that each clinician candidate or trainee must complete to satisfy the overall Core Requirements of the Program. If there is an existing institutional K30 program, explain how the K12 Program will link with and make use of the K30 program to meet the objectives of the K12 core didactic component. Using specific, real or hypothetical examples, describe how individualized trainee career development plans will be developed that take into account past experiences and competencies before providing new experiences and skills by the Program. Describe any certification, degree or other form of recognition, if any, that trainees will receive after completing the core requirements.
 - c. Research base/Resources and Facilities/Mentors (See Item 9 below). Describe the existing funded laboratory and patient-oriented research activities and the interactive nature of the research environment that will meet and sustain needs of this Program. Include in this description the number and types of early to late phase clinical therapeutic clinical trials being conducted in the institution and the general range of activities in these trials.

Resources and Facilities: Describe the research infrastructure, patient populations, facilities etc. that are available and accessible to this career development Program,

Mentors: Describe the pertinent research experience and track record in training cancer clinician scientists of each mentor participating in the Program.
 - d. Program Management:
 1. **Principal Investigator:** Describe the qualifications and role of the Program Leader to provide scientific and administrative leadership and coordination of the Program.
 2. **Recruitment Strategies:** Describe the selection criteria for candidates recruited to this Program. Describe the various strategies that will be used to ensure that the different clinical oncology disciplines represented by this Program are included and to ensure an adequate candidate pool size. Address the nature of

any other competing institutional Programs that might limit the number of candidates and describe strategies for addressing this competition.

3. **Plans for Recruitment of Underrepresented Minorities:** Describe plans for recruitment of underrepresented minorities (e.g., African Americans, Hispanic Americans, Native Pacific Islanders, Native Americans and Alaskan Natives) and how these strategies will be implemented.
4. **Advisory Committee:** Describe how the AC will function in providing oversight of the development, implementation and evaluation of recruitment strategies; in the recruitment and selection of candidates; in the evaluation of special curricula and/or links to curricula developed through a K30 grant (if present); in the monitoring and evaluation of **each candidate's progress** with recommendations for changes in the training plan, if necessary, or termination of a candidate who is not making adequate progress; and monitoring of the overall effectiveness of the Program.
5. **Individual Training Plans:** Provide **brief summaries/ examples** of the individual training plans that the Program will employ or has been able to achieve (Required for Competing Renewal Applications) in preparing candidates to design, implement and participate in patient-oriented therapeutic cancer research and collaborate effectively with a basic scientists in translating the discoveries of the basic scientists into therapeutic clinical trials. If relevant to your K12 program, provide examples of plans for short-term (2 years) appointments.
9. Summary Information on the Program. Sample tabular formats are provided for your convenience. "Click on" [TABLES \(Word for Windows\)](#) or [TABLES \(Word Perfect\)](#), whichever you prefer to download this information.
10. Human Subjects: Follow instructions provided in the Form PHS 398 You will need to follow current NIH policy on providing in your application information on data and safety monitoring. Refer to the following website for information on NCI policies on data and safety monitoring for training awards: <http://www.cancer.gov/clinicaltrials/conducting/dsm-guidelines>
11. Vertebrate Animals: follow instructions provided in the Form PHS.
12. Appendices: follow instructions provided in the Form PHS 398.

ANNUAL PROGRESS REPORT/APPLICATION FOR CONTINUATION

A. Submission of the Annual Progress Report and Application for Continuation:

The Program Leader/ Principal Investigator of an active **K12** grant is required to submit on an annual basis an application for continuation of funding. This continuation application must contain descriptions of the progress made during the last year of support, the budget needs for the next year, and any major changes in personnel and objectives that occurred during the previous year of funding and are planned for the next year. The National Institutes of Health will mail the face page for this application together with return mailing label(s) to the principal investigator/program leader approximately **four months** prior to the anniversary date of the grant. Look for this notification; if you do not receive it, call the NIH Data Management Branch at (301) 435-0896. The applicant **must** submit the application at least **2 months** prior to the anniversary date of the grant. If for some reason time becomes an issue, contact the NCI (see XI. INQUIRIES).

Applications are to be submitted on the Non-competing Grant Progress Report Form PHS 2590 (last revised, 5/01). This form can be obtained directly by "clicking on" the following NIH website address:

<http://grants.nih.gov/grants/funding/2590/2590.htm>. Forms can also be found at the other sources noted above for competing applications.

Since the Form PHS 2590 does not apply easily to the **K12** grant, adapt the application for continuation Form PHS 2590 generally so it contains the following:

- Appropriate face page A (Form page 1) as instructed in the Form 2590
- A budget page (Form Page 2) that provides the salary and fringe benefits for each candidate or trainee by name or by position if no individual is filling the position at the time of the application. Provide all other budgetary information (e.g., supplies, travel, technical help) by trainee name or by the position broken out specifically for each candidate and/or trainee up to the \$30,000 limit.
- A brief description of the Objectives and Goals of the Program
- A brief summary listing by name delineating which faculty, mentors, and Advisory Committee members have left the Program and which new individuals are taking their places. Include for each person their degree and department affiliation (or equivalent).
- Biographical sketches of
 - i. New faculty
 - ii. New mentors
 - iii. New Advisory Committee (AC) Members
 - iv. New Trainees
- Progress of Individual Trainees: For each trainee, provide the start date (month/year) of the appointment to the Program and the cumulative number of years supported by the K12 grant; the names of the basic and clinical research mentors; and a brief paragraph for each candidate or trainee describing the basic laboratory and clinical research and didactic training experiences completed and ongoing, the relationship between the two research training experiences, and the specific future plans for satisfying the Core Requirements of the Program. The individual reports should also include: 1) A list of publications for the trainee resulting from their work in the Program; 2) Descriptive titles of clinical trials developed and/or implemented by each trainee and resulting from their work in the program, identifying the role of the trainee in each of the trials; and 3) A listing of all active research support for which a trainee is the PI, clearly showing the percent effort commitment of the trainee and addressing potential overlap issues with the research objectives of the K12-supported research. It is acceptable to describe all of the career-related activities in which the trainee participates during their appointment to the K12 program. However, it is important to differentiate progress made on activities directly relevant to the Program from progress made on other activities.
- A Report from the Advisory Committee (AC) that is separately attached summarizing the actions or the AC during the last year, evaluating the performance of the Program in meeting its objectives and the intent of the NCI, evaluating the effectiveness of recruitment strategies and providing recommendations for improving the Program (e.g, new mentors, changes in core requirements, changes in recruitment strategies etc.)
- A separate report from the AC on progress made in recruiting underrepresented minorities into the Program. Information must be included on successful and unsuccessful recruitment strategies. The report should include the following information on underrepresented minorities: 1) Candidates who applied for admission within the participating department(s) relative to the Program; 2) Candidates who were offered admission to the Program; 3) Candidates who were appointed to the program.
- Evaluation: In carrying out its stewardship of human resource related programs, the NCI may request information essential to an assessment of the effectiveness of this program. Accordingly, recipients (PI's, individual candidates/trainees) 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.

VIII. REVIEW PROCEDURES AND CRITERIA:

A. Review Procedure:

Upon receipt, applications will be reviewed for completeness by the CSR and for adherence to the guidelines of this PA by the NCI program staff. Applications not adhering to the guidelines of this PA, and those applications that are incomplete as determined by CSR or by NCI program staff, will be returned to the applicant without review.

Applications that are complete and adhere to the guidelines of this PA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities of the NCI in accordance with the review criteria stated below.

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

- Receive a written critique.
- Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score.
- Receive a second level review by the National Cancer Advisory Board.

B. Review Criteria:

1. **PRINCIPAL INVESTIGATOR:** Qualifications (and track record for competing renewal applications) of the PI to provide both scientific and administrative leadership of the Program.
2. **ADVISORY COMMITTEE:** Quality (and track record for competing renewal applications) of the Advisory Committee and appropriateness for performing its critical functions in recruitment of candidates, assignment of mentors, establishment and monitoring of individual training plans, and evaluating and making mid-course corrections for the Program. Additionally, for competing renewal applications, adequacy of addressing any concerns expressed in the Summary Statement for the prior five year award.
3. **PROGRAM/CORE REQUIREMENTS:** Merit of the Program (and track record for competing renewal applications), as defined in the didactic core requirements, basic research core requirements, and clinical core requirements, to train patient- oriented clinical scientists who can collaborate effectively with basic scientists in translational research and conduct all phases (e.g., Phase I, Phase II and Phase III) of hypothesis-driven, therapeutic cancer clinical trials.
4. **ENVIRONMENT:** Quality, sufficiency and interactiveness of the basic and clinical research of the institution to provide the environment necessary for the Program to meet its goals and objectives.
5. **MENTORS:** Experience and quality of the mentors to ensure a successful outcome of the Program.
6. **CANDIDATES:** Adequacy of the plans for (and track record for competing renewal applications) recruiting high quality trainees, to ensure a supply of high quality trainees for the Program representing at least two oncology disciplines. Adequacy of the specific measures proposed or taken to recruit underrepresented minority candidates to the Program. This does not include Continuing Umbrella of Research Experiences (CURE) supplements to the K12 program.
7. **INSTITUTIONAL COMMITMENT:** The strength of the institution's commitment to the Program, especially with regard to ensuring that each candidate will have protected time to commit 75% effort to research career development.
8. **OVERLAP:** The potential of this Program to overlap with other existing training programs.

C. Additional Review Criteria (For details, refer to [PAR-CA-03-083](#)):

- Protection of human subjects from research risk.
- Inclusion of women, minorities and children in research.
- Care and use of vertebrates in research.

D. Additional Considerations (For details, refer to [PAR-CA-03-083](#)):

- Training in the responsible conduct of research.
- Minority recruitment and retention plan.

- Budget: Appropriateness of the budget and the requested period of support to achieve the stated goals and objectives of the Program.

IX. 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:

- Scientific merit of the proposed project as determined by peer review.
- Availability of funds.
- Relevance to NCI priorities.
- Acceptability of the plan for minority recruitment.
- Acceptability of the proposal for instruction in the responsible conduct of research.

X. QUESTIONS AND ANSWERS

1. How many trainees can be supported by a **K12** grant?

As many as can be accommodated by the \$700,000 cap on each **K12** grant, and by the resources available to the program.

2. Can the support provided for OTHER EXPENSES be used to offset costs incurred in advertising and recruiting for the program?

No. The OTHER EXPENSES are to be used **only** to partially support supplies, equipment, travel, and other expenses related to an individual trainee's individual career development.

3. Who should be on the Advisory Committee?

The **K12** program requires representation by each oncology discipline participating in the program. The individual members of the committee should be **K12** program faculty, preferably with well-established grant supported programs and with a substantial track record in training the types of individuals who will be appointed to the **K12** program.

4. Since human subjects are to be involved in every **K12** program, must each trainee obtain his/her own Institutional Review Board (IRB) approval?

No, if the trainee will be participating in a larger research program that already has received IRB approval.. Yes, if the research proposed is not part of an ongoing research project with an IRB approval.

5. Is there a preference in the oncology disciplines represented in the **K12** program?

No. The only requirement is that at least 2 oncology disciplines must be represented in the program.

6. Can I assign a trainee to a laboratory project with a basic research component?

Yes. However, this should not comprise a major proportion of the total planned research experience of the trainee; and the basic research component ideally would be integrated with the patient-oriented clinical research project. The actual assignments of trainees will depend on prior experience. For example, if a trainee has already had significant laboratory/basic research experience, then there is no reason to provide more of this experience as part of the **K12**.

7. Can the trainee's salary be supplemented?

Yes, but only from non-PHS sources and if there is no requirement for additional work. A trainee can be compensated for work while receiving salary from the **K12** grant. However, the percent effort committed to this work cannot exceed 25 percent of full-time professional effort.

8. When is the next announcement of the K12 program?

Applications were previously solicited through an RFA. The **K12** program is now being announced as a Program Announcement with a once-a-year June 1 submission date.

9. Will my grant application be reviewed by a CSR study section?

No. Applications for the NCI Institutional Clinical Oncology Career Development Program (**K12**) are reviewed by an NCI peer review group that is particularly sensitive towards training and career development needs in patient-oriented and translational cancer research.

10. Can a **K12** grant be awarded for less than 5 years?

No. The length of the award is 5 years.

11. What are the **K12** requirements for training in responsible conduct of research?

K12 grants does not have any mandatory requirements. However, it is strongly recommended that trainees deficient in this area obtain training in the responsible conduct of research.

12. Are there preferred formats for the tables requested in the grant application?

Yes. The NCI has made available suggested formats for organizing the requested data. Use of these formats is encouraged in order to make the applications standard and assist the review process. ("Click on" [TABLES \(Word for Windows\)](#) or [TABLES \(Word Perfect\)](#), which ever you prefer, to download this information.)

13. Does the NCI **K12** grant operate under Expanded Authority?

Yes. However, automatic carryover of unexpended funds is not permitted. If there is a need for carryover prior approval by NCI Grants Administration Staff is required. Under most circumstances, each K12 is fully funded each year and there is little need for carryovers.

14. Is it possible to provide an additional position to a **K12** grant for a member of an ethnic group that is underrepresented in biomedical research ?

Yes. The Principal Investigator may apply for a minority supplement to the **K12** grant. The Program Director of the **K12** grant should contact the NCI Comprehensive Minority Biomedical Branch (CMBB) for information on these supplements. The CMBB can be reached at the following website address: <http://deainfo.nci.nih.gov/cmbs/index.htm>.

15. If I have a K12 award and I would like to ask for post award changes? How do I go about this?

You must contact the NCI Grants Administration official to determine the appropriate procedures to use in making a request for post award changes in your grant. This also applies to any of your needs that require a prior approval from the NCI. In general, you will have to make a request that is signed by you and a business official of your institution. After receiving the request, the Grants Administration official will consult with the NCI scientific program staff as necessary to determine whether the request can be approved.

XI. INQUIRIES (K12):

We have tried to provide you with the most complete information possible about the **K12**, as well as answer the most frequently asked questions. If you need information and explanation concerning the **K12**, please make your inquiries as follows:

A. Programmatic or scientific issues:

If you need more information and/or advice about the objectives and scope of this award, eligibility requirements, structure and organization of grant applications and peer review trends, please contact us by "clicking on" the INQUIRIES link directly below. You will be contacted promptly by one of the scientific professionals of the Cancer Training Branch of the NCI.

B. Fiscal Issues:

If you need information about the appropriate procedures for dealing with issues that involve changes in the sponsoring institution, the scope of the project as awarded, budget and period of support of the award or that involve any other issues requiring approval by the NCI or post award actions, please contact us by "clicking on" the INQUIRIES link directly below. You will be contacted promptly by one of the Grants Administration officials of the NCI.