

Guidance and Advice
K01
Howard Temin Award
National Cancer Institute

I. IMPORTANT ANNOUNCEMENTS:

The following guidance and advice is derived from a National Cancer Institute (NCI) Program Announcement (title:Howard Temin Award; number: PAR-03-104) issued in the NIH Guide on February 22, 2000. You can access this directly by "clicking on" the following NIH website address <http://grants1.nih.gov/grants/guide/pa-files/PAR-03-104.html>. After consulting the official announcement, the information and clarifications provided below together with the Form PHS 398 application kit should be all that you need to prepare an application for The Howard Temin Award.

II. BACKGROUND:

The purpose of the Howard Temin Award (K01) is to encourage basic scientists to focus their research on human cancer and to bridge the transition of these scientists from a mentored postdoctoral research environment to an independent cancer research career. The award is primarily for basic scientists who already have received considerable postdoctoral mentoring, who are demonstrating unusually high potential as independent scientists and who wish to develop research **directly** relevant to understanding the biology, etiology, pathogenesis, prevention, diagnosis and treatment of **human** cancer. A major objective of the award is to sustain and advance the early cancer research careers of the most promising doctoral level scientists as they complete their training and develop independently funded research programs.

The NCI named this award in honor of Dr. Howard Temin, Nobel laureate, who died during his period of service as a member of the National Cancer Advisory Board (NCAB). It is the only named career award offered by the NCI. It recognizes Dr. Temin for his humanity, his many contributions to cancer research, including his pioneering work with reverse transcriptase, and his excellence as a scientist and mentor. Most of all, the Howard Temin Award is intended to symbolize the kind of scientific excellence that the NCI hopes its recipients will achieve in their own research.

The NCI is interested in encouraging more basic scientists to become interested in research problems of direct relevance to human biology. In the past, the major effort of the NCI has been to encourage medically trained individuals to become interested in basic research problems as the main strategy for increasing the ability of the cancer biomedical research community to effectively translate observations in the laboratory into patient and population research settings. However, well-trained basic scientists, who focus their research on human biology and human disease, also will be an essential component of the translational research enterprise. Specifically, the Howard Temin Award provides an opportunity for basic scientists to initially work under a mentor in an institutional environment that will enable them to transition to an independent research position and acquire research support focused on issues and problems directly relevant to human cancer.

III. ELIGIBILITY:

1. **Institution:** Applications **must** be submitted, on behalf of the candidate, by a domestic, public or private, non-Federal organization, such as a university or other institution of higher education.
2. **Sponsor:** Candidates applying for this award **must** identify a suitable sponsor or mentor with extensive experience in human cancer research who will be responsible for supervising the candidate's training.

3. **Candidate:** Candidates **must** have completed **at least three years** of "mentored" postdoctoral research and have a biomedical sciences doctoral level degree or the equivalent at the time of the award. Candidates **must** have demonstrated highly productive research activities and the potential for becoming successful independent investigators. Candidates **must commit a minimum of 75% of a full-time professional effort** conducting research and research career development

Candidates **must** be U.S. citizens or non-citizen nationals, or must have been lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-551) or some other verification of legal admission as a permanent resident. Non-citizen nationals, although not U.S. citizens, owe permanent allegiance to the U.S.; they usually are born in lands that are not states, but are under U.S. sovereignty, jurisdiction or administration. **Individuals on temporary and student visas are NOT ELIGIBLE.**

A candidate can apply from a Federal agency (e.g. NIH, EPA) in same way as any other candidate, as long as the specific provisions and requirements of the Howard Temin Award are met, except there can be no compensation for salary or other research costs while employed in a Federal research facility. Compensation from an NCI grant would begin at the stage of the transition to an independent position in a non-Federal, extramural institution. Former or current principal investigators on NIH Small Grants (R03s) or Exploratory/Developmental Grants (R21s) remain ELIGIBLE to apply. However, former or current principal investigators on NIH research project grants (R01s), FIRST Awards (R29s), sub-projects on Program Project Grants (P01s) or center grants (P50s) and their equivalents are **NOT ELIGIBLE.**

IV. MECHANISM OF SUPPORT

The Howard Temin Award uses the K01 grant mechanism and provides candidates up to five years of support. Planning, direction, and execution of the program will be the responsibility of the candidate and his/her mentor on behalf of the applicant institution. **K01s are not renewable.**

V. ALLOWABLE COSTS

The NCI Howard Temin Award (**K01**) provides for the following costs:

1. **Salary:** Candidates may request \$75,000 per year plus fringe benefits and must commit a minimum of 75% full-time professional effort to the conduct of research and research career development. The actual salary **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 members of equivalent qualifications, rank, and responsibilities, in the department concerned.

The institution may supplement the NIH salary contribution up to a level that is consistent with the institution's salary scale; however, supplementation may not be from Federal funds unless specifically authorized by the Federal program from which the funds are derived. Because the salary amount is based on a full-time institutional salary, no other Public Health Service (PHS) funds may be used for salary supplementation. Institutional supplementation of salary must NOT require extra duties or responsibilities that would interfere with the purpose of the **K01**. Under expanded authorities, institutions may rebudget funds within the total costs awarded to cover salaries consistent with the institution's salary scale.

2. **Research Development Support:** During the mentored phase of the award, \$30,000 per year will 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 . The amount will increase to \$50,000 per year when the career awardee makes

the transition from a mentored position to an independent research position either at the same institution or at a different institution.

3. **Ancillary Personnel Costs:** Salaries for mentors, secretaries, administrative assistants and other ancillary personnel costs are **NOT ALLOWED**.
4. **Facilities and Administrative costs (formerly called indirect costs):** The institution may be reimbursed at **8%** of modified total direct costs, or at the actual cost rate, whichever is less.
5. **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 career award recipient. These fees must be assigned to the grantee institution for disposition by one of several approved NIH methods.
 - b. **Funds freed up** from other NCI-supported research or training grants as a result of a K01 award may not be rebudgeted by the institution.
 - c. Prior approval for **travel to a foreign laboratory** as a part of the training is required only if the stay exceeds three months.
 - d. A career awardee may request up to a 12 month **leave of absence** without award support with prior written approval from the NCI.
 - e. The NCI will consider a **change of institution, mentor and other unusual actions**. The request for change must be in writing to the Program Director.

For appropriate advice and specific instruction regarding the above and other budgetary and administrative policies that you must follow in managing a K01 award, please refer to section **XI. INQUIRIES**.

VI. SPECIAL PROVISIONS AND REQUIREMENTS:

1. **Salary and Research Development Costs:** The NCI establishes the upper limits of \$75,000 for salary support plus fringe benefits and \$30,000 (mentored) and \$50,000 (independent) for research development costs. Other institutes and centers at the NIH implement different dollar levels for these categories at their discretion.
2. **Time requirements for the "mentored" and "independent" phases of this grant:** The candidate must spend not less than one-year and not more than three-years in the mentored phase of this award. Support beyond three years is **contingent on** the career awardee moving to an unmentored, independent research environment on the **award anniversary dates** of the second, third or fourth year of support.
3. **Required procedure for the transition from a mentored to an independent research position:** Awardees planning a transition from a mentored to an independent position **MUST** contact NCI program staff of this intent as early as possible. The procedure for making the transition to an independent position is outlined in the NCI Program Announcement, "Howard Temin Award" - PAR-03-104 issued in the NIH Guide on February 22, 2000. This can be accessed directly by "clicking on" the NIH website, <http://grants.nih.gov/grants/guide/pa-files/PAR-03-104.html> under the heading SUPPLEMENTAL GUIDELINES FOR TRANSITION TO THE UNMENTORED PHASE. This transition must be on the anniversary date of the second, third, or fourth year of the award. There are a number of steps that need to be completed and approved by NCI staff:

- a. A **statement from the mentor** verifying that the candidate is ready to pursue an independent research career.
 - b. Approval of the independent **position** by NCI staff based on the soundness of the "Letters of Commitment" from the institution to provide the career awardee protected time (i.e., no less than 75% effort dedicated to the development of a research Program with the remaining effort to be used in research-related activities); a permanent, preferably tenure-track position, adequate facilities for conducting a research program, and additional resources conducive to the development of a research project and establishment of a successful research career
 - c. Approval by NCI staff of the **research plan** to ensure that the candidate's proposed independent research is clearly relevant to human biology and human disease as related to cancer etiology, pathogenesis, prevention, control, diagnosis and treatment.
 - d. If the candidate is transferring his/her research to a **new institution**, this involves special procedures and approval of NCI staff.
4. **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 may be contacted after completion of this award for periodic updates on various aspects of their employment history, publication, 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:

There are two types of applications submitted by candidates during the competing and non-competing stages of a Howard Temin Award or K01:

1. The **COMPETING APPLICATION:** this application will be peer reviewed for scientific merit and your potential to become an independent scientist. **Based on this peer review, the NCI will make a funding decision.**
2. The **NON-COMPETING CONTINUATION:** if you competed successfully for funding, each year thereafter you will be required to submit a non-competing continuation application and progress report before being funded on the anniversary date of your grant. Because of the requirement in the Howard Temin award that each candidate must move from a mentored to an independent position, there are potentially three kinds of non-competing continuation applications that could be submitted during the five-year course of this grant:
 - a. A non-competing continuation of the mentored phase of the award: This is a **routine** application format. Whether or not you submit this kind of application will depend upon how many years you spend in the mentored phase of the award (i.e., one, two or three). If you made the transition to the independent phase at the beginning of the second year of funding, there would be no non-competing continuation during the mentored phase.
 - b. A non-competing application for **TRANSITION** to the independent phase of the award: This stage has **very specific requirements** for an application and represents only your research. NCI Program staff must approve the suitability of the independent position you have negotiated with an institution, as well as ensure that the research you propose is focused on human cancer (See section **VI. SPECIAL PROVISIONS AND REQUIREMENTS**). Also, if you are **changing institutions**, then there are special procedures that you must follow. Therefore, **BEFORE** you plan to make this transition, it is important that you consult NCI Staff.

- c. A non-competing application while you are in the independent phase of the award: This is a **routine** application submitted prior to the anniversary date of the grant.

With the above special features of the Howard Temin Award or **K01** in mind, the NCI offers the following specific information and instruction about submitting competing and non-competing continuation applications.

SUBMISSION, REVIEW AND AWARD OF A **COMPETING APPLICATION**

A. Application Receipt, Review and Award Dates:

The receipt dates for the Howard Temin Award or **K01** applications are February 1, June 1, and October 1. Initial scientific merit peer review by an NCI initial review group is usually completed in June, October, and February, respectively. Review by the National Cancer Advisory Board (NCAB) is usually completed by October, January and May, respectively. The earliest possible Award dates are December 1, April 1, and July 1, respectively.

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 Grant Application 398 (4/98) to:

Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive, MSC 7710
Bethesda, Maryland 20892-7405 (For Express Mail use Rockville, MD 20817)

At the time of submission, to expedite the review, please send **two additional copies** of the application to:

Referral Office
Division of Extramural Activities
National Cancer Institute
6116 Executive Boulevard, Room 8062
MSC/8329
Bethesda, Maryland 20892-8329 (For Express Mail use Rockville, MD 20852)

C. Format for Submitting the Competing Application:

In submitting a competing **K01** Howard Temin Award, the applicant must use the Form PHS 398 (last revised 4/98). In general, you should follow the special instructions provided in the Form 398 for individual research career awards on pages IV-1 through, IV-7, page LL, and page MM. However, because the K01 has the unusual feature of bridging a candidate's career from the mentored to the independent state, the NCI asks that you use the **modified instructions below** that are adaptations to the standard instructions available in the Form PHS 398. You can obtain the application forms directly by "clicking on" the following NIH website address: <http://www.nih.gov/grants/funding/phs398/phs398.html>. Forms also are available at most institutional offices of sponsored research and from the Division of Extramural Outreach and Information Resources, NIH, 6701 Rockledge Drive, MSC7910, Bethesda, MD 20892-7910, Phone (301) 435-0714, FAX (301) 480-0525, Email: GrantsInfo@nih.gov.

Notes of Caution:

1. **Type density and size** for the entire application **must conform** to the instructions on Page 6 of the general instructions in PHS Form 398 or CSR will return the application.
2. NIH does not allow **simultaneous submission** of a career award and a research grant application for evaluation in the same review cycle. If this happens, **your application will be returned**.

General Advice in Preparing an Application:

1. In preparing an application, it is highly recommended that you make regular reference to the **Review Criteria** under section **VIII. REVIEW PROCEDURES AND CRITERIA**. The success of your application in addressing these criteria will determine its competitiveness for funding.
2. Please note that on Page LL you are required to indicate whether you are a U.S. citizen or a non-citizen national OR a permanent resident of the U.S. **If you are a permanent resident, you must have a notarized statement to this effect provided to the NCI before an award can be made.**

MODIFIED INSTRUCTIONS for Preparing Competing Application for a Howard Temin Award or K01:

In general, you should use the instructions in the Form PHS 398 on Pages IV-1 through IV-7, page MM and page LL and address all of the issues asked for in the NIH Guide Announcement at the following website: <http://grants.nih.gov/grants/guide/pa-files/PAR-03-104.html>. Pay special attention to the specific emphases and differences noted below for the K01:

- a. The FACE PAGE (page AA): check "yes" for item 2 and include the title: "NCI Howard Temin Award (K01)" and number beginning with PAR..... Please do not forget to include a specific Title in item 1 that reflects the nature of your research.
- b. On page IV-3, item 6. Other Support. It is very important that the SPONSOR **provide all current and pending research support** that is relevant to the candidate's research plan.
- c. On page IV-4 of the instruction, each of the three **Sealed Letters of Reference** using page MM should specifically address the following issues rather than those noted on page MM:
 - The adequacy of the candidates's scientific background for the proposed research and career goals.
 - The quality of the candidate's scientific productivity and achievements (e.g., publications, intellectual contributions to your research environment)
 - The candidate's ability to work with other scientists in various interactive situations (e.g., seminars, journal clubs), on collaborative research projects, and with support staff (e.g., technicians, nurses, secretaries, etc.)
 - Evidence of the candidate's originality and innovativeness in pursuing a research problem
 - VERY IMPORTANTLY, the candidate's special potential to develop, establish and manage an independent research program
- d. On page IV-4 under the section on **The Candidate**, you should clearly describe what **additional** postdoctoral training is needed to help prepare you to develop the research skills needed to establish an independent research program focused on **human cancer**.
- e. On page IV-4, under the section on **Statements by the Sponsor(s)**, the sponsors (i.e., mentors) should specifically describe what **additional training and the duration of the training (i.e., not more than 3 years)** you will receive that will help you achieve your career goals and prepare you for the transition to an independent position conducting

research directly relevant to human cancer. There should be a **signed letter from the Sponsor** making a clear statement about whether the research project of the candidate can be taken all or in part to his/her independent position or whether the candidate will be expected to develop an entirely new project in an independent position.

- f. On page IV-6 under the section on **Research Plan**, remember that reviewers will evaluate this plan from the perspective that you are a **more advanced candidate** who is nearly ready for independent research career rather than just beginning postdoctoral training. The Research Plan primarily should address the mentored research activities, but the peer reviewers should know whether all or parts of this research will be taken by the candidate to his/her independent position or whether the candidate will develop a totally new project.
- g. **Don't forget** that, as appropriate to your research plan, you **must** include all information on Gender and Minority Inclusion, Inclusion of Children, Human Subjects, and Vertebrate Animals as instructed on pages 16-18 of Form PHS 398 application kit.

ANNUAL PROGRESS REPORT/APPLICATION FOR CONTINUATION

The recipient of an active Howard Temin Award or **K01** 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 and any major changes in objectives that occurred during the previous year of funding and are planned for next year. The National Institutes of Health should mail the **face page** for this application together with return mail labels to the career awardee 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 awardee must submit the application at least **two months** prior to the anniversary date of the grant. If for some reason time becomes an issue, contact the National Cancer Institute (see IX. INQUIRIES).

Because the Howard Temin Award is comprised of a mentored phase and an independent phase, there are different sets of instructions provided below depending upon the phase of the award:

1. Submission of the Continuation Application while in the **Mentored Phase**:
After receiving the face page from the NIH, applications are to be submitted on the grant application Form PHS 2590 (last revised 4/98) using the special instructions for Research Career Awards on Pages IV-1 and IV-2. You can obtain this form directly by "clicking on" the following NIH website address: <http://www.nih.gov/grants/funding/2590/2590.htm>. The Form PHS 2590 is also available at most institutional offices of sponsored research and from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC7910, Bethesda, MD 20891-7910, Phone 301-435-0714, FAX: 301-480-0525, Email: GrantsInfo@nih.gov.
2. Submission of the Continuation Application for **TRANSITION TO THE INDEPENDENT PHASE**: you should consult NCI staff **well in advance** of the anniversary date of your transition to receive specific instructions about this process. This application will be evaluated by NCI Staff to ensure that it meets the special requirements for the research (i.e., focus on human cancer) and that the institution has provided you with a suitable position for career development as an independent investigator. There are two options for this application depending upon whether you are remaining at the same institution or transferring your grant to a new institution:
 - a. If you have obtained a position at the **same institution**: Use the standard Form PHS 2590 noted in one above. Follow the instructions on pages IV-1 and IV-2 with the following additions: a letter of support from the sponsor that you are

ready to become independent, Specific Aims and a full Research Plan that represent your independent research, and Letters of Commitment from the institution.

- b. If you have obtained a position at a **new institution** and are **transferring your award**, you must obtain an application transfer kit from the NCI Grants Administration Branch (see IX. INQUIRIES). The application must be submitted on the anniversary date of the grant and include the following additions: a letter of verification of independent status from the sponsor or mentor and Letters of Commitment from the institution. The facilities and administrative costs (i.e., previously called indirect costs) will remain at 8%.
3. Submission of a continuation application as an **independent investigator**: As an independent investigator at the same institution or a new institution, you must follow the instructions provided for the Form PHS 2590 for a research grant.

VIII. REVIEW PROCEDURES AND CRITERIA:

A. Review Procedure for Competing Applications:

Upon receipt, the competing application will be reviewed by both CSR and the NCI for completeness and for conformance to all eligibility requirements and special provisions and requirements (See section III. **ELIGIBILITY** and section VI. **SPECIAL PROVISIONS AND REQUIREMENTS** above). Incomplete and ineligible applications **will be returned** to the applicant without further consideration.

Those applications judged to be both complete and eligible will be further evaluated according to the peer review criteria stated below for scientific merit by a standing peer review group convened by the *Division of Extramural Activities* (<http://deainfo.nci.nih.gov/extra/dea.htm>) of the NCI. A second level of review by the NCAB will also review the application to ensure that it meets the broad program needs and priorities of the NCI.

B. Review Criteria for the **COMPETING APPLICATION**:

1. **The Candidate** (Using Letters of Reference and the Section on The Candidate)
 - Commitment of the candidate to a career in basic cancer research that will be focused on problems directly relevant to human biology and human cancer disease.
 - Ability of the candidate to interact and collaborate with other scientists.
 - Quality of the prior scientific training and experience, including publications that establish the innovativeness of the candidate in research and a high potential for an independent research career.
 - Recommendations of three well-established scientists attesting to the special potential of the candidate to pursue an independent career in cancer research.
2. **Career Development Plan**:(Using the Section on the **Candidate** and Section on **Statement of Sponsor(s)**)
 - The likelihood that the plan will contribute substantially to the scientific development of the candidate and the achievement of an independent research program directly relevant to human biology and human cancer disease based on the candidates prior training and research experience.
 - The appropriateness of the goals and scope of the plan to complement prior training/research experience and achieve the stated training and research objectives. These include:
 - Appropriateness of the proposed durations of the mentored and unmentored phases.

- Appropriateness of the proposed activities during the mentored and unmentored phases for a five-year award.
- Adequacy of prior or proposed training in the responsible conduct of research.

3. **Research Plan:**

The Plan should provide a description of the research and training experiences that will occur during the mentored and unmentored phases of the award.

- Degree of relevance of the research plan to developing an independent research program focused on human biology and human disease as they relate to the etiology, pathogenesis, prevention, diagnosis, and/or treatment of human cancer.
- A sound research project that is consistent with the development plan for an independent career in cancer research and the candidate's level of research development (All applicants for this award will have had previous postdoctoral research experience and in some cases may have been Principal Investigators on small research grants)
- Usefulness of the research plan as a vehicle for enhancing existing research skills as described in the career development plan
- The originality and quality of the research hypothesis/question, design and methodology, judged in the context of the candidate's previous training and experience
- Attention to and implications of what aspects of the plan will go with the applicant at the time of transition to an independent position
- Adequacy of the plan's attention to children, gender, and minority issues when human subjects are involved.

4. **Sponsor(s) (i.e.,Mentor/Co-Mentor(s)):**

- Appropriateness of the mentor(s) research qualifications in the area of the proposed research.
- Quality and extent of the mentor(s) proposed role in providing guidance and advice to the candidate
- Previous experience in fostering the development of cancer researchers.
- History of research productivity and peer-reviewed support.
- Adequacy of existing support for the mentored phase of the proposed research project.
- Adequacy and clarity of the mentor(s)'s statement describing what aspects of the research plan that will go with with the candidate when the transition is made to an independent position.

5. **Environment and Institutional Commitment:**

- Clear commitment of the institution to ensure that a minimum of 75 percent of the candidate's effort will be devoted **directly to research**, with the remaining percent effort being devoted to activities related to the successful development of a research career.
- Adequacy of research facilities and training opportunities
- Quality and relevance of the environment for the scientific and professional development of the candidate

6. **Budget:**

- Justification of the requested budget in relation to the career development goals and research aims.

IX. AWARD CRITERIA

Shortly after the NCAB approves of the competing application, the NCI will notify the applicant of his/her funding status. Awards are made based on availability of funds during each fiscal year, the scientific merit of the proposal as judged by peer review, and the program priorities of the NCI.

X. COMMON QUESTIONS AND ANSWERS:

1. What is the minimum time after award of the K01 must the career awardee (Principal Investigator) remain in the mentored phase?

The career awardee must spend at least one year but not more than three years in the mentored phase. The awardee and the mentor must agree when the change of phase will occur. The NCI Program Director must be notified well in advance of this transition.

2. What is considered a suitable position for the independent phase of the award.?

The NCI believes that a tenure track position at a level reflective of the accomplishments and responsibilities of the career awardee is most appropriate. The NCI program staff will carefully review these aspects:

- Resources offered to career awardee for independent research program;
- Stability of position, e.g., tenure track or equivalent;
- Clear commitment for protective time to develop research program;

3. What if I don't have three years of postdoctoral experience?

All of the career awards in the K-series are based on different levels of experience. It would be to your disadvantage to compete against individuals with much more research experience than yourself. Always look for an award at the NIH or NCI that compares to your experiential level in order to have the best chance of success in the peer review process.

You must have three years of postdoctoral experience to apply a The Howard Temin Award or K01. This award is specifically designed to capture someone at a more advanced postdoctoral level who wishes to redirect their research toward human cancer before becoming independent.

4. I am a holder of a current Alien Registration Card ("Green Card") should I include a notarized copy of this card with the initial application?

Yes, a notarized copy of your card will help to expedite funding if the information is already available.

5. Can the career awardee stay at his/her current institution in an unmentored phase?

Yes. The NCI Staff must approve the transition to an unmentored phase in the same way as if moving to another institution. The career awardee must show that he/she is independent of the mentor and performing as an independent researcher and the institution must demonstrate that this is suitable position to conduct independent research.

6. Should the career awardee apply for other support (R01, R03, R21) immediately after change of phase from mentored to unmentored?

It is important that the career awardee become fully independent as soon as possible and gaining independent funding is a major step to fully implement the purpose of this award.

7. If the career awardee changes institutions during the first year of the award must he/she designate a new sponsor?

Yes. The NCI must approve the transfer from one mentor to another as well as change of institution. But this is not recommended since the success of your application in peer review was based significantly on the sponsor's research environment and ability to provide mentorship.

8. If a career awardee changes from a mentored to unmentored phase, will the salary remain the same?

A change of institution or status may result in a change of salary. The new salary must be consistent with the established salary of other members of equivalent qualifications, rank and responsibilities in the organization. The institution may request up to \$75,000 per year plus fringes benefits and commit to the career awardee a minimum of 75% full-time professional effort to conduct research and research career development. There will be a change in the Research Development support. During the mentored phase \$30,000 will be provided for the career awardee. The amount will increase to \$50,000 per year when he/she moves to an unmentored, independent research environment.

9. How are the salary levels and other costs associated with Career Development Awards determined?

Each institute and center at the NIH has the authority to determine the upper salary levels and other cost levels for Career Development Awards (i.e., K-awards) as a matter of institute policy. Thus, the NCI's levels do not necessarily equal or match the levels supported by another institute. For the NCI, all individual career awards for **"mentored" postdoctoral scientists** and for **junior faculty**, establishing their first independent research programs, use the same salary but different other cost levels.

10. What is the "career development plan" always referred to in NIH Announcements?

This can be confusing to some applicants because announcements advertised in the NIH Guide always refer to a career development plan while the instructions available in the Form PHS 398 application kit make no specific mention of a career development plan. The career development plan is the combination of the candidates goals and objectives combined with the specific opportunities available in the mentor's research group and within the environment of the institution.

11. Why do I need to send extra copies of my career award application?

These extra copies are vitally important to the timely processing and review of your application.

The copies sent to the **Center for Scientific Review (CSR)**, which is the central receipt point for all grant applications to the NIH, ensures that the application is given the appropriate grant number and assigned to the National Cancer Institute for peer review. CSR does the initial critical logging and processing of the paperwork. Unlike the regular research grants (e.g., R01s), CSR does NOT ORGANIZE and conduct the peer review system for career awards. Each institute and center at the NIH manages their own peer review system for career awards. The extra copies that you send directly to **the NCI** ensure that the review process is initiated in a timely way.

12. Should I send a cover letter with my career award application?

The first processing step by CSR is to assign funding responsibility for your application to an institute; this is called the "referral" process. If your research is obviously cancer research, then it will be assigned to the NCI. But if you feel that your application is cancer research and are concerned that it could be assigned to an institute other than the NCI, then a cover letter explaining the significance of the research to cancer will be helpful. Also, if you feel that your research is related to other areas of research as well as to cancer, it may be to your advantage to provide an explanation. However, if you want your application assigned for funding decisions to the NCI, the cancer relevance should be emphasized.

13. How important is the font size in preparing the application?

This is very important. Follow the directions on page 6 of the Form PHS 398 application kit or your application **will be returned** by CSR.

14. Can I supply additional information after I have submitted my Career Award application to the NIH?

Yes, but this must be submitted after receiving approval from the NCI scientific review administrator (SRA) in charge of reviewing your grant. You must identify and contact the SRA, explain your situation, receive approval and send the additional information in time to provide reasonable opportunity for the reviewers to include it in their evaluations. Examples of additional information that is important for reviewers to examine would be new experimental data that strengthens the rationale for pursuing the research project and manuscripts that have been accepted for publication, especially if they are to peer-reviewed journals.

15. What happens if I already have considerable postdoctoral experience and want to pursue additional training or change fields?

This will depend upon the strength of your rationale for extending your period of postdoctoral training and on the perceptions of reviewers. If reviewers see your application as just another postdoctoral experience, it is not likely to succeed. But if they view your application as an essential step in a carefully considered career development plan to gain the multi-disciplinary skills necessary to become an independent investigator in your field of choice, this will be considered positively.

There are some unexplainable tendencies in peer review. For example, if you are trained as an M.D./Ph.D. versus obtaining an M.D. and then a Ph.D., reviewers are much more favorably inclined toward multiple postdoctoral experiences. We do not know the reason for this, but if you are in the second category, you will have to provide in your career development plan a very strong justification of the need for additional postdoctoral training.

16. What's the difference between a "mentor" and a "sponsor"?

The various announcements and the Form PHS 398 use mentor, sponsor and preceptor interchangeably. There is no difference.

17. What is the importance of the sponsor(s) or mentor(s)?

The sponsor will be critical to the success of your application. The sponsor provides the supportive research environment to the career awarded, and is central to a successful application. The sponsor should be involved in research that matches the career goals and objectives of the career awarded AND should have a strong track record in training individuals who have become successful independent investigators.

18. Can there be more than one sponsor?

Yes. It is important that the primary sponsor be on-site. The remaining sponsors may be off-site. If off-site sponsors are planned, it is important in your application to describe plans for keeping in touch with them. With today's increasingly multi-disciplinary, translational research emphases, it may be more logical to have the necessary expertise elsewhere but still available by FAX/Email/Phone. You should state how you plan to communicate with these sponsors, including a schedule of personal meetings.

19. Should the Sponsor's plan be signed by the sponsor?

Yes. Reviewers want verification of everything in the plan by the signature of the sponsor.

20. Who will review my career award application?

Your application will be reviewed by a scientific review group organized by an NCI Scientific Review Administrator. It will have the necessary expertise to judge the merit of your application, the suitability of the sponsor, the institutional commitment, and your potential to develop into an independent investigator.

21. How will reviewers evaluate my application?

The reviewers will evaluate your application using the review criteria provided in the NIH/NCI announcement that corresponds to the particular career development award that applies to you. It is very important that you prepare your application in response to these criteria because your ultimate success in receiving funding will depend upon how well your application addressed these criteria.

22. Do I have to be a U.S. citizen to receive a career award?

At the time of award, you must be a U.S. citizen or U.S. noncitizen national or have been lawfully admitted into the U.S. as a permanent resident and possess an Alien Registration Receipt Card (I-151 or I-551) or some other verification of legal admission as a permanent resident. Please note that on page LL of the Form PHS 398 application kit, you are required to indicate whether you are a U.S. citizen or noncitizen national or provide verification of your permanent resident status. No award can be made until this is confirmed.

23. Should I follow "just in time procedures" for providing "Other Support" documentation in the preparation of a Career Development Award?

Yes, however the Form PHS 398 asks the sponsors / mentors to provide "other support." This is often overlooked. The peer reviewers will want to see this information. Without it, the review of your application can be compromised.

24. Can I apply for a research grant from the PHS and still keep my career development award?

Yes, but you cannot receive any additional salary from another Federal grant if it were to be funded even if the career award does not equal your actual salary. The institution can pay you additional salary from non-Federal sources or from grants from Private funding organizations, as long as it does not exceed the institutional salary scales.

25. If I submit a research grant application after receiving a Career Development Award, how is this reconciled in terms of percent effort and restriction?

Many NIH centers and institutes make you give up a career award if you are awarded an NIH research grant. With the proviso that you are expected to spend no less than a 75% full-time professional effort on the research **proposed in your career award**, the NCI usually allows applicants to receive research grant support under the following conditions:

- a. If the research grant proposal is **the same** as that in the career award, then you cannot have any more than a 25% effort on the research grant. The NCI assumes that you are spending a 100% effort on the research as proposed in your career award and allows you to use the remaining 25% of your time for this purpose that goes beyond the minimum 75% full-time effort.
- b. If the research grant proposes some of the **same objectives** as that proposed in the career award as well as **other objectives** not in the career award, the NCI allows you to apply for up to a 50% effort on the grant. In this case, the first 25% effort on the research grant is considered overlap with and subsumed by the 75% full-time commitment on the career award and the second 25% effort on the research grant is considered what you are doing with your remaining time on the career award.

In neither of these two cases can you receive any salary from the NIH grant. All of the salary provided from the PHS must come from your career award.

If a special situation exists, you should consult the appropriate Grants Administration Official (see XI. INQUIRIES).

26. Does my career plan have to include training in the Responsible Conduct of Research?

Yes. This is a Congressional legislative requirement. You should provide evidence that you have already received this training or here should be substantive activities related to instruction on the responsible conduct of research that will be incorporated into your research training plan. Most programs consider training in the following areas: conflict-of-interest, responsible authorship, policies for handling scientific misconduct, policies regarding use of human and animal subjects, and data management/record keeping. This aspect of your training will not affect the merit score given to your application BUT, if this training is not in the application, it cannot be funded until proper arrangements have been made.

27. What should my application contain if it deals with human subjects, clinical trials or vertebrate animals?

If your research proposal deals with human subjects, you must check item 4a "yes" on the face page of the Form PHS 398 application and provide documentation that this research has been certified by your institution's IRB. You must also provide the required information for Gender and Minority Inclusion and Inclusion of Children as Participants in research involving Human Subjects OR provide sufficient information/justification for exemptions to be evaluated by peer reviewers. This information is located on pages 16, 17, 18 and 27, 29 of the Form PHS 398 application kit.

If you are using vertebrate animals, you must check item 5 on the Form PHS 398 and follow the instructions on page 18 of the Form PHS 398 application kit.

Without the proper information on Gender and Minority Inclusion, Inclusion of Children and Vertebrate Animals, an award cannot be considered until this aspect of the review is completed. If an application is fundable, the NCI must be provided with the human subject IRB certification before an award can be made.

28. If I have a K01 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.

X. INQUIRIES (K01):

We have tried to provide you with the most complete information possible about the **K01**, as well as answer the most frequently asked questions. If you need information and explanation concerning the **K01**, 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.