PATHWAY TO INDEPENDENCE (PI) AWARD (K99/R00)
Program Announcement: PA-10-063

Note: the information below is extracted from the current Program Announcement; before applying for a K99/R00 award you should obtain and read the current program announcement and application instructions.

The objective of the NIH Pathway to Independence Award (K99/R00) initiative is to assist postdoctoral investigators in transitioning to a stable independent research position with NIH or other independent research funding. One of the most challenging transitions in any research career is the transition from postdoctoral trainee to independent scientist.

Prospective candidates are encouraged to contact the relevant NIH staff for IC-specific information at: http://grants.nih.gov/grants/guide/contacts/parent_K99_R00.html

Eligibility:

Citizenship and Residency: U.S. citizens and non-U.S. citizens with the skills, knowledge, and resources necessary to carry out the proposed research are invited to develop an application for support. Information on citizenship/residency status must be provided in the application as part of section 9.

Degree and Research: Eligible PD/PIs include outstanding postdoctoral candidates who have a clinical or research doctorate (including Ph.D., M.D., D.O., D.C., N.D., D.D.S., D.M.D., D.V.M., Sc.D., D.N.S., Pharm.D. or equivalent doctoral degrees) and who have no more than 5 years of postdoctoral research training at the time of application (resubmissions must also comply with this requirement). Clinicians (including those with M.D., D.D.S, D.V.M. and other licensed health professionals) in a clinical faculty position that denotes independence in clinical responsibilities but not in research may also be eligible for the K99/R00 award.

Career Level: This award is intended for and limited to postdoctoral scientists who are in mentored training positions and do not have sufficient research experience or institutional authority to lead an independent research program. Individuals with a full-time tenure track assistant professor position (or equivalent) at the time of application are not eligible.

Level of Effort: Candidates must be able to commit a minimum of 9 person-months (75% of full-time professional effort) conducting research career development activities associated with this award. The remaining 3 months (25% effort) can be divided among other research, clinical, and teaching activities only if these activities are consistent with the goals of the NIH K99/R00 Award, i.e., the candidate’s development into an independent investigator.

Individuals are NOT eligible if they:

• Have currently or previously held an independent research faculty or tenure-track faculty position, or its equivalent, in academia, industry or elsewhere; or
• Have more than 5 years of related postdoctoral research training at the time of initial application or resubmission(s); or
• Have been an independent principal investigator on NIH research grants (e.g. R01, R03, R21), NIH career development awards(e.g., K01, K07, K08, K23, K25), or other peer reviewed NIH or non-NIH research grants over $100,000 direct costs per year, or project leaders on program project (P01) or center (P50) grants.

Ph.D. (or equivalent research doctorate) candidates in positions other than postdoctoral fellow positions:
It is recognized that some institutions appoint postdoctoral fellows in positions with other titles although they are still in non-independent training positions. Candidates in such positions are encouraged to obtain confirmation of their eligibility before they begin to prepare their applications. Evidence for non-independence may include:

• The candidate’s research is entirely funded by other investigator’s grants.
• The candidate’s research is conducted entirely in another investigator’s assigned space.
• According to institutional policy, the candidate cannot hire postdoctoral fellows or be the responsible supervisor of graduate students.
• According to institutional policy, the candidate is not allowed to submit an application as the principal investigator of an NIH research grant application (e.g., R01).
• The candidate lacks other rights and privileges of faculty, such as attendance at faculty meetings.

Conversely, evidence for independence, and therefore lack of eligibility, includes:
• The candidate has a full-time tenure track assistant professor position (or equivalent).
• The candidate received a startup package for support of his/her independent research.
• The candidate has research space dedicated to his/her own research.
• The candidate may attend faculty meetings, be the responsible supervisor for graduate students, and/or hire postdoctoral fellows.
• The candidate is eligible to apply for independent research funding as the principal investigator of an NIH R01 or other equivalent research grant.

Clinicians (including those with M.D., D.D.S, D.V.M. and other licensed professionals) in positions not designated as postdoctoral positions

Following clinical training or fellowship training periods, clinicians often obtain a clinical faculty position that denotes independence in clinical responsibilities but not in research. A clinical faculty member who does not hold an independent research faculty position may be eligible for the K99/R00 award, and should contact a Program Director at the relevant NIH Institute for guidance. Clinicians in such positions are encouraged to obtain confirmation of their eligibility before they begin to prepare their applications.

Career Development Award Supplemental Form Component Sections

K99/R00 applications follow the format & requirements of other Mentored Career Development Awards and use the Career Development Award Supplemental Form Component Sections (see handout on K01, K08 & K23 Awards). Aspects that are specific to K99/R00 Awards are described below:

Candidate Information and Career Development Plan

Candidate’s Background:
• Describe the candidate’s commitment to a career in a biomedical or behavioral research, potential to develop into a successful independent investigator, and current as well as long-term research and career objectives, as defined for other Mentored Career Development Awards.
• If currently supported by an institutional or individual Ruth L. Kirschstein NRSA, describe the candidate’s current research training or fellowship program.
• For individuals in postdoctoral positions with other titles although still in non-independent training positions, describe evidence of non-independence.

Career Goals and Objectives:
• Present a systematic plan that: (1) shows a logical progression from the candidate’s prior research and training experiences to the training and research experiences proposed for the mentored phase of the award (K99) and subsequently to independent investigator status (R00); and (2) justifies the need for further mentored career development to become an independent research investigator; and (3) that utilizes the relevant research and educational resources of the institution.
• Candidates planning to be sponsored by an extramural institution should consult with the proposed mentor to discuss the proposed research training/career development plan for the mentored phase and the research plan to be presented in the application for the subsequent independent scientist phase.
• If the candidate is planning an NIH intramural laboratory for the mentored phase, a mentor will need to be selected with whom the candidate can consult in preparing and submitting the application for the intramural mentored phase of the award.
Career Development/Training Activities:

- Describe the career development plan and how it fits with the candidate’s goals and prior experience. A systematic plan should be presented for obtaining the necessary biomedical, behavioral, or clinical science background and research experience to launch an independent research career. The career development plan must be specifically tailored to meet the needs of the candidate and the ultimate goal of achieving independence as a researcher.

- Describe the current training activities and how they relate to the career development plans and the career goals of the candidate. Candidates must justify the need for the award, both the mentored phase and the independent scientist phase, and must provide a convincing case that the proposed period of support (1-2 years as a mentored candidate followed by up to 3 years as an independent scientist) will substantially enhance his/her career and/or will allow the pursuit of a novel or promising approach to a particular research problem.

- The candidate should describe how the career development plan will promote the candidate’s success and scientific independence. This plan should describe activities such as those that will lead to new and/or enhanced research, grant-writing, communication and laboratory management skills and knowledge. The candidate should also describe how these skills will contribute to research productivity and facilitate the development of new approaches and directions for investigation. Courses or other activities that might allow the candidate to expand the scope of his/her research in order to improve the potential for success in gaining further independent funding are particularly encouraged.

- The candidate must describe the plan for evaluation of his/her progress during the mentored phase and for the transition to the independent phase.

- The candidate and K99 phase mentor (see below) must describe plans for the transition to the independent phase.

Training in the Responsible Conduct of Research:

- As described for other Mentored Career Development Awards.

Research Plan

- The candidate should describe his/her research that is relevant to the proposed R00 research plan. Ideally, this would include a brief description of research performed prior to the mentored phase, a description of the research planned during the mentored phase and a detailed description of the research planned for the independent phase. This narrative should describe what the candidate will accomplish during the mentored phase research that will enable him/her to launch an independent research program (i.e. what does the candidate still need to accomplish during the mentored phase in order to compete successfully once independence is achieved). It is anticipated that candidates will be best able to describe their current and past research.

- The research description should demonstrate not only the quality of the candidate’s research thus far but also the novelty, significance, creativity and approach of the R00 phase research, as well as the ability of the candidate to carry out the research. Consequently, the research plan should provide a detailed rationale, experimental approach and plan for the independent phase research.

- The application must also describe the relationship between the mentor’s research and the candidate’s proposed research plan. The application should describe how the candidate will gain independence from his/her mentors and achieve separation of his/her scientific research program from that of the mentor(s).

- If more than one K99 phase mentor is proposed, the respective areas of expertise and responsibility should be described.

- Data and Safety Monitoring (when applicable): Candidates proposing to conduct clinical trials should consult with relevant IC staff.
Statements of Support

Statement by Mentor, Co-Mentors, Consultants, Contributors *(combine & upload as single pdf)*:

- The candidate must name a primary mentor (sponsor), who, together with the candidate, is responsible for the planning, direction, and execution of the K99 phase program. The qualities of the mentor are identical to other Mentored Career Development Awards and supported by statements as described for those awards.
- The mentor must agree to provide annual evaluations of the candidate’s progress for the initial mentored phase as required in the annual progress report.
- The mentor must agree to review and comment on the extramural independent scientist (R00) phase application.

Environment and Institutional Commitment to the Candidate

Description of Institutional Environment:

- As described for other Mentored Career Development Awards; in addition, describe how the institutional research environment is particularly suited for the development of the candidate's research career and the pursuit of the proposed research plan and progression to the R00 phase.

Institutional Commitment to Candidate’s Research Career Development:

- As described for other Mentored Career Development Awards, including a strong statement of commitment to the candidate that is not contingent upon receipt of the K99/R00 award.
- Provide assurances that the candidate will be able to devote a minimum of 9 person-months (75% of full-time professional effort) to the development of their research program. The remaining effort should be devoted to activities related to the development of the candidate’s career as an independent scientist.
- If the candidate is not a U.S. Citizen or permanent resident, the sponsoring institution must include information about their visa status and an assurance that the candidate’s visa provide sufficient time to complete both phases of the K99/R00 award at a U.S. Institution.

Definitions of Criteria and Considerations for Critiques of K99/R00 Awards

Reviews of K99/R00 applications follow the same criteria as other Mentored Career Development Awards (see handout on K01, K08, & K23 Awards). Additional criteria are applied to K99/R00 Awards as follows:

1. Candidate.
   - Given the candidate’s prior training, proposed career development plan, and the referees’ evaluations, is it reasonable to expect that the candidate will be able to achieve an independent, tenure-track or equivalent position within the time period requested for the K99 phase of this award?

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring
   - For individuals currently supported by research training programs, how does the proposed career development plan enhance or augment the applicant’s training to date?
   - To what extent are the plans for evaluating the K99 awardee’s progress adequate and appropriate for guiding the applicant towards a successful transition to the independent phase of the award?
   - Is the timeline planned for the transition to the independent phase of the award appropriate for the candidate’s current stage of scientific and professional development and the career development proposed for the K99 phase of the award?

   - Is the proposed K99 phase research significant?
   - Are the scientific and technical merits of the K99 research question, experimental design and methodology appropriate for the candidate’s level of training, an appropriate vehicle for developing the
research skills described in the career development plan, and appropriate for developing a highly successful R00 research program?

- Is the proposed R00 phase research scientifically sound and a logical extension of the K99 phase research?
- Is there evidence of long-term viability of the proposed R00 phase research plan?
- Evaluate the innovation and creativity of the proposed R00 phase research, i.e., does the project address an innovative hypothesis or challenge existing paradigms?
- Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies?
- To what extent is the proposed R00 phase research likely to contribute significantly to our understanding of biomedical problems?
- To what extent is proposed R00 phase research likely to foster the career of the candidate as an independent investigator in biomedical research?

4. Mentor(s), Consultant(s), Collaborator(s).

- Evaluate the nature and extent of the proposed supervision that will occur during the mentored phase of support, i.e. is it adequate, and is the commitment of the mentor(s) to the applicant’s continued career development appropriate?
- Does the mentor have a comprehensive plan to support the proposed K99 phase career development and research plans as well as the candidate’s efforts to transition to independence?
- Is this plan adequate and appropriate?
- Are the consultants'/collaborators’ research and/or mentoring qualifications appropriate for their roles in the proposed K99 phase of the award?

5. Environment and Institutional Commitment to the Candidate.

- What evidence is provided that the K99 sponsoring institution is strongly committed to fostering the candidate’s development and transition to the independent (R00) phase?

Additional Review Criteria:

As described for other Mentored Career Development Awards.