

## **Guidelines For Written Reviewer Comments Pathway to Independence (PI) Award Program K99/R00**

The K99/R00 Pathway to Independence Award Program (PI) is designed to facilitate receiving an R01 award earlier in an investigator's research career. The goal of this initiative is to facilitate a new investigator's ability to transition from a postdoctoral status to an independent scientist capable of applying for and receiving their first R01 award and securing a stable research position. The PI Award will provide up to five years of support consisting of two phases. The initial phase will provide 1-2 years of mentored support for highly promising, postdoctoral research scientists. This phase will be followed by up to 3 years of independent support contingent on securing an independent research position. The PI Award is limited to postdoctoral trainees who propose research relevant to the mission of one or more of the participating NIH Institutes and Centers. For more detail refer to the Program Announcement on the enclosed CD.

### **Review Criteria**

In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research and career development plans will have a substantial impact on the pursuit of these goals. Reviewers will evaluate: the candidate; the career development plan; the research plan; the mentor; the environment and institutional commitment to the candidate; the training in the responsible conduct of research; the plans to evaluate progress; and several additional criteria where applicable.

The format outlined below should be followed in preparing your comments for each K99 application assigned to you for review. Include additional headings when they seem appropriate to the review. If this is an amended application, address progress, changes, and responses to the critique from the previous review, indicating whether the application is improved, the same as, or worse than the previous submission. However, you are not constrained to address only the points identified in the previous review. These comments on progress and/or responsiveness to previous critiques may be provided either in a separate paragraph and/or under the appropriate criteria.

The Primary (1) and Secondary (1) reviewers should each address all of the review criteria outlined below. The Secondary (2) or Discussant reviewer will prepare a brief written critique. A short paragraph highlighting the strengths and weaknesses of the application or bulleted lists of strengths and weaknesses are both examples of acceptable critiques written by the Secondary (2) or Discussant reviewer. If you prefer to prepare a full critique equivalent to a Primary (1) or Secondary (1) reviewer, you also have that option. The scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to receive a high priority score. These criteria are listed in logical order and not in order of priority.

#### **Candidate:**

- Potential for carrying out independent research, based on the postdoctoral candidate's experience level and research training background leading up to the current application;
- Candidate's potential for becoming an outstanding successful independent investigator who will contribute significantly to a chosen health-related research field;
- Evidence of the candidate's research productivity, including quality of peer-reviewed scientific publications;
- The overall quality of the candidate's postdoctoral research training experience including expertise gained at the current stage of his/her career;
- How this experience will prepare the candidate to implement successfully the independent phase project;
- Letters of reference from well-established scientists addressing the above areas and any other evidence that the candidate has a high potential for becoming an independent investigator;
- Mentor's (sponsor) statement, and statement from the institutional training grant director (if applicable), as well as the quality of the research project proposed for the independent phase.

#### **Career Development Plan:**

- Appropriateness of the career development plan and the likelihood that the award will contribute substantially to the scientific development of the candidate;

- Appropriateness of the content and duration of the proposed didactic and research components of the award;
- The consistency of the career development plan with the candidate's prior research experience and current research career goals;
- For individuals currently supported in research training programs, appropriateness of the current training and how such training is preparing the candidate for continued support leading to independent career status.

#### **Research Plan:**

Reviewers will recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the depth and breadth of that submitted by a more experienced investigator. Nevertheless, a fundamentally sound research plan must be provided.

- Scientific and technical merit of the research question design and methodology;
- A sound research project that is consistent with the candidate's stage of research development and as a vehicle for developing the research skills described in the career development plan;
- Appropriateness of the proposed specific aims for the mentored phase of research, and evidence of long-term viability of the proposed research at the subsequent independent scientist phase;
- A brief description of the planned mentored phase career development program, followed by a thorough description of the planned independent phase research project.
- Potential of the proposed research to contribute significantly to the research and scientific literature associated with the mission of the NIH awarding component (NIDDK)
- Significance of the proposed research.
- Approach to the planned research.
- Innovation of the proposed research, i.e. do the plans develop or employ novel concepts, approaches or methodologies, tools, or technologies for the specific area of research?

#### **Mentor:**

- Appropriateness of the mentor's research qualifications, scientific stature, experience and mentoring track record for the applicant's career development needs;
- Adequacy and extent of proposed supervision that will occur during the mentored phase period of support, and the commitment of the mentor to the applicant's continued career development;
- Evidence of mentor's consultations and collaborations with sponsoring institution (intramural NIH or extramural institution) ensuring commitment to the candidate;
- Appropriateness of mentor's support of the candidate's efforts to transition to independence and support of the proposed career development and research plans;
- Appropriateness of the mentor's description of the elements of the research training plan and career development activities, including formal course work.

#### **Environment and Institutional Commitment to the Candidate:**

- Adequacy of research facilities and the availability of appropriate educational opportunities, including collaborating faculty, when necessary;
- Clear commitment of the sponsoring institution to ensure that the required 75-percent effort of the candidate will be devoted directly to the research training, career development, and research activities described in the proposed career development and research plans;
- Strength of the institutional commitment to fostering the career development of the candidate;
- Unique features of the scientific environment that benefit the proposed research; i.e., employ useful collaborative arrangements or subject populations
- Quality and relevance of the environment for scientific and professional development of the candidate.

#### **Plans to Evaluate Progress:**

- Adequate plans for evaluation of the mentored awardee's progress to determine suitability for transition to the independent phase of the award.
- Appropriate timeline planned for the transition to the independent phase of the award.

#### **Training in the Responsible Conduct of Research:**

- Appropriateness and adequacy of training in the responsible conduct of research.

**Protection of Human Subjects from Research Risks:** Explain concerns regarding the proposed use of human subjects, including any possible physical, psychological, or social injury individuals might experience while participating as subjects in the research. Indicate whether their rights and welfare will be protected adequately or whether they may be subjected to ethically questionable procedures. For additional information, refer to the "NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications" which is included on the CD.

**Data Safety Monitoring Plan:** If a data and safety monitoring plan is required, indicate if it is adequate.

**Inclusion of Women, Children, and Minorities Plans:** Determine if an appropriate balance of gender and minority representation in the study population will be sought, if this is scientifically acceptable, and justify the gender and minority codes to be assigned. Determine whether children (**individuals under 21 years of age**) have been included in the research and if their inclusion or exclusion has been explained adequately to justify the code to be assigned.

**Vertebrate Animal Welfare:** If animals are to be used in the project, discuss if their use is justified and if they will be given proper care and humane treatment so that they will not suffer unnecessary discomfort, pain, or injury. The five items described under Section F of the PHS Form 398 research grant application instructions should have been addressed by the candidate. This includes (a) a detailed description of the use of animals in the proposed research including the identification of the species, strains, ages, sex, and numbers of animals required; (b) the rationale for using animals and the appropriateness of the species and numbers of animals to be used for the proposed research; (c) a complete description of the veterinary care of the animals being used; (d) an assurance that discomfort, distress, pain, and injury to animals will be limited to that which is unavoidable in the conduct of scientifically sound research and that analgesic, anesthetic, and tranquilizing drugs will be employed where appropriate to minimize discomfort, distress, pain, and injury; and (e) a description of any euthanasia method to be applied. Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

**Biohazards:** Describe any potentially hazardous materials and procedures and whether the protection to be provided will be adequate.

**Budget:** The reasonableness of the proposed budget and the requested period of support in relation to the proposed research transition award program. The candidate's salary must be based on a full time, 12 month appointment. During the mentored K99 phase the total support may not exceed \$90,000 per year. The total support for the independent investigator R00 phase may not exceed \$249,000 per year. This amount includes salary, fringe benefits, research support allowance and applicable F&A costs. The priority score should not be affected by the evaluation of the budget.

**Model Organism Sharing Plan:** All NIH applications that plan to produce new, genetically modified variants of model organisms and related resources are expected to include a sharing plan or to state why such sharing is restricted or not possible. Please comment on the adequacy of the sharing plan, taking into consideration the organism, the timeline, and the applicant's decision to distribute the resource or deposit it in a repository. Your assessment of the sharing plan will not be factored into the priority score of the application. Your comments will be captured in an administrative note.