

K99/R00 GUIDE FOR REVIEWERS

NIH Pathway to Independence (PI) Award

EXECUTIVE SUMMARY

NIH Pathway to Independence (PI) Award (K99/R00)

- Supported by NCI, NEI, NHLBI, NHGRI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDCD, NIDCR, NIDDK, NIDA, NIEHS, NIGMS, NIMH, NINDS, NINR, NLM, FIC, NCCAM, NCMHD, and NCRR
- Provides opportunity for promising postdoctoral scientists to receive both mentored and independent research support from the same award
- Initial phase provides 1-2 years of mentored support for highly promising, postdoctoral research scientists followed by up to 3 years of independent support contingent on securing an independent research position
- Candidates should have less than five years of postdoctoral training at the time of submission.
- Award recipients will be expected to compete successfully for independent R01 support from the NIH during the career transition award period.

Visit parent FOA at <http://grants2.nih.gov/grants/guide/pa-files/PA-09-036.html>.

INSTRUCTIONS FOR WRITTEN CRITIQUE AND PRELIMINARY SCORES

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

The overall goal of NIH-supported research career development programs is to help ensure that a diverse pool of highly trained scientists are available in adequate numbers and in appropriate research areas to address the Nation's biomedical, behavioral, and clinical research needs.

The Scientific Review Officer (SRO), and in particular the funding opportunity announcement (FOA) for each specific career development award, provide additional guidance for each core and additional review criterion. **Reviewers must become fully familiar with the detailed review criteria provided in each FOA before assessing any K award application in response to that announcement.**

Written Critiques

- The format of the critiques should follow the structured template provided for each mechanism, which can be downloaded from the Internet Assisted Review (IAR) site and found on the CD.
- Each core criterion and additional review criteria are represented in the reviewer template and should be commented on, listing the strengths and weaknesses of each in a bulleted form.
- The goal is to provide the maximum and most pertinent information in a concise manner.
- After considering all of the review criteria, briefly summarize the strengths and weaknesses of the application in the Overall Impact section of the template.
- Assigned reviewers must upload critiques before entering an overall impact/priority score.
- Criterion scores should be entered in IAR before the review meeting.
- Assigned reviewers may submit criterion scores only after their critiques have been uploaded. At the SRO's discretion, discussants who are assigned to the application and SRG members who are not assigned to the application may submit criterion scores without critiques.
- The criterion scores may be changed during FINAL SCORING on your electronic or paper Voter/Scoring Sheet, or following the review meeting during the EDIT phase.
- Please do not write your criterion scores on the critique template.

Preliminary Scores

- Each core review criterion should be given a score using the nine-point rating scale in accordance with the new Enhanced Peer Review Criteria.
- The criterion scores for the applications should be entered in the meeting Internet Assisted Review (IAR) site in NIH Commons before the review meeting using the same page that is used for submitting the preliminary impact/priority score and critique.
- The criterion scores may be changed following the review meeting during the EDIT phase.
- In the READ phase of the meeting reviewers may submit their scores and critiques, but may not edit them. Core criterion scores can be submitted only after your critique had been uploaded into IAR.
- The criterion scores will appear in the summary statement as part of your critique.

Core Review Criteria

Reviewers are asked to consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. These individual criterion

scores are considered part of your critique and will not be discussed at the review meeting. They may be changed in the EDIT phase in IAR.

Candidate

- What is the candidate's record of research productivity, including the quality of peer-reviewed scientific publications?
- What is the quality of the candidate's pre- and postdoctoral research training experience, including expertise gained?
- Based on the postdoctoral candidate's experience, track record and prior research training, what is the candidate's potential to become an outstanding, successful independent investigator who will contribute significantly to his/her chosen field of biomedical-related research?
- To what extent does the application provide evidence of the candidate's research creativity, and does this evidence suggest that the candidate has the potential to develop a creative, independent research program?
- Evaluate the letters of reference. Are there letters from at least three well-established scientists? Relative to the above review criteria, how do these scientists evaluate the candidate? Do the letters provide strong evidence that the candidate has a high potential to become an independent investigator?
- 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?

Career Development Plan

- Are the content and duration of the proposed didactic and research components of the career development plan appropriate for the candidate's current stage of scientific and professional development and proposed research career goals?
- Is the proposed career development plan likely to contribute substantially to the scientific and professional development of the candidate including his/her successful transition to independence?
- For individuals currently supported by research training programs, how does the proposed career development plan enhance or augment the applicant's training to date? Is the additional proposed training needed and appropriate for the proposed research plan and the applicant's future career plans?
- 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?

Research Plan

- 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?

Mentor(s), Consultant(s), Collaborator(s):

- To what extent does the mentor have a strong track record in training future independent researchers?
- To what extent are the mentor's research qualifications and experience, scientific stature, and mentoring track record appropriate for the applicant's career development needs?
- Does the mentor(s) adequately address the above review criteria including the candidate's potential as well as his/her strengths and areas needing improvement?
- 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?

Environment and Institutional Commitment to the Candidate

- To what extent does the institution provide a high quality environment for the candidate's development? To what extent are the research facilities and educational opportunities, including collaborating faculty, adequate and appropriate for the

candidate's research and career development goals during the K99 phase of the award?

- 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?
- Is there adequate assurance that the required (minimum of 75%) 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?

Additional Review Criteria

As applicable for the project proposed, reviewers are asked to consider the following additional items in the determination of scientific and technical merit, but not to give separate scores for these items.

Training in the Responsible Conduct of Research

Does the application include appropriate and adequate documentation in prior instruction, or plans for training in the responsible conduct of research?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 (as described in [Human Subjects Protection and Inclusion](#)), reviewers are asked to evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. If all of the criteria are adequately addressed, and there are no concerns, write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable. If one or more criteria are inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRO immediately to determine if the application should be withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt, evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. If the claimed exemption is not justified, indicate "Unacceptable", and, if unacceptable, explain why it is unacceptable.

For additional information to assist you in making these determinations, please refer to http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf and http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Worksheet.pdf.

Inclusion of Women, Minorities and Children

When the proposed project involves clinical research, reviewers are asked to evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them. Each project involving human subjects must be assigned a code using the categories "1" to "5" below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (no U.S. subjects). If the study uses both then use codes 1 thru 4. Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded "U".

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate.

For additional information to assist you in making these determinations, please refer to http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf and http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Worksheet.pdf.

<u>Gender Inclusion Code</u>	<u>Minority Inclusion Code</u>	<u>Children Inclusion Code</u>
G1 = Both genders	M1 = Minority and nonminority	C1 = Children and adults
G2 = Only women	M2 = Only minority	C2 = Only children
G3 = Only men	M3 = Only nonminority	C3 = No children included
G4 = Gender composition unknown	M4 = Minority composition unknown	C4 = Representation of children unknown
	M5 = Only foreign subjects	

Vertebrate Animals

Reviewers are asked to evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

For additional information to assist you in determining if the Vertebrate Animals section is "Acceptable" or "Unacceptable", please refer to:
<http://grants.nih.gov/grants/olaw/VASchecklist.pdf>.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission Applications

When reviewing a Resubmission application (formerly called an amended application), please evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal Applications

This award may not be renewed.

Overall Impact

Reviewers will provide an overall impact critique to reflect their assessment of the likelihood for candidate to maintain a strong research program, taking into consideration all of the criteria above (as appropriate for the application) in determining the overall impact/priority score. Your critique should indicate the most significant strengths and weaknesses.

Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

Budget and Period Support

Is the proposed budget and period of support appropriate in relation to the proposed research and the career development needs of the candidate?

Select Agents

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s). Select agent information is available via http://grants.nih.gov/grants/policy/select_agent/.

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable:

1) Sharing Model Organisms

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>). All NIH grant applications are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. Unlike the NIH Data Sharing Policy, the submission of a model organism sharing plan is NOT subject to a cost threshold of \$500,000 or more in direct costs in any one year, and is expected to be included in all applications where the development of model organisms is anticipated.

2) Genome Wide Association Studies

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-013.html>). Applications and proposals that include GWAS, regardless of the requested costs, are expected to include as part of the Research Plan either a plan for submission of GWAS data to the NIH designated data repository or an appropriate explanation for why submission to the repository will not be possible.

Additional Comments to the Applicant

Reviewers may provide guidance to the applicant or recommend against resubmission without fundamental revision.