K23 GUIDE FOR REVIEWERS

Mentored Patient-Oriented Research Career Development Award

EXECUTIVE SUMMARY

Mentored Patient-Oriented Research Career Development Award (K23)

- Supported by NCI, NEI, NHLBI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDCD, NIDCR, NIDDK, NIDA, NIEHS, NIGMS, NIMH, NINDS, NINR, NCCAM, and ODS
- Supports the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research
- Clinically trained professionals or individuals with a clinical degree who are interested in further career development in biomedical research that is not patient-oriented should refer to the Mentored Clinical Scientist Career Development Award (K08)

Visit parent FOA at http://grants2.nih.gov/grants/guide/pa-files/PA-09-043.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

- Does the candidate have the potential to develop as an independent and productive researcher focusing on patient-oriented research?
- Is the candidate's academic, clinical, and (if relevant) research record of high quality?

- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator focusing on patient-oriented research?
- Do the letters of reference from at least three well-established scientists address the above review criteria, and do they demonstrate evidence that the candidate has a high potential for becoming an independent investigator?

Career Development Plan

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence?
- Is the candidate's prior training and research experience appropriate for this award?
- Are the goals and scope of the plan when considered in the context of prior training/research experience and the stated training and research objectives, appropriate?
- Are the content and duration of the proposed didactic research activities during the proposed award period clearly stated and appropriate?
- Are there adequate plans for evaluating the candidate's research and career development progress?

Research Plan

- Are the proposed research question, design, and methodology of significant scientific and technical merit?
- Is the research plan relevant to the candidate's research career objectives focusing on patient-oriented research?
- Is the plan for developing/enhancing the candidate's research skills appropriate and adequate?
- If applicable, are there adequate plans for data and safety monitoring of clinical trials?

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

- Are the mentor's research qualifications in the area of the proposed patient-oriented research appropriate?
- Do the mentor(s) adequately address the above review criteria including the candidate's potential and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is the mentor's description of the elements of the research career development activities, including formal course work adequate?
- Is there evidence of the mentor's, consultant's, collaborator's previous experience in fostering the development of independent investigators?

- Is there evidence of previous research productivity and peer-reviewed support focusing on patient-oriented research?
- Is there active/pending support for the proposed research project appropriate and adequate?
- Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?

Environment and Institutional Commitment to the Candidate

- Is there clear commitment of the sponsoring institution to ensure that a minimum of 75% of the candidate's effort will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?
- Is the institutional commitment to the career development of the candidate appropriately strong?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for scientific and professional development of the candidate of high quality?
- Is there assurance that the institution intends the candidate to be an integral part of its research program?

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.

Gender Inclusion Code

- **G1 =** Both genders
- **G2 =** Only women
- **G3 =** Only men
- **G4 =** Gender composition unknown

Minority Inclusion Code

- **M1 =** Minority and nonminority
- **M2 =** Only minority
- **M3 =** Only nonminority
- **M4 =** Minority composition unknown
- **M5 =** Only foreign subjects

Children Inclusion Code

- **C1** = Children and adults
- **C2** = Only children
- **C3** = No children included
- **C4 =** Representation of children unknown

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_Inclu

sion.pdf and
http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Worksheet.pdf.

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/VAChecklist.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.