GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON MENTORED PATIENT-ORIENTED RESEARCH CAREER DEVELOPMENT AWARD (K23)APPLICATIONS

PA-05-143

Complete details at: http://grants.nih.gov/grants/guide/pa-files/PA-05-143.html

The purpose of the Mentored Patient-oriented Research Career Development Award (K23) is to support the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research. This mechanism provides support for three to five years of supervised study and research for clinically trained professionals who have the potential to develop into productive, clinical investigators focusing on patient-oriented research.

Applicants must justify the need for a period of mentored research experience and provide a convincing case that the proposed period of support and career development plan will substantially enhance their careers as independent investigators in patient-oriented research.

For the purposes of this award, patient-oriented research is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator directly interacts with human subjects. This area of research includes: 1) mechanisms of human disease; 2) therapeutic interventions; 3) clinical trials; and 4) the development of new technologies.

The objectives of the Mentored Patient-Oriented Research Career Development Award (K23) are to:
• encourage research-oriented clinicians to develop independent research skills and gain experience in advanced methods and experimental approaches needed to conduct patient-oriented research.
• increase the pool of clinical researchers who can conduct patient-oriented studies, capitalizing on the discoveries of biomedical research and translating them to clinical settings.
• support the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research.

Review Criteria
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.

- Candidate
- Career Development Plan
- Research Plan
- Training in the Responsible Conduct of Research
- Appropriateness of and statements by Mentor, Co-Mentor(s), Consultant(s), and Collaborator(s)
- Environment and Institutional Commitment to the Candidate

For revised applications, also comment briefly on whether the application is improved, the same, or worse. In addition, provide a one-sentence summary of your evaluation at the end of each section. After considering all of the review criteria, briefly summarize the

strengths and weaknesses of the application and recommend an overall level of merit in a section titled Summary and Recommendation (see below). Please note that your comments will be used essentially unedited in the final summary statement sent to the candidate.

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

- Quality of the candidate's academic and clinical record.
- Potential to develop as an independent and productive clinical researcher focusing on patient-oriented research.
- Commitment to meeting the program objectives to become an independent researcher in patient-oriented research.
- Quality of the letters of reference from three well-established scientists evaluating the candidate's potential to pursue an independent career in patient-orientedresearch.
- Letters of reference submitted by mentor(s)/co-mentor(s) will be considered independent of and in addition to the three required reference letters.

Career Development Plan

Likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence, based on:

- The candidate's prior training and research experience.
- Appropriateness of the goals and scope of the plan when considered in the context of prior training/research experience and the stated training and research objectives.
- Appropriateness and clarity of the content and duration of the proposed didactic research activities during the proposed award period.
- Plans for evaluating the candidate's research and career development progress.
- Documentation of commitment to devote the required minimum of 75% effort to the career development award, and appropriateness of the proposed professional responsibilities/activities (including other research projects) beyond the minimum required 75% effort commitment to the K23 award for ensuring career progression to independent investigator status in patient-oriented research.

Research Plan

Reviewers recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced investigator. Nevertheless, a fundamentally sound research plan must be provided. For candidates who require substantial didactic training as part of their program, the research plan may cover less than the full period of the award.

- Degree of relevance of the research plan to developing an independent research program focused on patient-oriented research.
- Usefulness of the research plan as a vehicle for enhancing existing research skills as described in the career development plan.
- Scientific and technical merit of the research question, design and methodology judged in the context of the candidate's previous training and experience.

Training in the Responsible Conduct of Research

- Quality and appropriateness of the proposed training in responsible conduct of research.

Statements by 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 previous experience in fostering the development of independent investigators in patient-oriented research.
- Quality and extent of proposed role(s) in providing guidance and advice to the candidate.
- History of research productivity and peer-reviewed support.
- Adequacy of active/pending support for the proposed research project.
- Strength of the mentor's statement.
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Environment and Institutional Commitment

- Clear commitment of the institution to ensure that a minimum of 75% 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 in patient-oriented research including clinical responsibilities.
- Strength of the institutional commitment to the career development of the candidate.
- Adequacy of research facilities and training opportunities, including faculty capable of productive collaboration with the candidate.
- Quality and relevance of the environment for the scientific and professional development of the candidate, and
- Assurance that the institution intends for the candidate to be an integral part of its research program.

Summary and Recommendation

In one paragraph, briefly summarize the most important points of the Critique, addressing the strengths and weaknesses of the application in terms of the six review criteria. An application does not need to be strong in all categories to receive a good rating. Each scored application will receive a numerical rating that will reflect your opinion of its merit. The numerical rating is based on a scale from 1.0 for the most meritorious to 5.0 for the least meritorious with increments of 0.1 unit. Reviewers should score the "average" application they customarily review in their Scientific Review Group with a score of 3.0. This practice is designed to have 3.0 be the median.

Additional Review Criteria:
In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score and should be addressed in the critique.

Protection of Human Subjects from Research Risks: Evaluate the application with reference to the following criteria: risk to subjects, adequacy of protection against risks, potential benefit to the subjects and to others, importance of the knowledge to be gained. (If the applicant fails to address **all** of these elements, notify the SRA immediately to determine

if the application should be withdrawn.) 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. If the application indicates that the proposed human subjects research is exempt from coverage by the regulations, determine if adequate justification is provided. If the claimed exemption is not justified, indicate "Unacceptable" and explain why you reached this conclusion. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRA 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.

Inclusion of Women Plan:
Inclusion of Minorities Plan:
Inclusion of Children Plan:
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".

Category	Gender (G)	Minority (M)	Children (C)
1	Both Genders	Minority & non-minority	Children & adults
2	Only Women	Only minority	Only children
3	Only Men	Only non-minority	No children included
4	Gender unknown	Minority representation unknown	Representation of children unknown
5		Only Foreign Subjects	

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.

Vertebrate Animals: 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: Note any materials or procedures that are potentially hazardous to research personnel and indicate whether the protection proposed will be adequate.

OTHER CONSIDERATIONS: These comments are useful to NIH but should not influence your overall score.

Administrative Note: (e.g., There is potential overcommitment and/or scientific overlap with other existing grants and/or pending applications.)

Data Sharing Plan: Applications requesting more than $500,000 direct costs in any year of the proposed research are expected to include a data sharing plan in their application. Certain Program Announcements may request a data sharing plan for all applications regardless of the amount of direct costs. Assess the reasonableness of the data sharing plan or the rationale for not sharing research data.

Model Organism Sharing Plan: The NIH policy on sharing of model organisms for biomedical research was announced in the May 7, 2004 issue of the NIH Guide (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html). Starting with the October 1, 2004 receipt date, all new and competing-renewal NIH grant applications that plan to produce model organisms will be expected to include a sharing plan. 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.

Budget: Evaluate the direct costs only. Do not focus on detail. For all years, determine whether all categories of the budget are appropriate and justified. Provide a rationale for each suggested modification in amount or duration of support.

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