

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

PA-00-004

Complete details at: <http://grants1.nih.gov/grants/guide/pa-files/PA-00-004.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.

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) include:

- Encouraging research-oriented clinicians to develop independent research skills and gain experience in advanced methods and experimental approaches needed to conduct patient-oriented research
- Increasing the pool of clinical researchers who can conduct patient-oriented studies, capitalizing on the discoveries of biomedical research and translating them to clinical settings

CRITIQUE

Each major review element within the Mentored Patient-oriented Research Career Development Award application (Candidate, Career Development Plan, Training in the Responsible Conduct of Research, Research Plan, Mentor/Co-mentor, Environment and Institutional Commitment, and Budget) should be commented on in a separate section of your written critique. 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 Recommendations (see below). Please note that your comments will be used essentially unedited in the final summary statement sent to the candidate.

The following review criteria will be applied:

Candidate

- Quality of the candidate's academic and clinical record

- Potential to develop as an independent clinical researcher focusing on patient-oriented research
- Commitment to a career in patient-oriented research

Career Development Plan

- Likelihood that the career development plan will contribute substantially to the scientific development of the candidate
- Appropriateness of the content and duration of the proposed didactic and research phases of the award
- Consistency of the career development plan with the candidate's career goals and prior research experience

Training in the Responsible Conduct of Research

- Quality of the proposed training in responsible conduct of 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.

- Scientific and technical merit of the research question, design and methodology
- Relevance of the proposed research to the candidate's career objectives
- Appropriateness of the research plan to the stage of research development and as a vehicle for developing the research skills as described in the career development plan
- Adequacy of the plan's attention to gender and minority issues associated with projects involving human subjects
- Adequacy of plans for including children, as appropriate, for the scientific goals of the research, or justification for exclusion

Mentor/Co-Mentor

- Appropriateness of mentor(s) research qualifications in the area of this application
- Quality and extent of mentor's proposed role in providing guidance and advice to the candidate
- Previous experience in fostering the development of more junior researchers
- History of research productivity and support
- Adequacy of support for the proposed research project

Environment and Institutional Commitment

- Adequacy of research facilities and the availability of appropriate educational opportunities

- Quality and relevance of the environment for scientific and professional development of the candidate
- Applicant institution's commitment to the scientific development of the candidate and assurances that the institution intends the candidate to be an integral part of its research program
- Applicant institution's commitment to an appropriate balance of research and clinical responsibilities including the commitment of 75 percent of the candidate's effort to research and research related activities.

Budget

- Justification of the requested budget in relation to career development goals and research aims

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.

OTHER CONSIDERATIONS

Foreign Training: In a separate section, describe the scientific advantages of the proposed training in a foreign country and compare it to relevant training opportunities available in this country. Comment on any special talents, resources, populations, or environmental conditions that are not readily available in the United States or that augment existing resources. This consideration should not be factored into your overall recommendation and rating.

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 withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

Gender, Minority And Children Subjects: 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 the "Research Plan" section of the critique, and should be factored into the score as appropriate.

Animal Welfare: 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.

Further information about NIH research training and career development opportunities can be found at <http://grants.nih.gov/training>