

GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON MENTORED RESEARCH SCIENTIST DEVELOPMENT AWARD (K01) APPLICATIONS

PA NUMBER: PA-00-019

Complete details at: <http://grants.nih.gov/grants/guide/pa-files/PA-00-019.html>

The Mentored Research Scientist Development Award (K01) provides support for intensive, supervised career development experiences in one of the biomedical, behavioral, or clinical sciences. The goal of the award is to develop skills that will translate into research independence by the end of the award period.

General considerations when reviewing Mentored Research Scientist Development Award applications:

- The candidate must have a research or a health-professional doctorate or its equivalent, and must have demonstrated the capacity or potential for highly productive independent research in the period after the doctorate.
- The candidate must identify a mentor with extensive research experience.
- The candidate must be willing to spend a minimum of 75 percent of full-time professional effort conducting research and research career development during the entire award period.
- The candidate must clearly describe the need for intensive research supervision for a period lasting three, four, or five years leading to research independence.
- The candidate must provide a plan for achieving independent research support by the end of the award period.

Note: Although most of the NIH Institutes and Centers (ICs) use K01 awards to support career development experiences that lead to independence, characteristics of ideal candidates may vary. For example, some of the ICs reserve this award for individuals who propose to train in a completely new field or for individuals who have had a hiatus in their careers because of illness or pressing family circumstances. Other ICs reserve the K01 for faculty from underrepresented groups or faculty at minority serving institutions who may want to enhance their research skills and knowledge through a period of supervised training at a research center. Reviewers are strongly encouraged to contact their study section's Scientific Review Administrator and discuss any special review considerations for K01 applications they are preparing to review.

CRITIQUE

Each major review element within the Mentored Research Scientist Development Award application (Candidate, Career Development Plan, 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 should be considered when writing your critique:

Candidate

- Research, academic and (if relevant) clinical record
- Potential to develop as an independent researcher
- Commitment to a research career

Career Development Plan

- Appropriateness of the content, the phrasing, and the proposed duration of the career development plan for achieving scientific independence
- Consistency of the career development plan with the candidate's career goals
- Likelihood that the plan will contribute substantially to the achievement of scientific independence
- Quality of the proposed training in responsible conduct of research

Research Plan

Reviewers should focus on the overall soundness of the research plan while considering the applicant's prior research experience in judging the level of detail provided.

- 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 described in the career development plan
- Adequacy of the plan's attention to children, gender and minority issues when human subjects are involved

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 researchers
- History of research productivity
- Adequacy of support for the proposed research project

Environment and Institutional Commitment

- Adequacy of research facilities and training 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 level of 75 percent effort proposed by the candidate.

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 be 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>