GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON MENTORED CLINICAL SCIENTIST DEVELOPMENT AWARD (K08) APPLICATIONS

PA NUMBER: PA-00-003

Complete details at: http://grants.nih.gov/grants/guide/pa-files/PA-00-003.html

The purpose of the Mentored Clinical Scientist Development Award (K08) is to support the development of outstanding clinician research scientists. This mechanism provides specialized study for individuals with a health professional doctoral degree committed to a career in laboratory or field-based research. Candidates must have the potential to develop into independent investigators. The K08 supports a three, four, or five year period of supervised research experience that may integrate didactic studies with laboratory or clinically-based research. The proposed research must have intrinsic research importance as well as serving as a suitable vehicle for learning the methodology, theories, and conceptualizations necessary for a well trained independent researcher.

General Considerations when reviewing K08 applications:

- The candidate must have a clinical doctoral degree or its equivalent. Illustrative examples include, but are not limited to: M.D., D.D.S., D.M.D., D.O., D.C., O.D., N.D. (Doctor of Naturopathy), D.V.M. or Pharm.D. Individuals with the Ph.D. or other doctoral degrees in clinical disciplines such as clinical psychology, nursing, clinical genetics, speech-language pathology, audiology and rehabilitation are also eligible. Individuals holding the Ph.D. in a non-clinical discipline but are certified to perform clinical duties also might be eligible
- The candidate must be able to 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
- Some of the participating NIH institutes and centers require completion of postgraduate clinical training by the time of award
- Ineligible individuals include current and former principal investigators on NIH research project (R01), FIRST Awards (R29), comparable career development awards (K01, K07, K23), sub-projects of program project (P01) or center grants (P50), and the equivalent. Former principal investigators of NIH Small Grants (R03) or Exploratory/Developmental Grants (R21) remain eligible.
- Applications may be submitted, on behalf of candidates, by domestic, non-Federal organizations, public or private, such as medical, dental, or nursing schools or other institutions of higher education

CRITIQUE

Each major review element within the Mentored Clinical 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 will be applied:
(Note that different NIH Institutes and Centers may employ different or additional review criteria)

Candidate

- Quality of the candidate's academic and clinical record
- Potential to develop as an independent researcher
- Commitment to a research career

Career Development Plan

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

Research Plan

Reviewers recognize that applicants will have variable amounts of previous research experience. Those with limited research experience are less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced investigator. All applications must include a fundamentally sound research plan, but reviewers will consider 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 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 criteria, 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