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

PA NUMBER: PA-06-512

Complete details at: http://grants.nih.gov/grants/guide/pa-files/PA-06-512.html

The Mentored Clinical Scientist Research Career Development Award (K08) provides support and "protected time" to individuals with a clinical doctoral degree for an intensive, supervised research career development experience in the fields of biomedical and behavioral research, including translational research. Candidates must have the potential to develop into independent investigators. The K08 supports a three to five year period of supervised research experience that may integrate didactic studies with laboratory or clinically-based research. Applications must contain a career development plan as well as a research plan. The career development plan must justify the need for the requested period of support, be tailored to the prior research experience and career development needs of the candidate, and be designed to move the candidate from the mentored phase to the independent phase of their research career. 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 fulltime professional effort conducting research and research career development.
- Individuals are eligible for a K08 award if they have been, or currently are the PI of an NIH R03 or R21 grant or a PHS or non-Federal award that duplicates the provisions or research goals of an R03 or R21 grant. Individuals are NOT eligible if they: have pending an application for any other PHS career award (e.g., K01, K23, or another K08), an NIH institute-specific K22, or a Pathway to Independence Award (K99/R00); have been or are currently a PI on an NIH research grants (such as R01, R29, P01) or a subproject leader on a Program Project (P01) and Center Grant (P50), or a non-NIH equivalent to these grants/awards.
- 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, Training in the Responsible Conduct of Research, Mentor/Co-mentor, Environment and Institutional Commitment) 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

- Potential to develop as an independent and productive researcher;
- Quality of the candidate's academic, clinical, and (if relevant) research record;
- Commitment to meeting the program objectives to become an independent investigator in research;
- Quality of the letters of reference from three well-established scientists evaluating the candidate's potential to pursue an independent research career; and
- Quality of letters of reference submitted by mentor(s)/co-mentor(s) which 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:

- Appropriateness of the content, scope, phasing, and duration of the career development plan when considered in the context of prior training/research and the stated didactic and research objectives for achieving research independence; and
- Plans for monitoring and evaluating the candidate's research and career development progress.

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, addressing:

- Scientific and technical merit of the research question, design and methodology;
- Relevance of the plan to the candidate's research career objectives;

• Adequacy of the plan for developing/enhancing the candidate's research skills;
• Quality and appropriateness of the prior or proposed training in the responsible conduct of research; and
• If appropriate, adequacy of plans for data and safety monitoring of clinical trials.

Training in the Responsible Conduct of Research

• Quality and appropriateness of the proposed training or instruction in areas related to the responsible conduct of research.

Statements by Mentor/Co-Mentor(s), Consultant(s), and Collaborator(s)

• Appropriateness of mentor(s) research qualifications in the area of the proposed research;
• Quality and extent of mentor(s) proposed role in providing guidance and advice to the candidate;
• Previous experience in fostering the development of independent investigators;
• History of research productivity and peer-reviewed support;
• Adequacy of active/pending support for the proposed research project; and
• Strength of the mentor's statement.

Environment and Institutional Commitment to the Candidate

• Clear commitment of the sponsoring institution to ensure that a minimum of 75 % of the candidate's effort will be directed 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;
• 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 scientific and professional development of the candidate; and
• Assurance that the institution intends 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.

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

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