GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON MIDCAREER INVESTIGATOR AWARD IN PATIENT-ORIENTED RESEARCH (K24) APPLICATIONS

PA-00-005

Complete details at: http://grants1.nih.gov/grants/guide/pa-files/PA-00-005.html

The purpose of the Midcareer Investigator Award in Patient-Oriented Research (K24) is to provide support for clinicians to allow them protected time to devote to patient-oriented research and to act as mentors for beginning clinical investigators. The target candidates are outstanding clinical scientists who are actively engaged in patient-oriented research. Candidates are generally within 15 years of their specialty training. Candidates must be able to demonstrate the need for a period of intensive research focus as a means of enhancing their clinical research careers and must be committed to mentoring the next generation of patient-oriented researchers. The award is intended to further both the research and mentoring endeavors of outstanding patient-oriented investigators, to enable them to expand their potential for significant contributions to their field, and to act as mentors for beginning clinician researchers.

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.

Objectives of the Midcareer Investigator Award in Patient-Oriented Research (K24) include:

- Encouraging established, midcareer clinician scientists to devote more time to patient-oriented research and enhance their clinical research skills in order to conduct meritorious patient-oriented research and mentor beginning clinical investigators
- 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

This award enables candidates holding clinical doctoral degrees to undertake up to five years (a minimum of three years is required) of patient-oriented research. This period of support will further develop the candidate's research and mentoring skills by supporting additional protected time for patient-oriented research and service as a mentor and role model for beginning clinical researchers.

General considerations for reviewers:

- Candidates for this award must have a health-professional doctoral degree or its equivalent. Such degrees include but are not limited to the M.D., D.O., D.D.S., D.M.D., O.D., D.C., Pharm.D., N.D. (Doctor of Naturopathy), as well as doctorally

prepared nurses. In addition, individuals holding the Ph.D. degree may apply for the award if they normally perform clinical duties. This would include clinical psychologists, clinical geneticists, speech and language pathologists, and other doctoral level clinicians.

- Candidates must be patient-oriented researchers working in a research environment with a record of publications and successful competition for research support
- Candidates must have independent research support at the time of application for this program. This support could include NIH awards or awards from other sources.
- Candidates must also have a record of supervising junior clinical researchers
- Candidates must be able to demonstrate the need for protected time to advance their careers and mentoring activities
- Generally, candidates must have completed their specialty training within 15 years of submitting the application, but exceptions to this requirement can be made on a case-by-case basis. For example, an interruption in career progression due to family, military, or other personal circumstances might justify eligibility for candidates with more than 15 years of experience since the completion of clinical training
- Candidates must be willing to spend up to 50 percent effort (at least 25%) conducting patient-oriented research and mentoring. All programs should be carefully tailored to meet individual needs and capabilities of candidates.

CRITIQUE

Each major review element within the Midcareer Investigator Award in Patient-Oriented Research application (Candidate, Research Plan, Mentoring Plan, and 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:

Candidate

- Quality of the candidate's academic and clinical record, including capabilities and commitment to serve as a mentor
- Evidence of ongoing high quality patient-oriented research and the relationship of that research to this program
- Potential to conduct quality patient-oriented research
- Commitment to a continuing career in patient-oriented research

- Appropriateness of the content and duration of the proposed research program
- A record of monetary support for patient-oriented research

Research Plan

Although it is understood that K24 applications do not require the level of detail necessary in regular research grant applications, a fundamentally sound research plan must be provided. In general, less detail is expected with regard to research planned for the later years of the award, but the application should outline the general goals for these years.

- Appropriateness of the research plan as a vehicle for demonstrating skills and capabilities in patient-oriented research to prospective advisees
- Scientific and technical merit of the proposed research
- Relevance of the proposed research to the candidate's career objectives
- Availability of adequate resources to conduct the research program
- Demonstration that the proposed program and protected time will relieve the candidate from non-research patient care and administrative duties and allow him/her to devote additional time to patient-oriented research
- 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

Mentoring Plan

- Experience and potential to serve as a mentor
- Adequacy of the plans for mentoring or supervising beginning clinicians in patient-oriented research
- Appropriateness of the proposed level of effort committed to the mentoring component

Environment and Institutional Commitment

- 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
- 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 and others pursuing patient-oriented research
- Applicant institution's commitment to provide adequate protected time for conduct of the research and mentoring 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.

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