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

PA-04-107

Complete details at: http://grants.nih.gov/grants/guide/pa-files/PA-04-107.html

The purpose of the Midcareer Investigator Award in Patient-Oriented Research (K24) is to provide support for clinician investigators to allow them protected time to devote to patient-oriented research (POR) and to act as research mentors primarily for clinical residents, clinical fellows and/or junior clinical faculty. This award is primarily intended for clinician investigators who are at the Associate Professor level or are functioning at that rank in an academic setting or equivalent non-academic setting, and who have an established record of independent, peer-reviewed Federal or private research grant funding in POR. This award is intended to advance both the research and the mentoring endeavors of outstanding patient-oriented investigators. It is expected, for example, that investigators will obtain new or additional independent peer-reviewed funding as the PI for POR and establish and assume leadership roles in collaborative POR programs; and that there will be an increased effort and commitment to mentor beginning clinician investigators in POR to enhance the research productivity of the investigator and increase the pool of well-trained clinical researchers of the future.

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 specific objectives of the Midcareer Investigator Award in Patient-Oriented Research are to:

- encourage established, mid-career clinician scientists who are experienced in POR to devote more time to POR and enhance their clinical research skills in order to mentor new clinical investigators and to conduct meritorious patient-oriented research.
- increase the pool of clinical researchers who can conduct patient-oriented research, who will be able to successfully compete for peer-reviewed grants, and mentor the next generation of clinical investigators.

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 a doctoral
degree is in a clinical field and they usually perform clinical duties. This may include clinical psychologists, clinical geneticists, speech and language pathologists.

- Candidates should be at the Associate Professor level, or are functioning at that rank in an academic setting or equivalent non-academic setting and must have an established record of independent, peer-reviewed patient-oriented research grant funding and record of publications.
- This award is intended for individuals who are at a mid-career stage and have a record of supervising and mentoring patient oriented researchers.
- Candidates must be able to demonstrate the need for a period of intensive research focus as a means of enhancing their clinical research career and a need for protected time to enhance their mentoring activities
- Candidates must commit 25 to 50 percent effort to conducting patient-oriented research and mentoring.

CRITIQUE

In the written comments, reviewers will be asked to evaluate the following aspects of the application:

- Candidate
- Research Plan
- Mentoring Plan
- Progress Assessment (competing renewal applications only)
- Environment and Institutional Commitment to the Candidate

Each major review element 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 scientific review group will address and consider each of these criteria in assigning the application's overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to deserve a high priority score. The review criteria are listed in logical order, not in order of priority.

Candidate

- Evidence of ongoing high quality patient-oriented research and the relationship of that research to this program.
- Evidence of the candidate's capabilities and commitment to serve as a mentor for patient-oriented research.
- 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.
- Record of financial support for patient-oriented research.

Research Plan

Although it is understood that currently funded research described in K24 applications do not require the level of detail necessary in regular research grant applications, a fundamentally sound research plan must be provided. New research proposed in the K24 application that is not currently funded by a peer-reviewed grant should include a Statement of Hypothesis and Specific Aims; Background, Preliminary Studies and Aims. The application should outline the general goals for the later years and sufficient detail should be provided to permit evaluation of the scientific merit of the plan.

- Appropriateness of the research plan as a vehicle for demonstrating and developing skills and capabilities in patient-oriented research to prospective mentees.
- 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. This includes adequacy of plans for continued support of the research during the funding period of the grant.
- 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

- Adequacy of the plans for mentoring or supervising beginning clinicians in patient oriented research.
- Adequacy of plans to integrate appropriate clinical research curricula, such as those offered by available K30 programs at the institution, into the mentoring plans.
- Appropriateness of the proposed level of effort committed to the mentoring component.

Progress Assessment (Additional criteria for competing renewal applications)

- Extent to which the career, research and mentoring objectives of the previous award have been achieved.
- Justification of the need for an additional 3 to 5 years of support.
- Evidence of leadership in patient-oriented research such as through being principal investigator on independent peer-reviewed research grants and providing high quality mentorship.

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 continuing the scientific and professional development of the candidate and for others pursuing patient-oriented research;
- Applicant institution's commitment to provide adequate protected time for the candidate to conduct the research and mentoring program.
- Applicant institution's commitment to the career development in patient-oriented research of individuals mentored by the candidate.

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 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

Updated: 05/12/2006