

GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON INDEPENDENT SCIENTIST AWARD (K02) APPLICATIONS

PA NUMBER: PA-00-020

Complete details at: <http://grants.nih.gov/grants/guide/pa-files/PA-00-020.html>

The Independent Scientist Award (K02) provides up to five years of salary support for newly independent scientists who can demonstrate the need for a period of intensive research focus as a means of enhancing their research careers. This award is intended to foster the development of outstanding scientists and enable them to expand their potential to make significant contributions to their field of research.

General Considerations when reviewing K02 applications:

- Candidates must have a doctoral degree and independent, peer-reviewed research support at the time the award is made.
- Candidate must be willing to spend a minimum of 75 percent of full-time professional effort conducting research and research career development during the period of the award.
- Candidates must be able to demonstrate that the requested period of salary support and protected time will foster his/her career as a highly productive scientist in the indicated field of research.
- Scientists whose work is primarily theoretical may apply for this award in the absence of external research grant support.
- 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 Independent Scientist Award application (Candidate, Career Development Plan, Research Plan, Mentor, Training in the Responsible Conduct of Research, Institutional Environment and 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.

Candidate

- Capacity to carry out independent research
- Potential to become an outstanding scientist who will make significant contributions to the field
- Past and present research productivity as evidenced by contributions to the scientific literature, and success in obtaining independent funding.
- Ability to conceptualize and organize a long-term research approach
- Evidence of current independent, peer-reviewed, research support

- Level of training, experience, and competence commensurate with the purposes of the award.

Career Development Plan

- Likelihood that the award will contribute substantially to the continued scientific development and productivity of the candidate
- The extent to which the award will enable a candidate to devote full time (at least 75 percent effort) to research and related duties by release from teaching, administration, clinical work, and other responsibilities
- Consistency of the career development plan with the candidate's career goals
- Proposed collaboration with other active investigators and other opportunities for professional growth

Research Plan

- Quality of research plan and potential for advancing the field of study
- Scientific and technical merit of the proposed research plan
- Adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research.
- Plans for the recruitment and retention of subjects

Training in the Responsible Conduct of Research

- Quality of the proposed training or instruction in areas related to the responsible conduct of research.

Environment and Institutional Commitment

- Institutional commitment to the development of the candidate as an independent scientist and assurances that the candidate will be an integral part of its research and academic program
- Evidence that the candidate's full-time effort (at least 75 percent) will be set aside to pursue research and career development activities
- Strength of the institution's commitment to scientific research.

Budget

- Justification of budget requests in relation to career development goals and research aims and plans

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

Protection Of Human Subjects From Research Risks: If the application involves human subjects, 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 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 opportunities can be found at <http://grants.nih.gov/training>