

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

PA NUMBER: PA-06-527

Complete details at: <http://grants.nih.gov/grants/guide/pa-files/PA-06-527.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, 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; and
- 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;
- Consistency of the career development plan with the candidate's career goals;
- Quality and appropriateness of proposed collaboration with other active investigators and other opportunities for professional growth; and
- The extent to which the award will enable a candidate to devote full time (at least 75 percent effort) (or 9.0 calendar months) to research and related duties by release from teaching, administration, clinical work, and other responsibilities.

Research Plan

Many Institutes and Centers require the candidate to have an independent, peer reviewed research support at the time the K02 award is made (http://grants.nih.gov/grants/guide/contacts/pa-06-527_contacts.htm). In such instances, reviewers should not re-evaluate the research plan. Rather, the reviewers should evaluate how the research and career development plans together further the candidate's research career.

- Quality of research plan and potential for advancing the field of study;
- Scientific and technical merit of the proposed research plan;
- When applicable for the specific candidate and situation, letters from consultant(s) and collaborator(s) documenting their willingness to participate in the independent scientist award program and describing their roles; and
- 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 will also be evaluated.

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

- Commitment of the institution 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;
- Commitment of the institution to ensure 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; and
- Adequacy of research facilities and resources.

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.

ADDITIONAL CRITERIA

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 opportunities can be found at <http://grants.nih.gov/training>

Revised: 02/02/2005
Updated: 08/28/2006