

GUIDE FOR REVIEWERS' PRELIMINARY COMMENTS ON RUTH L. KIRSCHSTEIN NRSA AWARDS FOR INDIVIDUAL FELLOWSHIPS TO PROMOTE DIVERSITY IN HEALTH-RELATED RESEARCH (F31)

The program announcement associated with this F31 application is PA-07-106; it can be found at <http://grants.nih.gov/grants/guide/pa-files/PA-07-106.html>.

The goal of the Ruth L. Kirschstein National Research Service Awards for Individual Fellowships to Promote Diversity in Health-Related Research (F31) is to help ensure that highly trained, productive, and creative scientists will be available in adequate numbers and in appropriate research areas and fields to meet the Nation's health research needs. This award seeks to improve the diversity of the health-related workforce by supporting the training of predoctoral students from groups that have been shown to be underrepresented, such as individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds. Diversity eligibility criteria have been determined prior to review, and should not influence assessment of the scientific merit of these applications.

The goal of review is to identify those applicants who have the highest potential to develop into productive, independent scientists. Therefore, in preparing your comments, it is important to remember that the F31 program is a training award and not a research award. Major considerations in the review are the applicant's potential for a successful career and how the proposed training experience will help develop and realize that potential.

Each major element of the fellowship review (Candidate, Sponsor and Training Environment, Research Training Plan and Training Potential) should be commented on in a separate section of your written critique. For revised applications, comment briefly on how the application has addressed the previous critiques and whether the application is improved, the same, or worse. Your review should consist primarily of evaluative statements, avoiding excessive descriptive material (e.g., listing every school attended and every job held by the candidate and/or the sponsor). 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 Recommendation (see below).

Please note that your comments will be used essentially unedited in the final summary statement sent to the applicant.

REVIEW CRITERIA

CANDIDATE: Assess the applicant's potential for and commitment to a productive scientific career. Since the goal is to identify applicants who have the highest potential to develop into productive independent scientists, this element of review is critical to the overall score. When evaluating the applicant's potential, you may consider the following items where relevant:

- The extent and level of previous education, including undergraduate or graduate degree(s), the field, the date received or expected, academic performance, the mentor and the institution;
- Evidence of commitment to a career in research;

- Awards and honors, other relevant research experience, professional training, and publications;
- Reference letters, considering both the numerical rankings and the text of the letters (**Be sure to protect the confidentiality of the references**).

SPONSOR AND TRAINING ENVIRONMENT: Assess the following:

- The qualifications of the sponsor as a mentor, including training track record, and as a researcher, including successful competition for research support;
- Evidence of the sponsor's understanding of the applicant's research training needs and a demonstrated ability to assist in meeting these needs;
- The quality of the training environment including the institutional commitment to research training of scientists, the quality of the facilities and related resources (e.g. equipment, laboratory space, computer time, subject populations), and the availability of research support.
- The sponsor's training plan should be individually tailored to the applicant and should describe planned activities such as coursework, seminars, scientific conferences, and opportunities for interaction with other scientists. Training in career skills, such as grant writing, lecturing, and scientific presentations is encouraged.

RESEARCH TRAINING PLAN: Briefly evaluate the merit of the research proposal and the general approach, considering the applicant's research background and the respective contributions of the applicant and the sponsor in the development of the research proposal. The proposal must have scientific merit, but unlike a research grant proposal, it should be evaluated in the light of the applicant's previous training and career development. Therefore, avoid a detailed critique of technical aspects of the research, but check for flaws so severe that they cast doubt on the applicant's or the sponsor's scientific judgment and qualifications or on whether such flawed research can serve as an appropriate vehicle for the candidate's development. The emphasis here should be on potential of the training plan to provide the fellow with individualized supervised experiences that will develop the candidate's knowledge and research skills, and not on the likely significance or impact on the field of the proposed research. If the research proposal involves human subjects, include an evaluation of the plan to include representation of both males and females, children (individuals under the age of 21), and members of minority groups as it relates to the scientific goals of the research. Try to limit the written critique of the research training plan to a few paragraphs.

TRAINING POTENTIAL: Evaluate the value of the proposed fellowship experience as it relates to the candidate's needs in preparation for a career as an independent researcher and scientist.

SUMMARY AND RECOMMENDATION: Briefly summarize the strengths and weaknesses of the application and recommend an overall level of merit, weighting each of the review criteria as you feel appropriate. 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		

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.

Note: Sections on Vertebrate Animals, Human Subjects and Biohazards are to be included only when applicable. These sections are part of the scientific evaluation of the application and should enter into the final score.

OTHER CONSIDERATIONS: Comments on the three elements below should not be factored into the overall recommendation of score.

Training in the Responsible Conduct of Research: Every NRSA fellow must receive instruction in the responsible conduct of research (<http://grants.nih.gov/grants/guide/notice-files/not92-236.html>). Applications must include the sponsoring institution's plans to provide and the candidate's plans for obtaining instruction in the responsible conduct of research, including the rationale, subject matter, appropriateness, format, frequency and duration of instruction. The amount and nature of faculty participation must be described. **The plan will be discussed after the overall determination of merit, so that the review panel's evaluation of the plan will not be a factor in the determination of the priority score. The plan will be judged as acceptable or unacceptable. The acceptability of the plan will be described in an administrative note of the summary statement.** Regardless of the priority score, an application with an unacceptable plan will not be funded until the applicant provides a revised, acceptable plan. Staff in the NIH awarding component will judge the acceptability of the revised plan.

Budget (Length of Proposed Training Program): Fellowship budgets are fixed, and, therefore, no comment is needed. Consider instead whether or not the requested duration of the proposed training program is appropriate. Individuals may receive up to five years of aggregated Kirschstein-NRSA support at the predoctoral level. Training beyond this time limit may be possible by obtaining a waiver through the NIH awarding component.

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.

Further information about NIH research training opportunities can be found at <http://grants.nih.gov/training>.

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