GUIDE FOR REVIEWERS' PRELIMINARY COMMENTS ON RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARD SENIOR FELLOWSHIP APPLICATIONS (F33)

Note: The program announcement associated with this F33 application is PA-07-172. It can be found at http://grants.nih.gov/grants/guide/pa-files/PA-07-172.html.

The National Institutes of Health (NIH) awards Ruth L. Kirschstein NRSA senior fellowships (F33) to experienced scientists who wish to make major changes in the direction of their research careers or who wish to broaden their scientific background by acquiring new research capabilities. These awards will enable individuals with at least seven years of research experience beyond the doctorate, and who have progressed to the stage of independent investigator, to take time from regular professional responsibilities for the purpose of receiving training to increase their scientific capabilities. In most cases, this award is used to support sabbatical experiences for established independent scientists. This program is not designed for postdoctoral level investigators seeking to prove their research potential prior to independence. The proposed study must be full-time and must include level of research supervision and guidance appropriate to the applicant's background and career objectives. Senior fellowship support may be requested for a period of up to 2 years.

Please use the following guidelines when preparing written comments on senior fellowship applications assigned to you for review. Minimize descriptive and emphasize evaluative comments. Include the section heading titles and follow the order of this guide. For revised applications, comment briefly on how the application has addressed the previous critiques and 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 Recommendation (see below).

Your written reviews should not bear personal identifiers, because the reviews, essentially unaltered, will become part of the final summary statements sent to candidates.

REVIEW CRITERIA

CANDIDATE: Describe and evaluate the candidate's research competence through an assessment of academic background, pertinent awards and honors, research experience, professional training, publications, and references. Assess the candidate's continuing potential for important contributions to biomedical, behavioral, or clinical research.

SPONSOR AND TRAINING ENVIRONMENT: Assess the quality of the training environment and the qualifications of the sponsor as a mentor for the proposed research training experience.

RESEARCH TRAINING PROPOSAL: Briefly summarize the research proposal and evaluate its strengths and weaknesses, considering the quality and appropriateness of the research design and methods, as well as the significance of the problem to be addressed as it relates to the candidate's career plans.

TRAINING POTENTIAL: Evaluate the training value of the proposed fellowship experience as it relates to the candidate's training and career goals. Comment on whether it will enhance the candidate's capabilities as an independent researcher.

SUMMARY AND RECOMMENDATION: Provide an overall evaluation of the application and a preliminary recommendation of priority score rating. Assess the appropriateness of the years requested for accomplishing the research training and fully justifying any proposed change. 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: Consideration of the three elements below should not be factored into the overall recommendation or 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: The amount of the award for a senior fellowship will be determined individually at the time of award, based on the salary at the home institution.

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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