GUIDE FOR REVIEWERS' PRELIMINARY COMMENTS ON RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARD (NRSA) POSTDOCTORAL FELLOWSHIP APPLICATIONS (F32)

Note: The program announcement associated with this F32 application is PA-07-107. It can be found at http://grants.nih.gov/grants/guide/pa-files/PA-07-107.html.

The goal of the Ruth L. Kirschstein National Research Service Award (NRSA) Postdoctoral Fellowship (F32) Program is to help ensure that highly trained, productive, and creative scientists will be available to carry out the Nation's biomedical and behavioral research agenda. The goal of review is to identify those candidates who have the highest potential to develop into successful, independent scientists upon the completion of their training. Therefore, in preparing your comments, it is important to remember that the F32 program is a training award and not a research award. Major considerations in the review are the candidate's potential for a productive career, the candidate's need for the proposed training, and the degree to which the research training proposal, the sponsor, and the environment will satisfy those needs.

Each major element of the fellowship review (Candidate, Sponsor and Training Environment, Research Training Proposal, 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. 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).

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

REVIEW CRITERIA

CANDIDATE: Assess the candidate's potential to become an important contributor to biomedical or behavioral science. Since the goal is to identify candidates who have the highest potential to develop into productive independent scientists upon the completion of their training, this element of review is critical to the overall score. When evaluating the candidate'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;
- Dissertation topic(s) in one or two sentences;
- Previous postdoctoral research or clinical experience, including: the mentor, institution, topic, and dates;
- 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)**.

IMPORTANT NOTE: Candidates with clinical degrees (M.D., D.V.M., D.D.S., etc.) may have had little previous research experience but are eligible for postdoctoral fellowship support and may propose training that leads to a Ph.D. degree. The candidate's specific background should be considered in assessing the potential to develop into a productive scientist.

SPONSOR AND TRAINING ENVIRONMENT: Assess the qualifications of the sponsor including his or her research expertise and prior experience as a mentor. Also evaluate the degree to which the level of funding for the proposed project, the environment of the host laboratory, the proposed training program, and the institution will be conducive to successful postdoctoral training.

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 giving scientific presentations is encouraged.

RESEARCH TRAINING PROPOSAL: Briefly evaluate the merit of the research proposal and the general approach, considering the candidate's research background and the respective contributions of the candidate 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 candidate'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 candidate's or the sponsor's scientific judgment and qualifications. 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 proposal to two or three short paragraphs.

TRAINING POTENTIAL: Considering the candidate's qualifications and previous research experience, evaluate the proposed training experience as it relates to preparation for an independent research career. Candidates may choose to remain in a scientific area related to their previous work or shift to an entirely new area of research, but the proposed experience must augment the candidate's conceptual and/or experimental skills. The overall training potential should be considered in light of the requested period of fellowship support.

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 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 (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 three years of aggregated Kirschstein-NRSA support at the postdoctoral 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 the final recommendation and score.

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

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