GUIDE FOR REVIEWERS' PRELIMINARY COMMENTS ON RUTH L. KIRSCHSTEIN NRSA PREDOCTORAL M.D./PH.D. FELLOWSHIP APPLICATIONS (F30)

National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute on Deafness and Other Communication Disorders (NIDCD)
National Institute on Drug Abuse (NIDA)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of Mental Health (NIMH)
National Institute of Neurological Disorders and Stroke (NINDS)
Office of Dietary Supplements (ODS)

The program announcement associated with this specific fellowship application is PA-05-151; it can be found at http://grants.nih.gov/grants/guide/pa-files/PA-05-151.html

The purpose of the combined M.D./Ph.D. fellowships program is to help ensure that highly trained physician/scientists will be available in adequate numbers and in the appropriate research areas and fields to meet the Nation's research needs in areas relevant to the missions of the participating Institutes. In addition, this mechanism has the potential to train clinical investigators who wish to focus their research endeavors on patient-oriented studies. The applicant must be enrolled in an M.D./Ph.D. program at an approved medical school, accepted in a related scientific Ph.D. program, and supervised by a mentor in that scientific discipline when the application is submitted. The typical applicant will apply during the first year of medical school for funding to begin in the second year; however, applications may be submitted at any stage of medical school. For additional information on this type of award, including additional guidance on review criteria, reviewers are advised to consult the relevant program announcement on the CD-ROM.

The F30 award is similar to the F31 individual predoctoral fellowship in that the purpose is to provide support for research and research training to enhance the fellow's knowledge and skills, and therefore the review of an F30 application should be approached in similar manner to an F31 application. Each major element of the fellowship review (Candidate, Research Training Proposal, Sponsor and Training Environment, 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 candidate'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 physician 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

- 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**).

RESEARCH TRAINING PROPOSAL: 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. Thus, the proposed research training should have the potential to serve as a sound foundation that will lead the candidate to a productive research career in scientific areas related to the mission of one of the participating NIH Institutes.

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 physician-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 candidate and should describe planned activities such as coursework, seminars, scientific conferences and opportunities for interactions with other scientists. Training in career skills, such as grant-writing, lecturing, and giving scientific presentations is encouraged.

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 physician-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 and should enter into the final score.

OTHER CONSIDERATIONS: Consideration of the three elements topics below should not be factored into your 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 six 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 or rating.

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

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