F30 GUIDE FOR REVIEWERS

Ruth L. Kirschstein National Research Service Award (NRSA) Predoctoral M.D./Ph.D. Fellowship Applications

EXECUTIVE SUMMARY

Ruth L. Kirschstein NRSA Predoctoral M.D./Ph.D. Fellowship Applications (F30)

- Intended 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.
- Has the potential to train clinical investigators who wish to focus their research endeavors on patient-oriented studies.
- 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.
- 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.
- 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.

Visit the F30 program announcement PA-05-151 at http://grants1.nih.gov/grants/guide/pa-files/PA-05-151.html

INSTRUCTIONS FOR WRITTEN CRITIQUE AND PRELIMINARY SCORES

Please use the following guidelines when preparing written comments on F30 predoctoral M.D./Ph.D. fellowship applications assigned to you for review.

Written Critiques

- The format of the critiques should follow the structured template provided for each mechanism, which can be downloaded from the Internet Assisted Review (IAR) site and found on the CD.
- Each core criterion and additional review criteria are represented in the reviewer template and should be commented on, listing the strengths and weaknesses of each in a bulleted form.
- The goal is to provide the maximum and most pertinent information in a concise manner.

- After considering all of the review criteria, briefly summarize the strengths and weaknesses of the application in the Summary and Recommendation section of the template.
- Assigned reviewers must upload critiques before entering a summary and recommendation score.
- Criterion scores should be entered in IAR before the review meeting.
- Assigned reviewers may submit criterion scores only after their critiques have been uploaded. At the SRO's discretion, discussants who are assigned to the application and SRG members who are not assigned to the application may submit criterion scores without critiques.
- The criterion scores may be changed during FINAL SCORING on your electronic or paper Voter/Scoring Sheet, or following the review meeting during the EDIT phase.
- Please do not write your criterion scores on the critique template.

Preliminary Scores

- Each core review criterion should be given a score using the nine-point rating scale in accordance with the new Enhanced Peer Review Criteria.
- The criterion scores for the applications should be entered in the meeting Internet Assisted Review (IAR) site in NIH Commons before the review meeting using the same page that is used for submitting the preliminary summary and recommendation score and critique.
- The criterion scores may be changed following the review meeting during the EDIT phase.
- In the READ phase of the meeting reviewers may submit their scores and critiques, but may not edit them. Core criterion scores can be submitted only after your critique had been uploaded into IAR.
- The criterion scores will appear in the summary statement as part of your critique.

Review Criteria

Candidate

Assess the candidate's potential for and commitment to a productive scientific career. Because 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).

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.

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.

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.

Additional Review Criteria

As applicable for the project proposed, reviewers are asked to consider the following additional items in the determination of scientific and technical merit, but not to give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 (as described in Human Subjects Protection and Inclusion), reviewers are asked to evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation

according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. If all of the criteria are adequately addressed, and there are no concerns, select "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable. If one or more criteria are inadequately addressed, select "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern.

Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRO 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.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt, evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. If the claimed exemption is not justified, indicate “Unacceptable”, and, if unacceptable, explain why it is unacceptable.

If the project does not involve human subjects, select Not Applicable.

For additional information to assist you in making these determinations, please refer to http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf and http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Worksheet.pdf

Inclusion of Women, Minorities and Children

When the proposed project involves clinical research, reviewers are asked to evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

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".

Gender Inclusion Code	Minority Inclusion Code	Children Inclusion Code
G1 = Both genders	**M1 =** Minority and nonminority	**C1** = Children and adults
G2 = Only women	**M2 =** Only minority	**C2** = Only children
G3 = Only men	**M3 =** Only nonminority	**C3** = No children included
G4 = Gender composition unknown	**M4 =** Minority composition unknown	**C4 =** Representation of children unknown
	M5 = Only foreign subjects	

For additional information to assist you in making these determinations, please refer to http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf and http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Worksheet.pdf.

Vertebrate Animals

Reviewers are asked to evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

For additional information to assist you in determining if the Vertebrate Animals section is "Acceptable" or "Unacceptable", please refer to: http://grants.nih.gov/grants/olaw/VAChecklist.pdf.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission Applications

When reviewing a Resubmission application (formerly called an amended application), evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Summary and Recommendation

Remember that the F30 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.

Briefly summarize the strengths and weaknesses of the application and recommend an overall level of merit, weighing 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.

Additional Review Considerations

Consideration of the elements below should not be factored into the overall recommendation or score.

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 summary and recommendation score. The plan will be judged as acceptable or unacceptable. If unacceptable, it will be noted and described in an administrative note of the summary statement**.** Regardless of the summary and recommendation 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 and Period of Support

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

Evaluate 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.

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plan is reasonable.

Sharing Model Organisms

For many individual fellowships it is anticipated that plans for sharing model organisms would have already been reported to the NIH by the sponsor in his/her research application. When this has occurred, applicants will indicate so and include the appropriate grant number. However, if the development of a new model organism is anticipated, applicants will include a description of a specific plan for sharing and distributing unique model organism research resources or state appropriate reasons why such sharing is restricted or not possible (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html).

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.