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

The National Institutes of Health (NIH) awards 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. 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 FORMAT

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 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. For **revised** applications, comment briefly on whether the application is improved, the same, or worse.

OTHER CONSIDERATIONS

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISKS: If the application involves human subjects, 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 withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

GENDER, MINORITY AND CHILDREN SUBJECTS**:** 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	

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Research Proposal" in the major review criteria above, and should be factored into the score as appropriate.

ANIMAL WELFARE: 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.

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