Review Criteria for NIH Fellowships

This is the list of criteria given to study section members for review of NIH Predoctoral Fellows. Although this was given for an F31 study section, I’m sure that F30s are judged in essentially identical fashion. Completeness and level of detail matter. This is particularly true for the “training program.” Make sure you detail how the prelim/thesis committee is constituted and how often you meet with your committee; how often you meet with the mentor (and it better be > once per week) and/or co-mentor. What about seminar series and journal clubs? Where are you in the program? Have you passed your prelim? Note that not everything listed as a review criterion is actually asked for on the application. A good example is “biosafety.” So follow the directions, but also make sure that all the points below are covered. Let me know if you have any questions.

Jim Slauch

Applicant/Fellow

- The quality of the academic record and research experience of the applicant
- The applicant’s potential for independent contribution to scientific knowledge

Sponsor(s) and Training Environment

- The qualifications and caliber of the sponsor(s) as researcher(s), including successful competition for research support, and mentor(s), including track record in training, for the proposed research training experience
- Evidence of a match between the research interests of the applicant and the primary sponsor(s), including an understanding of the applicant’s research training needs and a demonstrated ability and commitment of the sponsor(s) to assist in meeting these needs
- The quality of the training environment including the institutional commitment to research training of predoctoral fellows and trainees, the quality and availability of facilities and related resources (e.g. equipment, laboratory space, computer time, subject populations), and the availability of research support
- If applicable, the quality and appropriateness of unique research training opportunities at a foreign site that are not available in the United States

Research Training Plan

- The merit of the scientific proposal
- The quality of the research training plan
- Scientific significance, originality, and feasibility of the proposed research
• The coherence and potential of the research training plan to provide the applicant with individualized and supervised experiences that will develop research skills needed in preparation for his/her research career
• Potential of the proposed research training to serve as a sound foundation that will lead the applicant to a productive career in scientific areas related to the mission of one of the participating Institutes

Training Potential

• The value of the proposed fellowship experience with respect to the applicant’s needs in preparation for a research doctoral degree

In addition to the above criteria, the following items may be considered in the determination of scientific merit and the priority score:

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in the section on Federal Citations, below).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see inclusion criteria in the sections on Federal Citations, below).

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described on page 1-26 of the PHS 416-1 fellowship application Part I instructions (rev. 10/2005) will be assessed (see http://grants.nih.gov/grants/forms.htm).

Biohazards: If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, the adequacy of the proposed protection will be assessed.

Additional Review Considerations

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 this 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 in
the summary statement. Regardless of the priority score, an application with an unacceptable plan will not be funded until the applicant provides an acceptable plan. Staff in the NIH awarding component will judge the acceptability of the revised plan.

This is the format of the review. It is somewhat redundant with the above information, but this is explicitly what is to be considered:

**THE APPLICANT'S PREPARATION FOR GRADUATE STUDY**, including his/her academic record (grades, GRE or MCAT scores, honor/awards); letters of recommendation; previous research experience (including any presentations or publications and pertinence of the prior experience to this proposal); and training and career goals. Any special qualifications or unusual circumstances should be noted.

**THE QUALITY OF THE TRAINING PROGRAM/INSTITUTION**, including the appropriateness of the program and requirements to the applicant's training/career goals; the applicant's rationale for choosing the program; how well students are advised and their progress monitored; and, in the case of M.D./Ph.D. programs, any special features to facilitate the integration of, and transition between, the graduate and medical components.

**THE PROPOSED RESEARCH** (if a thesis topic has been chosen), focusing on its merit and training potential, taking into consideration the applicant's training career goals; the significance and originality of the project and adequacy of the research plan and proposed methods; and the appropriateness of the relative contributions of the applicant and mentor in the preparation of the proposal. OR

**THE STATED RESEARCH INTERESTS OF THE APPLICANT** (for those who have not yet chosen a thesis topic), evaluated in terms of their appropriateness within the institutional setting and to the applicant's training/career goals. (Slauch Note: Applications that do not have a defined project and preliminary data are not competitive.)

**THE THESIS MENTOR** (if the applicant has chosen one), including the proposed mentor's qualifications and suitability to train the applicant based on the mentor's academic background, current position, research expertise, publication record, research support, and training experience. OR

**THE INTERIM SPONSOR** (if the applicant has not yet chosen a thesis advisor), including the appropriateness of the names sponsor in terms of guiding and monitoring the student's program/progress.

**OVERALL RECOMMENDATION** Indicate your overall level of enthusiasm (using the priority score guide) and recommend the length of support you feel is appropriate (provide a justification if different from the time requested).
**Human Subjects:** In applications with research proposals involving human subjects, consider the following:

**Are Human Subjects involved?** According to the new definition of human subjects, coded samples and data may not be considered human subjects if they meet the criteria of: a) the private information or specimens are not collected specifically for the proposed research through an interaction or intervention with living individuals, b) the investigator cannot ascertain the identity of the individual to whom the coded private information or specimens pertain.

**Exemptions Claimed:** Express any comments or concerns about the appropriateness of the exemption(s) claimed. It should be noted that Exemption 4 is rarely used, as applications that qualified for E-4 under the old guidelines (specimens or data sets) will qualify as no human subjects if they meet the two conditions cited above.

**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

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

**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.