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National Institutes of Health  
Office of Extramural Research

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## Definitions of Criteria and Considerations for F Critiques

Updated July 18, 2016

Standard criteria and considerations are shown below. Individual Funding Opportunity Announcements (FOAs) may have additional criteria and considerations.

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### Overall Impact/Merit

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the fellowship will enhance the applicant's potential for, and commitment to, an independent, productive scientific research career in a health-related field, in consideration of the scored and additional review criteria.

### Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

#### 1. Fellowship Applicant.

**F30.** Are the applicant's academic record and research experience of high quality? Are the applicant's interests consistent with a career as a physician-scientist or other clinician-scientist? Does the applicant have the potential to develop into an independent and productive contributor to biomedical, behavioral or clinical science as a physician-scientist or clinician-scientist? Does the applicant demonstrate commitment to a career as a physician-scientist or other clinician-scientist?

**F31, F32 and F33.** Are the applicant's academic record and research experience of high quality? Does the applicant have the potential to develop into an independent and productive researcher? Does the applicant demonstrate commitment to a research career in the future?

**F31 Diversity.** Are the applicant's academic record and research experience of high quality? Does the applicant have the potential to develop into an independent and productive researcher? Does the applicant demonstrate commitment to a research career in the future? For applicants in a dual-degree program only: Are the applicant's interests consistent with a career as a physician-scientist or other clinician-scientist? Does the applicant demonstrate commitment to a career as a physician-scientist or other clinician-scientist?

#### 2. Sponsors, Collaborators, and Consultants.

**All F30.** Are the sponsor(s)' research qualifications (including recent publications) and track record of mentoring individuals at a similar stage appropriate for the needs of the applicant? Is there evidence of a match between the research and clinical interests of the applicant and the sponsor(s)? Do the sponsor(s) demonstrate an understanding of the applicant's training needs as well as the ability and commitment to assist in meeting these needs? Is there evidence of adequate research funds to support the applicant's proposed research project and training for the duration of the research component of the fellowship? If a team of sponsors is proposed, is the team structure well justified for the mentored training plan, and are the roles of the individual members appropriate and clearly defined? Are the qualifications of any collaborator(s) and/or consultant(s), including their complementary expertise and previous experience in fostering the training of fellows, appropriate for the proposed project?

**F31, F32, F33.** Are the sponsor(s)' research qualifications (including recent publications) and track record of mentoring individuals at a similar stage appropriate for the needs of the applicant? Is there evidence of a match between the research and clinical interests (if applicable) of the applicant and the sponsor(s)? Do(es) the sponsor(s) demonstrate an understanding of the applicant's training needs as well as the ability and commitment to assist in meeting these needs? Is there evidence of adequate research funds to support the applicant's proposed research project and training for the duration of the research component of the fellowship? If a team of sponsors is proposed, is the team structure well justified for the mentored training plan, and are the roles of the individual members appropriate and clearly defined? Are the qualifications of any collaborator(s) and/or consultant(s), including their complementary expertise and previous experience in fostering the training of fellows, appropriate for the proposed project?

**Diversity F31.** Are the sponsor(s)' research qualifications (including recent publications) and track record of mentoring individuals at a similar stage appropriate for the needs of the applicant? Is there evidence of a match between the research and clinical interests of the applicant and the sponsor(s)? Do(es) the sponsor(s) demonstrate an understanding of the applicant's training needs as well as the ability and commitment to assist in meeting these needs? Is there evidence of adequate research funds to support the applicant's proposed research project and training for the duration of the research component of the fellowship? If a team of sponsors is proposed, is the team structure well justified for the mentored training plan, and are the roles of the individual members appropriate and clearly defined? Are the qualifications of any collaborator(s) and/or consultant(s), including their complementary expertise and previous experience in fostering the training of fellows, appropriate for the proposed project? For applicants in a dual-degree program only: Is there evidence of a match between the research and clinical interests of the applicant and the sponsor(s)?

#### 3. Research Training Plan.

**F30.** Is the proposed research project of high scientific quality, and is it well integrated with the proposed research training plan? Based on the sponsor's description of his/her active research program, is the applicant's proposed research project sufficiently distinct from the sponsor's funded research for the applicant's career stage? Is the research project consistent with the applicant's stage of research development? Is the training plan well-reasoned, and likely to

provide an effective, integrated research and clinical training experience and ease the transitions between the phases of the dual-degree program? Is the proposed time frame feasible to accomplish the proposed research and clinical training?

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#### 4. Training Potential.

**F30.** Are the proposed research project and research and clinical training plan likely to provide the applicant with an integrated perspective and appropriate skills for a physician-scientist or other clinical-scientist? Does the training plan take advantage of the applicant's strengths and address gaps in needed skills? Does the training plan document a clear need for, and value of, the proposed training? If applicable to the dual-degree program, are appropriate opportunities for electives, early and longitudinal clinical experiences, or other enhanced clinical training available to the applicant? Are appropriate opportunities available to ease the transition to clinical clerkships and for research electives during clinical training? Does the proposed integrated research and clinical training have the potential to serve as a sound foundation that will clearly enhance the applicant's ability to develop into a productive, independent physician-scientist or other clinician-scientist?

**F31.** Are the proposed research project and training plan likely to provide the applicant with the requisite individualized and mentored experiences in order to obtain appropriate skills for a research career? Does the training plan take advantage of the applicant's strengths, and address gaps in needed skills? Does the training plan document a clear need for, and value of, the proposed training? Does the proposed training have the potential to serve as a sound foundation that will clearly enhance the applicant's transition to the next career stage and enhance the applicant's ability to develop into a productive researcher?

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**F32, F33.** Are the proposed research project and training plan likely to provide the applicant with the requisite individualized and mentored experiences in order to obtain appropriate skills for a research career? Does the training plan take advantage of the applicant's strengths, and address gaps in needed skills? Does the training plan document a clear need for, and value of, the proposed training? Does the proposed training have the potential to serve as a sound foundation that will clearly enhance the applicant's ability to develop into a productive researcher?

#### 5. Institutional Environment & Commitment to Training.

**F30.** Are the research facilities, resources (e.g. equipment, laboratory space, computer time, subject populations, clinical training settings), and training opportunities (e.g. seminars, workshops, professional development opportunities) adequate and appropriate? Is the institutional environment for the applicant's scientific and clinical development of high quality? Are the facilities and resources appropriate to provide exposure to a research-oriented, clinical environment? Does the environment include individuals with similar training who will serve as role models for the applicant? Given the integrated nature of the training program, will appropriate advising be available to the applicant as he/she transitions between the research and clinical components of the integrated training program and to the next career stage? Is there appropriate institutional commitment to fostering the applicant's integrated training as a physician-scientist or other clinician-scientist? Does this commitment extend to support the applicant's research and training, if needed, for the duration of the proposed award?

**F31, F32.** Are the research facilities, resources (e.g. equipment, laboratory space, computer time, subject populations), and training opportunities (e.g. seminars, workshops, professional development opportunities) adequate and appropriate? Is the institutional environment for the applicant's scientific development of high quality? Is there appropriate institutional commitment to fostering the applicant's mentored training?

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**F33.** Are the research facilities, resources (e.g. equipment, laboratory space, computer time, subject populations), and training opportunities adequate and appropriate? Is the institutional environment for the scientific development of the applicant of high quality, and is there appropriate institutional commitment to fostering the applicant's mentored training?

## Additional Review Criteria

### 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, the committee will 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.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to [Guidelines for the Review of Human Subjects](#).

#### **Inclusion of Women, Minorities, and Children.**

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to [Guidelines for the Review of Inclusion in Clinical Research](#).

#### **Vertebrate Animals.**

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section](#).

#### **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.

#### **Resubmissions.**

For Resubmissions, the committee will 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.

#### **Renewals.**

For Renewals, the committee will consider the progress made in the last funding period.

#### **Revisions.**

Not Applicable.

## **Additional Review Considerations**

#### **All F's. Training in the Responsible Conduct of Research.**

All applications for support under this FOA must include a plan to fulfill NIH requirements for Instruction in the Responsible Conduct of Research (RCR). Taking into account the level of experience of the applicant, including any prior instruction or participation in RCR as appropriate for the applicant's career stage, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) Format – the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable); 2) Subject Matter – the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics; 3) Faculty Participation – the role of the sponsor(s) and other faculty involvement in the fellow's instruction; 4) Duration of Instruction – the number of contact hours of instruction (at least eight contact hours are required); and 5) Frequency of Instruction – instruction must occur during each career stage and at least once every four years. Plans and past record will be rated as **ACCEPTABLE** or **UNACCEPTABLE**, and the summary statement will provide the consensus rating of the review committee. See also: [NOT-OD-10-019](#).

#### **Applications from Foreign Organizations. (Not Applicable for F30)**

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

#### **Select Agent Research.**

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent (s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s). For more details, please see [Select Agents](#).

#### **Resource Sharing Plans.**

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) [Data Sharing Plan](#); 2) [Sharing Model Organisms](#); and 3) [Genome Wide Association Studies \(GWAS\)/Genomic Data Sharing](#) Plan.

#### **Budget and Period of Support.**

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. For more details please see [Budget Information](#).

#### **Additional Comments to the Applicant.**

Reviewers may provide guidance to the applicant or recommend against resubmission without fundamental revision.

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