

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the [NIH mission](#), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

- A fellowship application has a research project that is integrated with the training plan. The review will emphasize the applicant's potential for an independent, scientific research career, the applicant's need for the proposed training, and the degree to which the research project and training plan, the sponsor(s), and the environment will satisfy those needs.

Overall Impact/Merit

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the fellowship will enhance the candidate's potential for, and commitment to, an independent 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.

Fellowship Applicant

- 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 in biomedical, behavioral or clinical science?
- Does the applicant demonstrate commitment to a career as an independent researcher in the future?

Sponsors, Collaborators, and Consultants

- 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 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 research project and training for the duration 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 research project?

Research Training Plan

- Is the proposed research plan of high scientific quality, and is it well integrated with the applicant's training plan?
- Is the research project consistent with the applicant's stage of research development?
- Is the proposed time frame feasible to accomplish the proposed research training?
- 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?

Training Potential

- Do the proposed research project and training plan have the potential to provide the applicant with the requisite individualized and mentored experiences that will develop his/her knowledge and research and professional development skills?
- 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 research training have the potential to serve as a sound foundation that will facilitate the applicant's transition to the next career stage and enhance the applicant's ability to develop into an independent and productive research scientist?

Institutional Environment & Commitment to Training

- 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 toward his/her research career goals?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not 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, 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 the [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 the 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 the [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 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 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.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

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 of the review committee. See also: [NOT-OD-10-019](#).

Applications from Foreign Organizations

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).

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 \(GWAS\)](#).

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 training.

2. Review and Selection Process Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), in accordance with [NIH peer review policy and procedures](#), using the stated [review criteria](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a committee process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate NIH Institute or Center. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.