Department of Health and Human Services
Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov/))

Components of Participating Organizations

National Institute of Neurological Disorders and Stroke (NINDS (http://www.ninds.nih.gov))

Funding Opportunity Title

NINDS Ruth L. Kirschstein National Research Service Award (NRSA) for Training of Postdoctoral Fellows (F32 Clinical Trial Not Allowed)

Activity Code

F32 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=f32&Search.x=0&Search.y=0&Search_Type=Activity) Postdoctoral Individual National Research Service Award

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Announcement Type

Reissue of PAR-16-458 (https://grants.nih.gov/grants/guide/pa-files/par-16-458.html)

Related Notices

NOT-OD-19-109 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-109.html) , Requirement for ORCID iDs for Individuals Supported by Research Training, Fellowship, Research Education, and Career Development Awards Beginning in FY 2020.

Funding Opportunity Announcement (FOA) Number

PAR-20-021

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.853

Funding Opportunity Purpose

The purpose of this award is to support outstanding scientific training of highly promising postdoctoral candidates with outstanding mentors. Candidates are eligible to apply for support from this program from ~12 months prior to the start of the proposed postdoctoral position to within 12 months after starting in the proposed postdoctoral position. This NINDS F32 seeks to foster early, goal-directed planning and to encourage applications for bold and/or innovative projects by the candidate that have the potential for significant impact. Inclusion of preliminary data is strongly discouraged; rather, this F32 seeks innovative research ideas and thoughtful plans for training and mentorship that will facilitate the development of the postdoctoral fellow into an outstanding scientist. Applications are expected to incorporate strong training in quantitative reasoning and the quantitative principles of experimental design and analysis. Support by this program is limited to the first 3 years of a candidate's activity in a specific laboratory or research environment, so as to further encourage early, thoughtful planning and timely completion of "mentored training" within a particular lab or environment.

This Funding Opportunity Announcement (FOA) does not allow applicants to propose to lead an independent clinical trial, but does allow applicants to propose research experience in a clinical trial led by a sponsor or co-sponsor.

Key Dates

Posted Date

October 18, 2019

Open Date (Earliest Submission Date)

January 11, 2020

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

February 11, 2020, June 9, 2020, and October 14, 2020, February 11, 2021, June 9, 2021, October 14, 2021, February 9, 2022, June 8, 2022, and October 11, 2022.

All applications are due, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s).

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

May 7, 2020, September 7, 2020, January 7, 2021, May 7, 2021, September 7, 2021, January 7, 2022, May 7, 2022, September 7, 2022, January 7, 2023, by 5:00 PM local time of applicant organization. All types of AIDS and AIDS-related applications allowed for this funding opportunity announcement are due on these dates.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Scientific Merit Review

June 2020, October 2020, February 2020 (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward)

Advisory Council Review

Not Applicable for Fellowships

Earliest Start Date

November 2020, February 2021, June 2021

Expiration Date

January 8, 2023

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Fellowship (F) instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=42000) except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in   Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-20-021) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

[NIH's Diversity Statement (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html)The overall goal of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. NRSA fellowships support the training of pre-and postdoctoral scientists, dual-degree investigators, and senior researchers. More information about NRSA programs may be found at the [Ruth L. Kirschstein National Research Service Award (NRSA) (https://researchtraining.nih.gov/programs/fellowships)](https://researchtraining.nih.gov/programs/fellowships) website.

This NINDS F32 is designed specifically to support postdoctorates who are just beginning a postdoctoral training period in a given laboratory or research environment (support from this F32 FOA may be requested for either a first or subsequent postdoctoral mentored training position, but a subsequent postdoctoral position will only be supported if the laboratory, research environment and mentor(s) are completely different from those of the applicant's first postdoctoral position). The window during which applicants are eligible to apply (from approximately 12 months prior to starting in the proposed postdoctoral position to within 12 months of starting the postdoctoral position) precludes the expectation of applicant-generated preliminary data, and thus encourages projects that rely on creative, innovative ideas that address highly significant questions. Due to the early application window, it is expected that there will be no preliminary data in the application and applicants are strongly encouraged NOT to include preliminary data in the application. Further, this F32 will only support postdoctorates who are within the first 3 years of training in a specific laboratory or scientific environment (or with a specific mentor). Candidates seeking support that focuses on advanced postdoctoral career development can apply for the NINDS postdoctoral [K01 (https://www.ninds.nih.gov/Funding/Training-Career-Development/Award/K01-%E2%80%93-NINDS-Postdoctoral-Career-Development-Award)](https://www.ninds.nih.gov/Funding/Training-Career-Development/Award/K01-%E2%80%93-NINDS-Postdoctoral-Career-Development-Award), and candidates seeking support for completion of postdoctoral career development and transition to a faculty position can apply for a [K99/R00 (https://www.ninds.nih.gov/Funding/Training-Career-Development/Award/K99R00-NIH-Pathway-Independence-Award)](https://www.ninds.nih.gov/Funding/Training-Career-Development/Award/K99R00-NIH-Pathway-Independence-Award).

Projects are encouraged at all levels of investigation, including basic science that is targeted to understanding central and/or peripheral nervous system processes but may not have direct disease-relevance, basic science with direct relevance to one or more neurological diseases or disorders, clinical (patient-oriented) research or translational research (studies designed to move compounds or devices towards clinical use). The integrated program of research and training is expected to provide applicants with training at the forefront of science that will prepare them to launch independent research careers in areas that will advance the goals of the NINDS mission.

The application should consist of a well-conceived scientific project, integrated with a comprehesive training plan, designed by a collaborative discussion between candidate and mentor. Although not always possible, it is hoped that these discussions will begin prior to the start of the candidate's training in the laboratory to enable planned research and training to start quickly. In addition to preparing the candidate to be a subject matter and technical expert, both the project and training plans are expected

to provide the candidate with a profound understanding of quantitative principles of experimental design and analysis. Moreover, the candidate's approach should consider the experimental system quantitatively to ensure a deep understanding of the potential biological (as opposed to merely statistical) significance of experimental results.

The research should differ substantially from the applicant's prior research and training experience, and should not occur in a training environment already experienced by the candidate. A significant contribution to training potential is not only the novelty of the research project and skills obtained but the interaction with different investigators, in a different environment, to learn additional ways of approaching scientific, procedural and analytical problems.

The proposed research and training plan should enhance the individual's potential to develop into a productive, independent researcher by providing strong mentorship, appropriate training and career development opportunities, and strong institutional support and commitment. The training plan should explain how the proposed mentored research and training plan, in combination with the candidate's prior training and experience, will contribute to the individual's research career goals. The training plan should be explicitly designed to facilitate the forward progress of the fellow's research career towards the candidate's desired goals.

It is expected that the training experience will provide:

- Strong, active mentorship that will prepare the candidate to thrive in the scientific enterprise
- A rigorous approach to a significant research question;
- Expertise in a research area;
- The opportunity to publish the research findings as first author;
- A strong foundation in quantitative reasoning, research design, methods, statistics and analytic techniques appropriate to the proposed research;
- An understanding of, and adherence to, the principles of scientific investigation that will ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results;
- An expert understanding of the tools and methods used;
- Opportunities to present research findings, and interact with members of the scientific community, at national meetings as the work progresses, and
- Professional skills and scientific credentials needed to transition to the next stage of the applicant's research career

Note: This Funding Opportunity Announcement (FOA) does not allow applicants to propose to lead an independent clinical trial, but does allow applicants to propose research experience in a clinical trial led by a sponsor or co-sponsor.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Resubmission

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose independent clinical trials.

Note: Applicants may propose to gain experience in a clinical trial led by a sponsor/co-sponsor as part of their research training.

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide /url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Award budgets are composed of stipends, tuition and fees, and institutional allowance, as described below.

Award Project Period

Individuals may receive up to 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of support from institutional training grants (e.g., T32) and an individual fellowship award. For this FOA, support will be provided only during the first 3 years of postdoctoral experience in any one particular laboratory or research environment. For example, if an award is made 18 months after the start of the postdoctoral position in the fellowship laboratory or research environment, the award duration will be for a maximum of 18 months.

Other Award Budget Information

Stipends

Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research and clinical training experiences. See https://researchtraining.nih.gov/resources /policy-notices (https://researchtraining.nih.gov/resources/policy-notices)

Tuition and Fees

Fellowship awards will contribute to the combined cost of tuition and fees at the rate in place at the time of award. See https://researchtraining.nih.gov/resources/policy-notices (https://researchtraining.nih.gov /resources/policy-notices)

Institutional Allowance

The application should request a Kirschstein-NRSA institutional allowance to help defray the cost of fellowship expenses such as health insurance, research supplies, equipment, books, and travel to scientific meetings. See https://researchtraining.nih.gov/resources/policy-notices (https://researchtraining.nih.gov/resources/policy-notices).

In addition, $1,500 will be added during the candidate's 2nd postdoctoral year to support travel of the fellow and mentor specifically to an annual NINDS workshop for 2nd year F32 fellows and mentors.

Indirect Costs

Fellowship awards do not include a separate reimbursement for indirect costs (also known as Facilities & Administrative [F&A] Costs). Instead of costs for administering fellowships are covered by the Institutional Allowance. See https://researchtraining.nih.gov/resources/policy-notices (https://researchtraining.nih.gov/resources/policy-notices)

Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov /programs/fellowships).

NIH grants policies as described in the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide /url_redirect.htm?id=11120)* will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- ○ Public/State Controlled Institutions of Higher Education
- ○ Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- ○ · Hispanic-serving Institutions
- ○ · Historically Black Colleges and Universities (HBCUs)
- ○ · Tribally Controlled Colleges and Universities (TCCUs)
- ○ · Alaska Native and Native Hawaiian Serving Institutions
- ○ · Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- ○ Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- ○ Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- ○ Small Businesses
- ○ For-Profit Organizations (Other than Small Businesses)

Governments

- ○ Eligible Agencies of the Federal Government

Other

- ○ Non-domestic (non-U.S.) Entities (Foreign Institutions)

Before submitting a fellowship application, the applicant must identify a sponsoring institution. The sponsoring institution must have staff and facilities available on site to provide a suitable environment for performing high-quality research training. The training should occur in an environment that has appropriate human and technical resources and is demonstrably committed to training in the field(s) proposed by the applicant. The sponsoring institution may be private (profit or nonprofit) or public, including the NIH Intramural Programs and other Federal laboratories. All institutions with the appropriate resources and commitment are encouraged to apply.

An individual may request support for training abroad. In such cases, the applicant is required to provide detailed justification for the foreign training, including the reasons why the facilities, the sponsor, or other aspects of the proposed experience are more appropriate than training in a domestic setting. The

justification is evaluated in terms of the scientific advantages of the foreign training as compared to the training available domestically. Foreign training will be considered for funding only when the scientific advantages are clear.

The Kirschstein-NRSA F32 fellowship is designed to support research training experiences in new settings in order to maximize the acquisition of new skills and knowledge. In most cases, therefore, the sponsoring institution should be a site other than where the applicant trained as a graduate student. However, if the applicant is proposing postdoctoral training at the same institution as their previous research training, the application must clearly describe how the proposed research and training opportunities are completely distinct from prior experiences, as well as how the scientific environment and mentorship are distinct from prior experiences. Applications that propose postdoctoral experiences in the same lab, in fundamentally the same research environment, or with the same mentor(s) that supported the candidate's past training experiences will not be considered for funding.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.
Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide /url_redirect.htm?id=11118), **are** allowed.

Required Registrations
Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- ○ Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- ○ System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/)– Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- ○ · NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide /url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- ○ eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- ○ Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons.If the PD/PI is also the organizational Signing Official, they must have

two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any applicant fellow with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) is invited to work with his/her sponsor and organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. Multiple PDs/PIs are not allowed.

By the time of award, the individual must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status).

Applicants are encouraged to apply for the NINDS F32 before they have joined the proposed laboratory, and if it is a first postdoctoral experience, before they have completed their terminal doctoral degree requirements. This will ensure thoughtful and comprehensive planning before the start of the postdoctoral period and will maximize this award's training potential. However, candidates are also eligible to apply if they are within the first 12 months of joining the proposed laboratory or research environment. Early applications are strongly encouraged as the NINDS F32 cannot be used to support candidates beyond the 3rd year in a laboratory or research environment. Thus, successful applications submitted earlier will result in a longer support duration, up to a maximum of 3 years. Moreover, very early submission may facilitate the ability to resubmit applications within the eligibility window, if necessary (the eligibility window above applies to both new and resubmission applications).

In addition to standard, automatic NIH leave policies, fellows who have children while supported by this FOA, either through childbirth or adoption, are encouraged to consider requesting a six-month extension of their fellowship. NINDS may provide one six-month extension per candidate to ensure that fellowship research and training can be completed. Requests must be submitted in writing, following the procedures described in the NIH Grants Policy Statement, Section 11.2.6.

Before a Kirschstein-NRSA postdoctoral fellowship award can be activated, the individual must have received a PhD, MD, DO, DC, DDS, DVM, OD, DPM, ScD, EngD, DrPH, DNSc, ND (Doctor of Naturopathy), PharmD, DSW, PsyD, or equivalent doctoral degree from an accredited domestic or foreign institution. Certification by an authorized official of the degree-granting institution that all degree requirements have been met is also acceptable. A Kirschstein-NRSA fellowship may not be used to support the clinical years of residency training. However, these awards are appropriate for the research fellowship years of a residency program. Research clinicians must devote full-time to their proposed research training and confine clinical duties to those activities that are part of the research training program; the latter may constitute no more than 25% of full time professional effort.

Please note that the NIH Loan Repayment Programs (LRPs) (https://www.lrp.nih.gov/) are a set of programs to attract and retain promising early-stage investigators in research careers by helping them to repay their student loans. Recipients of fellowship and career development awards are encouraged to apply for an extramural LRP award.

2. Cost Sharing

This FOA does not require cost sharing as defined in the *NIH Grants Policy Statement*. (//grants.nih.gov /grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

Duration of Support

Individuals may not exceed the aggregate limit of NRSA support shown above in the Award Project Period (see Section II. Award Information). Applicant fellows must consider any prior NRSA research training in determining the duration of support requested. Information regarding previous Kirschstein-NRSA support must be included in the application and will be considered at the time of award.

Level of Effort

At the time of award, individuals are required to pursue their research training on a full-time basis, normally defined as 40 hours per week or as specified by the sponsoring institution in accordance with its own policies.

Sponsor

Before submitting the application, the applicant must identify a sponsor(s) who will supervise the proposed mentored training experience. The primary sponsor should be an active investigator in the area of the proposed research training and be committed both to the applicant's research training and to direct supervision of his/her research. The sponsor must have sufficient research funds and resources for high-quality research training of this applicant on the proposed project. The sponsor, or a member of the sponsor team, should have a successful track record of mentorship.

Applicants are encouraged to identify more than one sponsor, i.e., a sponsor team, if this is deemed advantageous for providing expert advice in all aspects of the training program. When there is a sponsor team, one individual must be identified as the primary sponsor, and will be expected to coordinate the applicant's overall training. The applicant is expected to work with the sponsor(s) in preparing the application. In many cases, the proposed research will be closely related to an ongoing project of the sponsor. Importantly, however, the proposed research project should derive from the collaborative intellectual input of both applicant and sponsor(s), and cannot merely be a research project previously devised by one or more sponsors.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Fellowship (F) instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=42000), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the SF424 (R&R) Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=41132) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile Expanded

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Fellowship Supplemental Form

The PHS Fellowship Supplemental Form is comprised of the following sections:

- Fellowship Applicant
- Research Training Plan
- Sponsor(s), Collaborator(s), and Consultant(s);
- Institutional Environment & Commitment to Training
- Other Research Training Plan Sections
- Additional Information
- Budget
- Appendix

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Applicants are strongly encouraged to identify their individual contributions and experimental work by using the first person singular narrative when describing their hypotheses, contributions and work to be done. Ideas, hypotheses and work done by others should be attributed appropriately. It is likely to diminish reviewer enthusiasm for the application if reviewers cannot clearly distinguish between the candidate's work and the work of others in the laboratory and/or research environment.

Fellowship Applicant Section

Applicant's Background and Goals for Fellowship Training

The applicant's research and clinical training plan, i.e. the activities planned under this award, should be individually tailored and well integrated with his/her research project. Describe the skills and techniques that the applicant intends to learn, knowledge to be gained, and any planned, non-research activities (e.g. those relating to professional development and clinical activities) during the award period. Describe the activities planned that will ensure that the candidate has a strong understanding of experimental design and the principles that underlie statistical methodology (note that it is unlikely for an introductory statistics course to fulfill this need).

Research Training Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy

Applicants must describe a well-defined research project (typically hypothesis-driven) that is well-suited to his/her stage of career development. The applicant should describe the background

leading to the proposed research, the significance of the research, the proposed approach (design and methods) for achieving the Specific Aims and the rationale for the proposed approach. Furthermore, applicants should clearly and specifically address the expected outcomes, potential pitfalls, and alternative approachs and/or directions should the expected outcomes not occur. The proposed research project should be derived from collaborative discussions between the applicant and sponsor(s) and should not simply be a duplication of one of the sponsors previously proposed projects (i.e. it is not appropriate for an F32 fellow to propose research already developed by the mentor and described in the Specific Aims of the mentor's grant(s)).

Because it is desirable for applicants to submit applications before or very soon after beginning their postdoctoral positions, applicants are strongly discouraged from including preliminary data in the application. However, applicants should nonetheless address technical feasibility, as well as the strengths and weaknesses of previously published (or unpublished) work that supports the project's significance and approach taken. Note that it is acceptable, and even encouraged, for the candidate to propose a highly significant, albeit perhaps risky, project. Given the lack of preliminary data in the application, and the acceptance of risk, it is especially important to include a discussion of the planned course of action should the proposed approach(es) be unsuccessful or the hypotheses be quickly disproven.

It is critical that the applicant clearly identify his/her hypotheses, research and experimental approach and analyses to be conducted from that of others in the laboratory or research environment. One recommended approach to achieving this clarity is for the candidate to use the first person singular narrative when discussing his/her ideas and plans, and citing others appropriately for their contributions. Applications written entirely in the first person plural narrative make it impossible for reviewers to clearly understand the ideas, specific research and skills to be learned by the candidate.

Training in Responsible Conduct of Research (RCR)

Applicants and sponsors are encouraged to create a plan for a comprehensive discussion of RCR issues that goes beyond the minimal NIH requirements. This may be based in a single lab or with multiple labs, and ideally would include regular, planned meetings to discuss topical issues. Applicants should include a complete description of their RCR training plan in the RCR section of the application.

If the applicant is proposing to gain experience in a clinical trial as part of his or her research training, describe the relationship of the proposed research project to the clinical trial.

Sponsor(s), Collaborator(s), and Consultant(s)

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Sponsor and Co-Sponsor Statements: The role of each sponsor, mentor, collaborator and consultant in the proposed research training plan should be described. The Sponsor/mentor and any Co-Sponsors/co-mentors should describe their qualifications to train a postdoctoral fellow who seeks mentored training in a research area relevant to the proposed project.

Describe the plan of mentored research training, and include a discussion of any didactics or other formal training that will ensure that the applicant acquires robust grounding in quantitative reasoning, principles of experimental method, a strong understanding of relevant statistical methodology, and the analytical and methodological techniques used. Describe the guidance mechanism by which progress will be evaluated and any necessary course-correction will be achieved to ensure that the applicant makes substantial progress towards the proposed research and career development goals. Describe the plan and/or approach that will help the candidate thrive in the scientific enterprise (might include, but not limited to, managing lab dynamics,

interacting with collaborators, responding to grant and paper critiques, communicating with editors, funders and potential employers, etc.). Describe a specific plan by which the applicant's transition to the next step of his/her research career will be facilitated.

Typically, although not necessarily, a fellowship project will be highly related to projects on-going in the mentor's laboratory. However, the proposed project should derive from the collaborative intellectual input of both the applicant and the sponsor(s) and cannot merely be a research project previously devised by one or more sponsors. The Sponsor is expected to explicitly describe his/her contribution to the research plan, thintellectual contribution of the applicant to the research ideas and plan, any part of the plan that originated with the applicant, and the relationship between the proposed research plan and funded or unfunded research projects previously devised by the sponsor. The sponsor must document the availability of sufficient research funds and resources for high-quality research training of the applicant on the proposed project.

If the applicant is proposing to gain experience in a clinical trial as part of his or her research training, the sponsor or co-sponsor must include a statement to document leadership of the clinical trial including source of funding, NCT# and appropriate expertise to guide the applicant in any proposed clinical trials research experience. The individual receiving support for the clinical trial (i.e., the sponsor/primary mentor or a co-sponsor) is the responsible individual of record for oversight of the trial though trainees and fellows can take part in all components of a clinical trial. Oversight includes (but is not limited to): interacting with relevant Institutional Review Board (IRB) staff; reviewing all informed consent documents; reporting potential serious adverse events; and maintaining responsibility for patient safety. However, the trainee or fellow can gain experience in all these components in conjunction with the mentor or individual leading the trial.

Letters of Support from Collaborators, Contributors, and Consultants: It is expected that collaborators and consultants will provide a letter that describes and confirms their commitment and role in the project.

Institutional Environment and Commitment to Training Section

Description of Institutional Environment and Commitment to Training

Describe the opportunites available to the applicant to develop professional skills, e.g., communication, grant-writing, laboratory management and leadership skills. Describe the contribution of the sponsor and sponsor's research environment to development of these skills and describe the opportunites available to the applicant that are overseen by the institution or outside of the sponsor's research environment.

Appendix

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record. If gaining research experience in a clinical trial led by a sponsor/co-sponsor, provide the sponsor's ClinicalTrials.gov identifier (i.e., NCT number).

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

- Do not provide an NCT# in Section 1, item 1.5. See instruction for Sponsor(s), Collaborator(s), and Consultant(s) above.
- Do not complete Section 4 – Protocol Synopsis information or Section 5 – Other Clinical Trial-related Attachments.

Delayed Onset Study

Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

Reference Letters

Applicants must carefully follow the SF424 (R&R) Application Guide, **including the time period for when reference letters will be accepted**. Applications lacking the appropriate required reference letters will not be reviewed. This is a separate process from submitting an application electronically. Reference letters are submitted directly through the eRA Commons Submit Reference Letter link (//grants.nih.gov/grants/guide/url_redirect.htm?id=41146) and not through Grants.gov.

Foreign Institutions

Foreign (non-U.S.) Institutions must follow policies described in the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11137)*, and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov.

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA

Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120)*. The National Research Service Award (NRSA) policies (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171) apply to this program. A Kirschstein-NRSA fellowship may not be held concurrently with another federally sponsored fellowship or similar Federal award that provides a stipend or otherwise duplicates provisions of this award.

Pre-award costs are generally not allowable for Fellowships.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

> **Important reminders:**
> All PD(s)/PI(s) and sponsor(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.
>
> The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.
>
> See more tips (//grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299) Any instructions provided here are in addition to the instructions in the policy. .

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide /url_redirect.htm?id=11149) 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 a productive 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 applicant's potential for, and commitment to, a productive 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 appropriate for the proposed project and career goals?
- Was the applicant appropriately productive during the predoctoral training period?
- Is there evidence, from prior training accomplishments and the proposed research plan that the applicant has the training to conduct rigorous scientific research?
- Did the applicant demonstrate strong logic and reasoning capabilities in preparation of the application?
- Is there evidence in the application that the candidate made a significant intellectual contribution to the the project idea, approach and/or hypotheses?

Sponsors, Collaborators, and Consultants

- 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?
- Did the sponsor describe his/her contribution to the research plan, the intellectual contribution of the candidate to the research plan, any portion of the research ideas and plan that originated with the applicant, and the relationship between the proposed research plan and funded or unfunded research projects previously devised by the sponsor?
- Did the sponsor document the availability of sufficient research funds and resources for high-quality research training of this applicant on the proposed project?
- 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? Were letters provided by collaborators and consultants that describe and confirm their commitment to the project?

○ Does the sponsor's research and training record, as well as mentoring statement, indicate that the applicant will receive outstanding training in the proposed research area, methodology relevant to the project, principles of rigorous experimental design and data analysis, and quantitative reasoning that will allow the fellow to obtain a deep understanding of the biological significance, as well as the statistical significance, of the results obtained?

○ Does the sponsor's record support the requirement that the applicant will have the opportunity to publish high quality papers as first author and present research data at national meetings as the project progresses?

○ If the applicant is proposing to gain experience in a clinical trial as part of his or her research training, is there evidence of the appropriate expertise, experience, resources, and ability on the part of the sponsor(s) to guide the applicant during the clinical trial research experience

Research Training Plan

○ Is the proposed research project of high scientific quality, and is it well integrated with the proposed research training plan?

○ Are the candidate's hypotheses and planned experimental work clearly distinguished from the hypotheses and experimental work to be done by others in the laboratory or research environment?

○ Is the research project consistent with the applicant's stage of research development?

○ Is the proposed time frame appropriate to accomplish the proposed training?

○ Does the training plan include activities that will ensure that the candidate has a thorough understanding of the principles of statistics?

○ Will the training plan provide a strong foundation in quantitative reasoning and analytic techniques appropriate to the proposed research?

○ Is the training plan designed to provide an understanding of, and adherence to, the principles of scientific investigation that will ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results?

○ Will the training plan provide the applicant with an expert understanding of the tools and methods used?

○ Does the training plan provide adequate opportunites to present research findings and meet with scientists in the community at national meetings as the work progresses?

○ Does the training plan provide the professional skills needed for the applicant to transition to the next stage of his/her research career?

○ Is there evidence that the sponsor will provide mentorship that will help the candidate thrive in the scientific enterprise?

○ Is there clear evidence that the proposed project resulted from an intellectual collaboration between applicant and mentor, and was not simply a duplication of one of the sponsor's previously proposed projects?

○ Did the discussion of expected results, potential pitfalls and alternative approaches provide confidence that, if an important component of the research is unsuccessful, the applicant has a viable path for continuation of the project, or appropriate re-direction to another aspect of the project?

○ If proposed, will the clinical trial experience contribute to the proposed project and/or the applicant's research training?

Training Potential

○ Are the proposed research project and training plan likely to provide the applicant with the individualized and mentored training, and acquisition of skills, required for an outstanding research career?

○ Does the training plan provide needed skills and address gaps in the applicant's training? Does the training plan document a clear need for, and value of, the proposed training? Are the training and experimental approaches different from prior training and experimental experiences of the candidate?

- When combined with prior training, is the proposed training likely to prepare the applicant for a rigorous, productive research career?
- At the conclusion of this research training plan, will the candidate have the quantitative reasoning skills to rigorously evaluate the biological significance of results in future research pursuits?

Institutional Environment & Commitment to Training

- 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 specific scientific needs of high quality?
- Is there appropriate institutional commitment to fostering the applicant's mentored training?
- Does the institutional and/or lab environment provide appropriate and suffcent opportunites for the applicant to gain the professional skills (e.g. oral and written communication, etc.) needed for a successful research career?

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 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 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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

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 individuals of all ages (including children and older adults) 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 (//grants.nih.gov /grants/guide/url_redirect.htm?id=11174).

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 (//grants.nih.gov/grants/guide

/url_redirect.htm?id=11150).

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

Not Allowed

Revisions

Not Allowed

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 (http://grants1.nih.gov/grants/guide /notice-files/NOT-OD-10-019.html).

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 (//grants.nih.gov /grants/guide/url_redirect.htm?id=11151); 2) Sharing Model Organisms (//grants.nih.gov/grants /guide/url_redirect.htm?id=11152); and 3) Genomic Data Sharing Plan (//grants.nih.gov/grants/guide /url_redirect.htm?id=11153).

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.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by the National Institute of Neurological Diseases and Stroke in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), 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 . 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.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide /url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide /url_redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide /url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Institutional Review Board or Independent Ethics Committee Approval: Grantee institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the awardee must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120)* as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide /url_redirect.htm?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html). The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html (https://www.hhs.gov /civil-rights/for-individuals/section-1557/index.html); and https://www.hhs.gov/civil-rights/for-providers /laws-regulations-guidance/index.html (https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html). Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see https://www.hhs.gov/civil-rights/for-individuals/disability /index.html (https://www.hhs.gov/civil-rights/for-individuals/disability/index.html). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS

Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov /omh/browse.aspx?lvl=2&lvlid=53 (http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).

As specified in the NIH Revitalization Act of 1993, Kirschstein-NRSA recipients incur a service payback obligation for the first 12 months of postdoctoral support. Policies regarding the Kirschstein-NRSA payback obligation are explained in the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide /url_redirect.htm?id=41171)*; applicants may also wish to review Frequently Asked Questions (//grants.nih.gov/grants/guide/url_redirect.htm?id=41172) for more details. The taxability of stipends is described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171).

Inventions and Copyrights

Fellowships funded primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required. More details, including exceptions for fellows training at NIH are provided in the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide /url_redirect.htm?id=41171)*.

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually. The report is due two months before the beginning date of the next budget period and must include information describing the current year's progress as well as the research and training plans for the coming year.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide /url_redirect.htm?id=11170) on all subawards over $25,000. See the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11171)* for additional information on this reporting requirement.

Other Fellowship Reporting Requirements:
- Individuals admitted to the United States as Permanent Residents must submit notarized evidence of legal admission prior to the award.
- The fellowship award recipient has up to six months from the issue date on the Notice of Award to activate the award using the Kirschstein-NRSA Individual Fellowship Activation Notice (PHS 416-5). Under unusual circumstances, the activation period may be extended at the request of the fellow. Such a request must be countersigned by the sponsor and an authorized institutional official.
- For the individual's initial 12 months of Kirschstein-NRSA postdoctoral support, a signed, original Payback Agreement Form (PHS 6031) must accompany the Activation Notice.
- At the conclusion of a fellowship, the fellow must submit a Termination Notice (PHS 416-7) via xTrain to the NIH within 30 days of termination. Fellows with service payback requirements must notify the NIH of any change in address and submit Annual Payback Activities Certification Forms (PHS 6031-1) until the payback service obligation is satisfied.

4. Evaluation

In carrying out its stewardship of human resource-related programs, the NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts,

honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: http://grants.nih.gov/support/ (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

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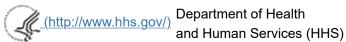# Section VIII. Other Information

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