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 Center for Complementary and Integrative Health (NCCIH) (http://www.nccam.nih.gov/) National Cancer Institute (NCI) (http://www.nci.nih.gov/) National Eye Institute (NEI) (http://www.nei.nih.gov/) National Human Genome Research Institute (NHGRI) (https://www.genome.gov/) National Heart, Lung, and Blood Institute (NHLBI) (http://www.nhlbi.nih.gov/) National Institute on Aging (NIA) (http://www.nia.nih.gov/) National Institute on Alcohol Abuse and Alcoholism (NIAAA) (http://www.niaaa.nih.gov/) National Institute of Allergy and Infectious Diseases (NIAID) (http://www.niaid.nih.gov/) National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) (http://www.niams.nih.gov/) Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) (http://www.nichd.nih.gov/) National Institute on Deafness and Other Communication Disorders (NIDCD) (http://www.nidcd.nih.gov/) National Institute of Dental and Craniofacial Research (NIDCR) (http://www.nidcr.nih.gov/) National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (http://www.niddk.nih.gov/) National Institute of Environmental Health Sciences (NIEHS) (http://www.niehs.nih.gov/) National Institute of Mental Health (NIMH) (http://www.nimh.nih.gov/) National Institute on Minority Health and Health Disparities (NIMHD) (http://www.nimhd.nih.gov/) National Institute of Nursing Research (NINR) (http://www.ninr.nih.gov/) National Institute of Neurological Disorders and Stroke (NINDS) (http://www.ninds.nih.gov/) National Library of Medicine (NLM) (http://www.nlm.nih.gov/) Office of Research Infrastructure Programs (ORIP) (http://dpcpsi.nih.gov/orip/index.aspx) National Institute on Drug Abuse (NIDA) (http://www.nida.nih.gov/) Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements at the Table of IC-Specific Information, Requirements, and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/parent_F31.html) website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged.
Funding Opportunity Title	**Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship (Parent F31)**
Activity Code	F31 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=f31&Search.x=0&Search.y=0&Search_Type=Activity) Predoctoral Individual National Research Service Grant Award
Announcement Type	Reissue of PA-20-246 (https://grants.nih.gov/grants/guide/pa-files/PA-20-246.html) - Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship (Parent F31)
Related Notices	None
Funding Opportunity Announcement (FOA) Number	**PA-21-051**
Companion Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.213, 93.398, 93.867, 93.172, 93.838, 93.837, 93.839, 93.840, 93.233, 93.866, 93.273, 93.855, 93.846, 93.865, 93.279, 93.173, 93.121, 93.847, 93.113, 93.242, 93.307, 93.853, 93.361, 93.879, 93.361, 93.879, 93.351
Funding Opportunity Purpose	The purpose of the Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship (Parent F31) award is to enable promising predoctoral students to obtain individualized, mentored research training from outstanding faculty sponsors while conducting dissertation research in scientific health-related fields relevant to the missions of the participating NIH Institutes and Centers. The proposed mentored research training must reflect the candidate's dissertation research project and is expected to clearly enhance the individual's potential to develop into a productive, independent research scientist. This Funding Opportunity Announcement (FOA) is designed specifically for candidates proposing research that does not involve leading an independent clinical trial, a clinical trial feasibility study, or an ancillary clinical trial, but does allow candidates to propose research experience in a clinical trial led by a sponsor or co-sponsor.

Key Dates

Posted Date	October 21, 2020
Open Date (Earliest Submission Date)	November 8, 2020
Letter of Intent Due Date(s)	Not Applicable
Application Due Date(s)	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11111) apply), by 5:00 PM local time of applicant organization. All types of non-AIDS 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.
AIDS Application Due Date(s)	Standard AIDS dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11112) apply, 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	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward) apply

Advisory Council Review	Not Applicable for Fellowships
Earliest Start Date	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply
Expiration Date	September 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.

   <div style="background:green;color:white;padding:8px;display:inline-block">Apply Online Using ASSIST</div>

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 (https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=pa-21-051) 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

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 NIH Research Training and Career Development (../../../../AppData/Local/Microsoft/Windows/INetCache/IE/AppData/Local/Microsoft/Windows/INetCache/IE/Downloads/NIH%20Research%20Training%20and%20Career%20Development) website.

The purpose of the Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship (Parent F31) is to enable promising predoctoral students to obtain individualized, mentored research training from outstanding faculty sponsors while conducting dissertation research. Candidates for this F31 program are expected to propose a dissertation research project and training plan in scientific health-related fields relevant to the mission of the participating Institutes and Centers. This training plan should reflect the candidate's dissertation research project, and facilitate and clearly enhance the individual's potential to develop into a productive, independent research scientist. The training plan should document the need for, and the anticipated value of, the proposed mentored research and training in relationship to the individual's research career goals. The training plan should also facilitate the fellow's transition to the next stage of his/her research career.

It is expected that the mentored research training experience will provide:

- A strong foundation in rigorous research design, experimental methods, and analytic techniques appropriate to the proposed research;
- The enhancement of the candidate's ability to conceptualize and think through research problems with increasing independence;
- Experience conducting research using appropriate, state-of-the-art methods, as well as presenting and publishing the research findings as first author;
- The opportunity to interact with members of the scientific community at appropriate scientific meetings and workshops;
- Skills needed to transition to the next stage of the candidate's research career; and
- The opportunity to enhance the candidate's understanding of the health-related sciences and the relationship of the proposed research to health and disease.

Candidates for the F31 must be candidates for the PhD degree and have identified a dissertation research project and sponsor(s).

The Kirschstein-NRSA Individual Predoctoral Fellowship (F31) program may provide up to five years (typically 2-3 years) of support for research training which leads to the PhD or equivalent research degree, the combined MD/PhD degree, or another formally combined professional degree and research doctoral degree in the biomedical, behavioral, or clinical sciences. Because this F31 program only supports dissertation research training, the Kirschstein NRSA Individual Predoctoral MD/PhD or Other Dual-Doctoral Degree Fellowship (Parent F30) program will be more appropriate for the training goals of individuals enrolled in dual-degree programs who seek support for both dissertation research training and clinical training.

Note: This Funding Opportunity Announcement (FOA) is designed specifically for candidates proposing research that does not involve leading an independent clinical trial, a clinical trial feasibility study, or an ancillary study to a clinical trial, but does allow candidates to propose research experience in a clinical trial led by a sponsor or co-sponsor.

Special Note: Because of the differences in individual Institute and Center (IC) program requirements for this FOA, prospective applicants are strongly encouraged to consult the Table of IC-Specific Information, Requirements, and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/parent_F31.html), to make sure that their application is appropiate for the requirements of one of the participating NIH ICs.

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 Renewal: Individual fellowship awards are generally not renewable. In rare cases in which fellowship awardees require further fellowship support, they should consult with NIH staff to obtain advice regarding submission of a renewal application. 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.
Clinical Trial?	Not Allowed: Only accepting applications that do not propose independent clinical trials. Note: Candidates 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 5 years of aggregate Kirschstein-NRSA support at the predoctoral level (up to 6 years for dual degree training, e.g., MD/PhD), and 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.

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.
Tuition and Fees	NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.
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.
Indirect Costs	NIH does not separately reimburse indirect costs (also known as Facilities & Administrative [F&A] Costs) for fellowships. Costs for administering fellowships are part of Institutional Allowance.

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 candidate 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 candidate. 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.

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.

An individual may request support for training abroad. In such cases, the candidate 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 (See Section IV.2). 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.

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/) (formerly CCR) – 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 and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. 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. Obtaining an eRA Commons account can take up to 2 weeks.

All PD(s)/PI(s) must be registered with ORCiD (https://orcid.org/). The personal profile associated with the PD(s)/PI(s) eRA Commons account must be linked to a valid ORCID ID. For more information on linking an ORCID ID to an eRA Commons personal profile see the ORCID topic in our eRA

Commons online help (https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D_____29).

Eligible Individuals (Program Director/Principal Investigator)

Any candidate 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).

The candidate must be at the dissertation research stage of training at the time of award and must show evidence of high academic performance in the sciences, and commitment to a career as an independent research scientist.

The candidate must be currently enrolled in a PhD or equivalent research degree program (e.g., EngD, DNSc, DrPH, DSW, PharmD, ScD) in the biomedical, behavioral, or clinical sciences at a domestic or foreign institution.

Students matriculated in a dual-degree program (e.g. MD/PhD, DO/PhD, DDS/PhD, or DVM/PhD) who seek support for both dissertation research training and clinical training are not eligible for this Kirschstein-NRSA F31 program because this F31 program does not support the clinical training component of a dual-degree program. Such students may apply for the Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral MD/PhD or Other Dual-Doctoral Degree Fellowship (Parent F30) to support both dissertation research training and clinical training.

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). Candidate 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 candidate 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 candidate's research training and to direct supervision of his/her research. The sponsor must document the availability of sufficient research funds and facilities for high-quality research training. The sponsor, or a member of the sponsor team, should have a successful track record of mentorship. Candidates 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 candidate's overall training. The candidate must work with the sponsor(s) in preparing the application.

Section IV. Application and Submission Information

1. Requesting an Application Package

Buttons to access the online ASSIST system or to download application forms 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.

IMPORTANT REMINDER: The personal profile associated with the eRA Commons username entered in the Credential field for the PD/PI (fellowship applicant) must include an ORCID ID. For more information on linking an ORCID ID to an eRA Commons personal profile see the ORCID topic in our eRA Commons online help (https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D_____29).

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 Section
- Additional Information
- Budget
- Appendix

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

Fellowship Applicant Section

Applicant's Background and Goals for Fellowship Training

Identify the skills, theories, conceptual approaches, etc., to be learned or enhanced during the award, including expertise in rigorous research design, experimental methods, quantitative approaches, and data analysis and interpretation, as applicable.

Research Training Plan

All instructions in the SF424 (R&R) Application Guide must be followed, including the following instructions for the Research Strategy section:

Explain the importance of the problem or critical barrier to progress that the proposed project addresses.

Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project.

Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

- *If the candidate 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:

- *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 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 fellow can gain experience in all these components in conjunction with the mentor or individual leading the trial.
- The Sponsor should also describe the roles and responsibilities that both he/she and the fellow are undertaking, including contributions to the research plan, the portion of the research ideas and plan that originated with the candidate, and the relationship between the proposed research plan and funded or unfunded research projects previously devised by the sponsor.

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 NIH-defined human subjects research, clinical research, and/or 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.

Study Record: PHS Human Subjects and Clinical Trials Information

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

- Do not 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 Applying Electronically (//grants.nih.gov/grants/guide/url_redirect.htm?id=11144). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Guidelines for Applicants Experiencing System Issues (//grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines). 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)..

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)](//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 candidate's potential for a productive career, the candidate'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

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, 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 candidate's academic record and research experience of high quality?
- · Does the candidate have the potential to develop into an independent and productive researcher?
- · Does the candidate demonstrate commitment to a research career in the future?
- · Does the research project reflect a significant contribution of the candidate to the originality of the project idea, approach and/or hypotheses relative to the career stage of the applicant?

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 candidate?
- · Is there evidence of a match between the research and clinical interests (if applicable) of the candidate and the sponsor(s)?
- · Do(es) the sponsor(s) demonstrate an understanding of the candidate'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 candidate'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?
- · If the candidate 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 candidate during the clinical trial research experience?
- · Does the sponsor's research and training record, as well as mentoring statement, indicate that the candidate will receive outstanding training in the proposed research area and have the opportunity to publish high quality papers and present research data at national meetings as the project progresses?

Research Training Plan

- · Is the proposed research project of high scientific quality, and is it well integrated with the proposed research training plan?
- · Is the prior research that serves as the key support for the proposed project rigorous?
- · Has the applicant included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?
- · Has the applicant presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- · Has the applicant presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- · Based on the sponsor's description of his/her active research program, is the candidate's proposed research project sufficiently distinct from the sponsor's funded research for the candidate's career stage?
- · Is the research project consistent with the candidate's stage of research development?
- · Is the proposed time frame feasible to accomplish the proposed training?
- · Does the training plan provide adequate opportunities to present and publish research findings and meet with scientists in the community at national meetings as the work progresses?
- · Will the training plan provide the professional skills needed for the candidate to transition to the next stage of his/her research career?
- · If proposed, will the clinical trial experience contribute to the proposed project and/or the candidate's research training?

Training Potential

- · Are the proposed research project and training plan likely to provide the candidate 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 candidate'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 candidate's ability to develop into a productive researcher?

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 candidate's scientific development of high quality?
- · Is there appropriate institutional commitment to fostering the candidate's mentored training?

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)](//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)](//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)](//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

Individual fellowship awards are generally not renewable. In rare cases in which fellowship awardees require further fellowship support, the committee will consider the progress made in the last funding period

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 candidate, including any prior instruction or participation in RCR as appropriate for the candidate'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).

Authentication of Key Biological and/or Chemical Resources

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

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) 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.

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 laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html (http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html).

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.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides 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/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and https://www.lep.gov (https://www.lep.gov). 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 https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).

- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html).
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html); https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html; and https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf (https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).
- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/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.

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, NIH may grant an extension of the activation period upon receipt of a specific request from the fellow. Such a request must be countersigned by the sponsor and an authorized institutional official.
- 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.

Because of the difference in individual Institute and Center (IC) program requirements for this FOA, prospective applications **MUST** consult the Table of IC-Specific Information, Requirements, and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/parent_F31.html) to make sure that their application is responsive to the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (//grants.nih.gov/grants/guide/url_redirect.htm?id=82301) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)

Telephone: 301-945-7573

Scientific/Research Contact(s)

Table of IC-Specific Information, Requirements, and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/parent_F31.html)l

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

Table of IC-Specific Information, Requirements, and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/parent_F31.html)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164)*. All 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)*.

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.

Authority and Regulations

Awards are made under the authorization of Section 487 of the Public Health Service Act as amended (42 USC 288) and under Federal Regulations 42 CFR 66.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?10-23-20)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

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Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files (/grants/edocs.htm).

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