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 (https://www.ninds.nih.gov/))

National Eye Institute (NEI (https://www.nei.nih.gov/))

National Institute on Aging (NIA (https://www.nia.nih.gov/))

National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://www.niaaa.nih.gov/))

National Institute of Biomedical Imaging and Bioengineering (NIBIB (https://www.nibib.nih.gov/))

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (https://www.nichd.nih.gov/))

National Institute on Deafness and Other Communication Disorders (NIDCD (https://www.nidcd.nih.gov/))

National Institute of Dental and Craniofacial Research (NIDCR (https://www.nidcr.nih.gov/))

National Institute on Drug Abuse (NIDA (https://www.drugabuse.gov/))

National Institute of Environmental Health Sciences (NIEHS (https://www.niehs.nih.gov/))

National Institute of Mental Health (NIMH (https://www.nimh.nih.gov/index.shtml))

National Center for Complementary and Integrative Health (NCCIH (https://nccih.nih.gov/))

The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Office of Behavioral and Social Sciences Research (OBSSR (https://obssr.od.nih.gov/))

NIH Blueprint for Neuroscience Research (http://neuroscienceblueprint.nih.gov/))

NIH BRAIN Initiative (https://braininitiative.nih.gov/ (https://braininitiative.nih.gov/))

Funding Opportunity Title

NIH Blueprint and BRAIN Initiative Diversity Specialized Predoctoral to Postdoctoral Advancement in Neuroscience (D-SPAN) Award (F99/K00 Clinical Trial Not Allowed)

Activity Code

F99/K00 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=f99&Search_Type=Activity&Search.x=0&Search.y=0) Pre-doc to Post-doc Transition Award

Announcement Type

Reissue of RFA-NS-19-011 (https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-19-011.html)

Related Notices

See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=35155) associated with this funding opportunity

NOT-OD-22-190 (/grants/guide/notice-files/NOT-OD-22-190.html) - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022

October 28, 2021 - Reminder: FORMS-G Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2022 - New Grant Application Instructions Now Available. See Notice NOT-OD-22-018 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-018.html).

September 13, 2021 - Updates to the Non-Discrimination Legal Requirements for NIH Recipients. See Notice NOT-OD-21-181 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-181.html).

August 5, 2021 - New NIH "FORMS-G" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2022. See Notice NOT-OD-21-169 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-169.html).

August 5, 2021 - Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements. See Notice NOT-OD-21-170 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-170.html)

April 20, 2021 - Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel. See Notice NOT-OD-21-109 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-109.html)

See Notices of Special Interest (//grants.nih.gov/grants/guide/notice-files/NOT-MH-22-045.html) related to this opportunity

• May 21, 2021 - Notice of a Pre-Application Technical Assistance Webinar for NIH Blueprint and BRAIN Initiative Diversity Specialized Predoctoral to Postdoctoral Advancement in Neuroscience (D-SPAN) Award (F99/K00). See Notice NOT-NS-21-067 (https://grants.nih.gov/grants/guide/notice-files/NOT-NS-21-067.html).

Funding Opportunity Announcement (FOA) Number

RFA-NS-21-012

Companion Funding Opportunity

None.

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.279; 93.286; 93.865; 93.273; 93.113; 93.853; 93.866; 93.867; 93.242; 93.121; 93.213

Funding Opportunity Purpose

The purpose of the NIH Blueprint and BRAIN Initiative Diversity Specialized Predoctoral to Postdoctoral Advancement in Neuroscience (D-SPAN) Award is to support a defined pathway across career stages for outstanding graduate students from diverse backgrounds, including those from groups underrepresented in biomedical and behavioral sciences. This two-phase award will facilitate completion of the doctoral dissertation and transition of talented graduate students to strong neuroscience research postdoctoral positions, and will provide career development opportunities relevant to their long-term career goal of becoming independent neuroscience

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

April 21, 2021

Open Date (Earliest Submission Date)

November 15, 2021

Letter of Intent Due Date(s)

30 days prior to application due date.

Application Due Date(s)

December 15, 2021; April 15, 2022; December 15, 2022; April 14, 2023; December 15, 2023.

All applications are due by 5:00 PM local time of applicant organization. All <u>types of non-AIDS applications</u> 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)

Not Applicable.

Scientific Merit Review

March 2022, July 2022, March 2023, July 2023, March 2024

Advisory Council Review

May 2022, August 2022, May 2023, August 2023, May 2024

Earliest Start Date

July 2022, September 2022, July 2023, September 2023, July 2024

Expiration Date

December 16, 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

- Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and <u>eRA Commons</u>
 ((<u>/grants/guide/ApplyButtonSplash.cfm?dest=https://public.era.nih.gov/commons/</u>) to track your application. Check with your institutional officials regarding availability.
- 3. Use <u>Grants.gov (/grants/guide/ApplyButtonSplash.cfm?dest=GrantsGov&oppNum=RFA-NS-21-012)</u> Workspace to prepare and submit your application and <u>eRA Commons (/grants/guide/ApplyButtonSplash.cfm?dest=http://public.era.nih.gov/commons/)</u> to track your application.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

This Funding Opportunity Announcement (FOA) is an initiative of the NIH Blueprint for Neuroscience Research (http://neuroscienceblueprint.nih.gov/ (http://neuroscienceblueprint.nih.gov/)) and the NIH BRAIN Initiative (http://braininitiative.nih.gov/)).

The purpose of the NIH Blueprint and BRAIN Initiative Diversity Specialized Predoctoral to Postdoctoral Advancement in Neuroscience Award or D-SPAN (F99/K00) is to support mentored research training for late-stage graduate students from diverse backgrounds, including those from groups that are underrepresented in neuroscience research, and who have demonstrated interest and potential in pursuing careers as independent researchers. Applicants must be currently enrolled as students in a PhD or equivalent research doctoral degree program at the time of application. See Section III for additional information regarding eligibility for this program.

The F99/K00 award will provide up to 6 years of support in two phases, described further below. Strong individualized research training plans and career development activities will outline a defined research pathway and are expected to enhance the development of independent neuroscience research careers. This 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 cosponsor.

Background

While the proportion of graduates from underrepresented groups in biomedical programs is increasing slightly, the representation of these groups in later career stages remains small. Individuals currently underrepresented in neuroscience research on a national basis (for example see surveys (http://www.sfn.org/Careers-and-Training/Higher-Education-and-Training/Training-Program-Surveys) conducted by the Society for Neuroscience Committee on Neuroscience Departments and Programs (http://www.sfn.org/Careers-and-Training/Higher-Education-and-Training/Training-Program-Surveys)), include: individuals from underrepresented racial and ethnic groups or individuals with disabilities (see also http://www.nsf.gov/statistics/wmpd/ (http://www.nsf.gov/statistics/wmpd/)). Among U.S. citizens at U.S. institutions, the percent of neuroscience trainees from underrepresented groups declines from the graduate (14%) to the postdoctoral level (9%) to only 5% in the neuroscience tenure stream (2011 Survey Report of Neuroscience Departments and Programs

(https://www.sfn.org/~/media/SfN/Documents/Professional%20Development/NDP/SurveyReportAY20102011.ashx)). Both graduate students and postdoctorates report decreased interest in faculty careers over time, with underrepresented minorities (URM) reporting a comparatively greater decrease than well-represented trainees (Fuhrmann et al., 2011 (http://www.ncbi.nlm.nih.gov/pubmed/21885820); Gibbs et al., 2014 (http://journals.plos.org/plosone/article?

<u>id=10.1371/journal.pone.0114736)</u>, <u>2015 (http://www.ncbi.nlm.nih.gov/pubmed/26582238)</u>; <u>Sauermann and Roach, 2012</u>

(https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3342243/)). Literature also shows that women from underrepresented groups face particular challenges at the graduate

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level and beyond in scientific fields (see, e.g., Inside the Double Bind, A Synthesis of Empirical Research on Undergraduate and Graduate Women of Color in Science, Technology, Engineering, and Mathematics http://her.hepg.org/content/t022245n7x4752v2/fulltext.pdf (http://her.hepg.org/content/t022245n7x4752v2/fulltext.pdf)).

The D-SPAN initiative will enhance the ability of predoctorates from diverse backgrounds, including those from underrepresented groups, to progress in what is often perceived as a challenging research career environment (Developing a 21st Century Neuroscience Workforce; Institute of Medicine (http://static1.1.sqspcdn.com/static/f/937462/26178614/1430224236187/IOM+NS+workforce.pdf?token=I1HukxKn0L3br0AsjxZn305nbBg%3D)). The program will address these issues by providing support to neuroscience trainees at a critical juncture in their career decision-making pathway. Among URM groups, compared to well-represented groups, research indicates that lower interest in faculty careers as a postdoctoral scholar is accompanied by lower feelings of intellectual and social belonging that starts in graduate school (Gibbs et al., 2015 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4710405/)). Studies have suggested that mentoring on self-efficacy, identity as a scientist, and commitment to a science career may remediate these barriers (Chemers et al., 2011 (https://www.researchgate.net/publication/229916357_The_Role_of_Efficacy_and_Identity_in_Science_Career_Commitment_Among_Underrepresented_Minority_Students)). Surveys of postdoctoral fellows have also shown that those trained in an environment with more structure, administrative oversight, and formal training are more likely to be satisfied with their postdoctoral experience, to rate their advisors highly, and be more productive (Davis_2005 (http://www.sigmaxi.org/docs/default-source/Programs_Documents/Critical-Issues-in-Science/postdoc-survey/highlights); Scaffidi and Berman, 2011 (http://link.springer.com/article/10.1007/s10734-011-9407-1)). Structured postdoctoral training programs have also been shown to help prepare these scholars for successful transition to academic positions (Derting et al., 2016 (http://www.ncbi.nlm.nih.gov/pubmed/27034985); Rybarczyk et al., 2011 (https://uncch.pure.elsevier.com/en/publications/postdoctoral-training-aligned-with-the-academic-profess

The D-SPAN is a structured program that requires formalized and defined training plans and seeks to increase levels of participation of trainees from diverse backgrounds transitioning from predoctoral to postdoctoral positions. As cited above, the literature shows that intervening at this graduate time point could change the trainee's perception about the pursuit of an academic/research career. The D-SPAN program creates accountability and structured processes for ongoing assessment of the training environment. A key component of the program is enhanced mentorship; D-SPAN requires the involvement of a vetted mentor or mentor team in both the graduate phase (F99) and the postdoctoral phase (K00). For the K00 phase, identification of the postdoctoral mentor or mentor team is not required at the time of application. D-SPAN also empowers trainees from diverse backgrounds to find postdoctoral environments that match their skills and scientific interests with minimal financial constraints by providing continuous support throughout the critical postgraduate career stage. The funding stability and professional development benchmarks will allow D-SPAN awardees to structure a specific plan forward in their early career as a researcher. It is envisioned that F99 phase funding support paired with the K00 phase funding support will enhance the pool of well-trained researchers who can compete for and conduct independent neuroscience research.

Background

The NIH Blueprint for Neuroscience is a collaborative and coordinated effort across 14 Institutes, Centers and Offices (ICOs), that supports research, research education, and research training with the goal of accelerating the pace of discovery in neuroscience research. By pooling resources and expertise, the NIH Blueprint for Neuroscience Research can take advantage of economies of scale, confront challenges too large for any specific ICO, and develop research tools and infrastructure that will serve the entire neuroscience community.

The BRAIN Initiative: The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative® is aimed at revolutionizing our understanding of the human brain. By accelerating the development and application of innovative technologies, researchers will be able to produce a new dynamic picture of the brain that, for the first time, will show how individual cells and complex neural circuits interact in both time and space. It is expected that the application of these new tools and technologies will ultimately lead to new ways to treat and prevent brain disorders.

Overview of this F99/K00 Transition Opportunity

The D-SPAN F99/K00 award is intended for individuals who have demonstrated an interest in a neuroscience research career in NIH Blueprint (https://neuroscienceblueprint.nih.gov/) mission-relevant areas and/or BRAIN Initiative (http://www.braininitiative.nih.gov/) research areas. Note that NIDCD participation is limited to BRAIN Initiative research areas only; NIDCD does not participate in the NIH Blueprint. At the time of award, applicants are expected to require 1-2 years to complete their PhD dissertation research training (F99 phase) before transitioning to mentored postdoctoral research training (K00 phase). The two award phases are intended to be continuous in time. Consequently, applicants are expected to propose an individualized research training plan for the next 1-2 years of dissertation research training and a plan for 3-4 years of mentored postdoctoral research training and career development activities that will prepare them for independent neuroscience-focused research careers.

The D-SPAN F99/K00 award is meant to provide up to 6 years of support in two phases. The initial phase (F99) will provide support for the final 1-2 years of dissertation research in a neuroscience related field (including final experiments, dissertation preparation) and the search for/selection of a postdoctoral mentor. The second phase (K00) will provide up to 4 years of mentored postdoctoral research career development support and is contingent upon successful completion of the doctoral degree requirements. A K00 award will be made only to a PD/PI who has successfully completed the F99-supported training, secured an appropriate neuroscience postdoctoral position, and has provided the D-SPAN oversight committee with a strong research and career development plan that will occur in a supportive and competitive research environment.

Prospective applicants are strongly encouraged to contact the Program Official prior to initiating plans for application submission. Additional resources and answers to frequently asked questions can also be found here: https://neuroscienceblueprint.nih.gov/training/nih-blueprint-d-span-award-f99k00 (https://neuroscienceblueprint.nih.gov/training/nih-blueprint-d-span-award-f99k00)

Note: The four years of K00 support of this award will not preclude the awardees from applying for other mentored career development (K) awards such as K99/R00. Awardees who can justify the need for additional mentored career development training beyond the four years of K00 may apply for additional mentored career development awards.

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

Resubmission New

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 NIH Blueprint and BRAIN Initiative intend to commit up to \$1,100,000 per fiscal year to fund approximately 25 awards per year. However, the total amount awarded and the number of awards made will depend upon the number, quality, and cost of the applications received. Future year amounts will depend on annual appropriations.

Award Budget

For the F99 phase award budgets are composed of stipends, tuition and fees, and institutional allowance, as described below. For the K00 phase, award budgets are composed of salaries and fringe benefits, research and career development support, and indirect costs, as described below.

Award Project Period

For the F99/K00 award, individuals may receive up to 6 years combined support for both phases, which includes up to 2 years in the F99 fellowship phase and up to 4 years in the K00 career development phase.

Other Award Budget Information

Stipends (F99)/Salary (K00)

ALLOWABLE COSTS: F99 PHASE

Stipends are provided as a subsistence allowance to help defray living expenses during the research training experience.

The stipend level for F99 predoctoral fellows is the same as for the F31 Ruth L. Kirschstein National Research Service Award (NRSA) fellows. Refer to the NIH Guide Notice on Ruth L. Kirschstein National Research Service Award stipends for more information.

ALLOWABLE COSTS: K00 PHASE

NIH Blueprint will contribute up to \$58,000 toward the salary of the career award recipient.

The total salary requested must be based on a full-time staff appointment. The salary must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure. Confirmation of salary may be required prior to the issuance of an award. Fringe benefits, based on the sponsoring institution's rate and the percent of effort, are provided in addition to salary.

Tuition and Fees

ALLOWABLE COSTS: F99 PHASE

NIH Blueprint will contribute to the combined cost of tuition and fees at the rate in place at the time of award, at the same level set for the F31 Ruth L. Kirschstein National Research Service Award (NRSA) fellowships; Refer to the NIH Guide Notice on Ruth L. Kirschstein National Research Service Award stipends for more information. Tuition and Fees are not allowable costs for the K00 Phase. See https://researchtraining.nih.gov/resources/policy-notices (https://researchtraining.nih.gov/resources/policy-notices)

Institutional Allowance

ALLOWABLE COSTS: F99 PHASE

The applicant should request an institutional allowance to help defray the cost of fellowship expenses such as health insurance, research supplies, equipment, books, and travel to scientific meetings. The annual institutional allowance level for the F99 phase is the same as that provided for the F31 Ruth L. Kirschstein National Research Service Award (NRSA) awards, plus an additional \$1000 to defray the travel costs to attend a mandatory NIH Neuroscience Blueprint-sponsored conference.

The most recent institutional allowance levels are described via a link on the Ruth L. Kirschstein National Research Service Award (NRSA) site. Requests for additional costs (such as to accommodate the disabilities of a fellow) must be explained in detail and justified in the application. Refer to the NIH Guide Notice on Ruth L. Kirschstein National Research Service Award stipends for more information.

ALLOWABLE COSTS: K00 PHASE

NIH Blueprint will contribute \$3,000 per year toward the research development costs of the award recipient, which must be justified and consistent with the stage of development of the candidate and the proportion of time to be spent in research or career development activities, plus an additional \$1000 annually to defray the travel costs to attend a mandatory NIH Neuroscience Blueprint-sponsored conference.

Salary for mentors, secretarial and administrative assistants, etc. is not allowed.

Indirect Costs ALLOWABLE COSTS: F99 PHASE

NIH does not separately reimburse indirect costs (also known as Facilities & Administrative [F&A] Costs) for fellowships. Costs for administering the F99 awards are part of the Institutional Allowance.

ALLOWABLE COSTS: K00 PHASE

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs.

NIH grants policies as described in the <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120)</u> 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

None

Other

None

F99 Eligibility: Domestic institution/organization types listed above that grant PhD or equivalent research degrees (e.g., DrPH, ScD) are eligible to submit an application. More than one F99 application per institution is allowed.

K00 Eligibility: Domestic institution/organization types listed above, including Federal laboratories, are eligible to submit K00 transition phase applications on behalf of F99 awardees. There is no limit on the number of K00 awardees that an organization may sponsor. Note that if the F99 awardee accepts a postdoctoral position in the NIH intramural research program or another federal agency, the postdoctoral phase (K00) will not be awarded, as federal employees are not eligible for NIH extramural grants. The postdoctoral phase will be then be supported directly by the federal agency offering the postdoctoral position.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations are not 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.

- <u>Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform)</u> 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.

- <u>eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123)</u> 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 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.

All PD(s)/PI(s) must be registered with <u>ORCiD (https://orcid.org/)</u>. 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 <u>ORCID topic in our eRA Commons online help (https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D 29).</u>

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 application, 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 applicant must have a baccalaureate degree and be currently enrolled as a graduate student in a PhD or equivalent research doctoral degree program (e.g., EngD, DNSc, DrPH, DSW, PharmD, ScD) in the biomedical, behavioral, or clinical sciences at a domestic institution. The applicant must be conducting neuroscience research in a topic area relevant to NIH Blueprint (https://neuroscienceblueprint.nih.gov/) mission-relevant areas and/or BRAIN Initiative (http://www.braininitiative.nih.gov/) research areas. Note that NIDCD participation is limited to BRAIN Initiative research areas only; NIDCD does not participate in the NIH Blueprint.

At the time of award, the applicant must be at the dissertation research stage of training and is expected to require 1-2 years to complete their PhD dissertation research training (F99 phase) before transitioning to mentored postdoctoral research training (K00 phase). At the time of application, the applicant will typically be in the third or fourth year of their graduate program. The applicant must show evidence of high academic performance in the sciences and commitment to a career as an independent neuroscience research scientist.

The D-SPAN F99/K00 award may not be used to support studies leading to the MD, DDS, or other clinical, health-professional degree (e.g., DC, DMD, DNP, DO, DPM, DVM, ND, OD, AuD). Students matriculated in a dual-degree program (e.g. MD/PhD, DO/PhD, DDS/PhD, or DVM/PhD) are not eligible for the F99/K00 program.

If an applicant begins a postdoctoral position or completes all PhD dissertation requirements before an F99 award is made, neither the F99 award nor the K00 award will be issued.

For the purpose of this announcement, institutions are encouraged to recruit potential student participants from diverse backgrounds (as defined in Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)), such as:

- A. Individuals from racial and ethnic groups that have been shown by the National Science Foundation to be underrepresented in health-related sciences on a national basis (see data at http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27)) and the report www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27)) and the report <a href="http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27)) and the report <a href="http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27)). The following racial and ethnic groups have been shown to be underrepresented in biomedical research: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders. In addition, it is recognized that underrepresentation can vary from setting to setting; individuals from racial or ethnic groups that can be demonstrated convincingly to be underrepresented by the grantee institution should be encouraged to participate in NIH programs to enhance diversity. For more information on racial and ethnic categories and definitions, see the OMB Revisions to the Standards for Classification of Federal Data on Race and Ethnicity (https://www.govinfo.gov/content/pkg/FR-1997-10-30/html/97-28653.htm (https://www.govinfo.gov/content/pkg/FR-1997-10-30/html/97-
- B. Individuals with disabilities, who are defined as those with a physical or mental impairment that substantially limits one or more major life activities, as described in the Americans with Disabilities Act of 1990, as amended (http://www.ada.gov/pubs/adastatute08.htm). See NSF data at, https://www.nsf.gov/statistics/2017/nsf17310/static/data/tab7-5.pdf (https://www.nsf.gov/statistics/2017/nsf17310/static/data/tab7-5.pdf).
- C. Individuals from disadvantaged backgrounds, defined as those who meet two or more of the following criteria:

 Students from low socioeconomic (SES) status backgrounds have been shown to obtain bachelor's and advanced degrees at significantly lower rates than students from middle and high SES groups (see https://nces.ed.gov/programs/coe/indicator_tva.asp (https://nces.ed.gov/programs/coe/indicator_tva.asp)), and are subsequently less likely to be represented in biomedical research. For background see Department of Education data at, https://nces.ed.gov/programs/coe/indicator_tva.asp), https://nces.ed.gov/programs/coe/indicator_tva.asp); https://nces.ed.
 - 1. Were or currently are homeless, as defined by the McKinney-Vento Homeless Assistance Act (Definition: https://nche.ed.gov/mckinney-vento/); (https://nche.ed.gov/mckinney-vento/));
 - Were or currently are in the foster care system, as defined by the Administration for Children and Families (Definition: https://www.acf.hhs.gov/cb/focus-areas/foster-care (https://www.acf.hhs.gov/cb/focus-areas/foster-care));
 - 3. Were eligible for the Federal Free and Reduced Lunch Program for two or more years (Definition: https://www.fns.usda.gov/school-meals/income-eligibility-guidelines (https://www.fns.usda.gov/school-meals/income-eligibility-guidelines));
 - Have/had no parents or legal guardians who completed a bachelor's degree (see https://nces.ed.gov/pubs2018/2018009.pdf);
 - 5. Were or currently are eligible for Federal Pell grants (Definition: https://www2.ed.gov/programs/fpg/eligibility.html); (https://www2.ed.gov/programs/fpg/eligibility.html));
 - 6. Received support from the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) as a parent or child (Definition: https://www.fns.usda.gov/wic/wic-eligibility-requirements)).

- 7. Grew up in one of the following areas: a) a U.S. rural area, as designated by the Health Resources and Services Administration (HRSA) Rural Health Grants Eligibility Analyzer (https://data.hrsa.gov/tools/rural-health (https://data.hrsa.gov/tools/rural-health)), or b) a https://www.gnates.gov/selousless-designated-Low-income and Health Professional Shortage Areas (<a href="https://www.gnates.gov/selousless-designated-Low-income.gov/selousless-designate
- D. Literature shows that women from the above backgrounds (categories A, B, and C) face particular challenges at the graduate level and beyond in scientific fields. (See, e.g., From the NIH: A Systems Approach to Increasing the Diversity of Biomedical Research

 Workforce https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5008902) /

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)).

Each candidate may submit one fellowship application at a time: An individual may not have two or more competing NIH individual fellowship applications pending review concurrently. A candidate for an NIH D-SPAN F99/K00 Award may not simultaneously submit or have an application pending for any other PHS fellowship award (e.g. F31 or any other PHS award that duplicates any of the provisions of the F99/K00 award).

Duration of Support

Individuals may not exceed the aggregate limit of support shown above in the Award Project Period (see Section II. Award Information).

Level of Effort

F99 awardees 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.

K00 awardees are required to have a full-time appointment at the applicant institution, and to commit a minimum of 9 person months (or 75% of their full-time professional effort at the applicant institution) to their career development and research training. K00 awardees may engage in other duties (e.g., other research, training, clinical and teaching activities) as part of the remaining 25% effort not covered by the award, as long as such duties do not interfere with or detract from the proposed career development program.

Sponsor

Before submitting the application, the applicant must identify an F99 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 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. 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 must work with the sponsor(s) in preparing the application.

Applicants are not required to identify a sponsor for the K00 phase at time of the initial F99/K00 application.

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 <u>SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=42000)</u>, 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.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicant organizations are asked to submit a letter of intent that includes the following information:

- · Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- · Names of primary sponsor and other key personnel
- · Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Michelle Jones-London, PhD

National Institute of Neurological Disorders and Stroke (NINDS)

Telephone: 301-451-7966

Email: NINDSDiversityTraining@mail.nih.gov (mailto: NINDSDiversityTraining@mail.nih.gov)

Page Limitations

All page limitations described in the SF424 Application Guide and the <u>Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=11133)</u> 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, with the following additional instructions:

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

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

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)

Biographical Sketch

Applicant

- Applicant must include the start date (month and year) of all education/training experiences.
- In the "Personal Statement" section, applicants should follow the instructions for "applicants for dissertation research awards" and include a description of their
 career goals, their intended career trajectory, and their interest in the specific areas of research supported by the NIH Neuroscience Blueprint or BRAIN Initiative.
 When relevant, applicants are encouraged to account for factors that affected past productivity.
- Under the section "Scholastic Performance," applicants should list undergraduate courses, but should not include undergraduate grades. Graduate courses and grades must be included.

Sponsor and Co-Sponsor(s)

• In the "Personal Statement" section, the sponsor and any co-sponsors should include a statement describing their past and current mentoring and training philosophy, including commitment to diversity and inclusion in their training environments.

PHS Fellowship Supplemental Form

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

- · Fellowship Applicant
- · Research Training Plan
- $\bullet \quad \text{Sponsor}(s), \ \text{Collaborator}(s), \ \text{and} \ \ \text{Consultant}(s);$
- 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:

Fellowship Applicant Section

Applicant's Background and Goals for Fellowship Training

This section should address both phases of the F99/K00.

- A. Doctoral Dissertation and Research Experience
 - · Follow instructions for "advanced graduate students"

B. Training Goals and Objectives

- Describe short- and long-term career goals that are integrated into a systematic plan that (1) shows a logical progression from prior research and training experiences to the research and career development experiences that will occur during the F99 and K00 periods and then to becoming a productive and independent neuroscience researcher; and (2) justifies the need for further career development to be a successful postdoc and subsequently become an independent investigator.
- For each phase, identify the skills, theories, conceptual approaches, etc., to be learned or enhanced during the award, including, as applicable, expertise in rigorous research design, experimental methods, quantitative approaches, and data analysis and interpretation. Explain how the plan will complement existing strengths as well as fill gaps in existing skills. If the K00 research direction is markedly different from the F99 research area, describe efforts and/or plans during the F99 phase training that provide preparation for the K00 research.
- · For each phase, discuss how the proposed research training plan will facilitate transition to the next career stage.

C. Activities Planned Under this Award

The activities planned under this award should be individually tailored and well-integrated with your research project. This should not just be a list of activities; provide justification for planned activities based on your goals and existing strengths and weaknesses. The plan and timeline should span the entire award period, e.g. both the F99 and K00 phases.

Describe, by year, the activities (research, coursework, professional development, etc.) you will be involved in during the proposed award. Estimate the
percentage of time to be devoted to each activity. The percentage should total 100 for each year.

- Describe the research skills and techniques that you intend to learn during the award period.
- Provide a timeline detailing the proposed research training, professional development, and other activities for the duration of the fellowship award. Detailed timelines of research activities involving animals, human subjects, or clinical trials are requested in other sections of the fellowship application and should not be included here. The timeline you provide here should be distinct from the Study Timeline in the PHS Human Subjects and Clinical Trials Information form.

Research Training Plan

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

Specific Aims: All applicants must use these two Specific Aims:

Specific Aim 1: The Dissertation Research Project.

Provide a detailed description of the overall dissertation research project, what has been accomplished to date (preliminary data may be included), and the research to be completed in the F99 phase.

Specific Aim 2: The Postdoctoral Research Direction.

Identify the research direction to be pursued for the K00 phase.

Research Strategy

Applicants should individually address the Significance and Approach for each Specific Aim.

Specific Aim 1:

Significance

Provide a thoughtful overview of the dissertation research, including the scientific question being addressed and its potential impact on the dissertation research field. The Research Strategy should offer a clearly stated rationale and hypothesis, go beyond just experimental details, and provide perspective about the work's expected outcomes and significance.

Approach

The Approach for this Aim should be organized into two sections:

- 1. A progress report on the dissertation research project thus far, including the approaches used, research outcomes obtained, and important methodologies learned and how they contribute to the long-term career goal;
- 2. A detailed research proposal for the work to be completed in the F99 phase, including experimental design, anticipated results, potential problems, alternative strategies, and potential follow-up studies. Highlight new technical and professional skills to be learned and their contribution to the long-term career goal. Applicants should outline research and career development milestones for the transition from the F99 phase of the award to the K00 award phase.

Specific Aim 2:

Significance

Describe a specific scientific question or observation that will be investigated. Explain the significance of and rationale for the K00 research direction. The postdoctoral research plan does not have to be a continuation or within scope of the predoctoral research but should have a logical connection to previous research experiences and must have relevance to participating NIH Blueprint research areas. Explain how this question or observation is related to the applicant's research interests and how this work will help advance this research direction.

Approach

Provide a general description of how the research will be conducted, including approaches and methodologies to be used, anticipated results, challenges that might arise and how to address them. Career and professional development skills to be acquired should also be detailed. Potential mentor(s) do not need to be identified, but a plan for identifying a mentor(s) should be included here, including specific attributes of the K00 mentor and features of the postdoctoral scientific environment that would benefit the proposed research and research training.

• 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 for F31 applications must be followed, with the following additional instructions:

Training Plan, Environment, Research Facilities

The research training plan for the F99 phase should be individualized for the applicant. This should not just be a list of activities; it should describe the applicant's strengths and gaps in needed skills, and outline how the training plan will capitalize on the applicant's strengths and fill any gaps to help them achieve their stated career goals.

- The F99 training plan should be coordinated with the applicant's Research Strategy and the goals and activities identified in the Applicant section.
- The plan should describe how the sponsor will facilitate the applicant's transition to the next stage of his/her career, including the search for the K00 mentor, and how the applicant's research and career development progress will be monitored and evaluated throughout the F99 phase, with specific milestones listed.
- The research environment and the availability and quality of needed research facilities and research resources (e.g., equipment, laboratory space, computing resources, subject populations) should be described for the F99 phase.
- 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.

Letters of Support from Collaborators, Contributors, and Consultants

Advisory committee members (if applicable): Signed statements must be provided by each member of the proposed advisory committee. These statements should
confirm their participation, describe their specific roles, and document the expertise they will contribute. Unless also listed as senior/key personnel, these
individuals do not need to provide their biographical sketches.

Institutional Environment and Commitment to Training Section

Description of Institutional Environment and Commitment to Training

In addition to the content described in the SF424 (R&R) Application Guide, institutions must include the Educational Information below.

Educational Information

- Describe the institution's graduate program in which the applicant is enrolled. This description should include the structure of the program, the required milestones and their usual timing, the number of courses, any teaching commitments or qualifying exams, and the average time to degree over the past 10 years.
- Describe the progress/status of the applicant in relation to the program's timeline, and the frequency and method by which the program formally monitors and evaluates a student's progress.
- Confirm that the applicant is in a PhD program in a neuroscience-relevant field (include month and year of entry into the PhD program) and has reached the dissertation phase (include month and year of transition to dissertation phase).
- Confirm that the applicant has 1-2 years from time of award before completion of their PhD (include month and year of anticipated graduation).
- · Provide the name of the primary sponsor or mentor and an affirmation of the institution's commitment to the applicant's training and research career goals
- Include the name of the individual providing this information at the end of the description. This information is typically provided by the director of the graduate program or the department chair.

Description of Candidate's Contribution to Program Goals: The sponsoring institution must provide a document on institutional letterhead that explains how the candidate's participation will further the goals of the fellowship program to promote diversity in health-related research. See the Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).

The Description of Candidate's Contribution to Program Goals" attachment must be dated and signed by an institutional official. In most cases, this will be the dean or the chairman of the department. The signature must appear over the signer's name and title at the end of the statement.

See instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=42000).

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 **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.

- · 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 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.

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.html?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to <u>Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128)</u> (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 <u>eRA Commons</u> (//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

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

date and time are subjected to the NIH Policy on Late Application Submission.

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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 <u>NIH Grants Policy Statement</u> (<u>///grants.nih.gov/grants/guide/url_redirect.htm?id=11120</u>). This 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 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 https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submission-guide/due-dates-and-submi

Important reminders:

All PD(s)/Pl(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 and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive 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. The review will also evaluate the research and career development plans for the K00 phase, emphasizing the need for the proposed career
development and the potential to lead to a productive, independent research career.

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

- Do the letters of reference provide evidence that the applicant has both a strong commitment to, and high potential for, becoming an independent research investigator?
- Are the applicant's academic record, prior training, and research experience of high quality?
- Does the applicant have the potential to become a successful independent investigator who will contribute to the neuroscience research field?
- Does the applicant demonstrate commitment to a neuroscience research career in the future?

Sponsors, Collaborators, and Consultants

- Are the research qualifications (including recent publications) of the sponsor(s) for the F99 phase, 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 interests of the candidate and the sponsor(s) in the F99 phase? 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 applicant's proposed research project and training for the duration of the F99 phase?
- 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?

- Have the applicant and sponsor(s) described an appropriate set of qualifications and characteristics for the mentor in the K00 career development phase of the award?
- 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 F99 research project of high scientific quality, and is it well integrated with the proposed training plan?
- Is the F99 research project consistent with the applicant's stage of research development, and relevant to his/her research career objectives?
- 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 proposed timeframe feasible to accomplish the proposed research training (F99) and transition to the career development phase (K00)?
- · Will the research experiences in the F99 phase prepare the applicant to successfully implement a postdoctoral research project for the K00 phase?
- Have the applicant and/or sponsor(s) outlined feasible research milestones for the transition from the fellowship phase of the award to the career development phase?
- Is the research direction outlined for the career development (K00) phase appropriate to the applicant's anticipated stage of development and as a vehicle for developing the research skills described in the career development plan?
- 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 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 training plan in the fellowship phase provide an appropriate foundation for transition to the career development phase of the award?
- Are adequate plans described for monitoring and evaluating the candidate's research and career development progress throughout the F99 training period?
- Have the applicant and sponsor(s) outlined appropriate milestones in terms of professional and career skills for transition to the career development phase of the award?

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 adequate evidence provided that the F99-sponsoring institution is strongly committed to fostering the applicant's development and preparation for transition to the K00 Phase?
- Are the research facilities, resources (e.g., equipment, laboratory space, computer time, subject populations), and training opportunities (e.g. seminars, workshops, professional development opportunities) adequate and appropriate?
- Is the institutional environment for the 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 <u>Guidelines for the Review of Human Subjects (//grants.nih.gov/grants/guide/url_redirect.htm?id=11175)</u>.

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 <u>Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.htm?id=11174)</u>.

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).

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.

Revisions

Not Allowed

Renewals

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

Not Applicable.

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

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) convened by NINDS, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria (file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1._Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection 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.

Appeals (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) of initial peer review will not be accepted for applications submitted in response to this FOA. Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Neurological Disorders and Stroke Council. 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 <u>eRA Commons</u> (//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 <u>NIH Grants Policy Statement</u> (//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 recipient's business official.

Awardees must comply with any funding restrictions described in <u>Section IV.5. Funding Restrictions</u>. 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.

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Any application awarded in response to this FOA will be subject to terms and conditions found on the <u>Award Conditions and Information for NIH Grants</u> (<u>///grants.nih.gov/grants/guide/url_redirect.htm?id=11158</u>) 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 <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120)</u> as part of the NoA. For these terms of award, see the <u>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, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at <u>Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158)</u>.</u>

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/understanding/section1557/index.html) and

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) and 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).
- 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.https://www.https://www.https://www.https://www.https://www.https://www.https://www.https://www.https://www.https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf
 https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf
 <a href="ht
- 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/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) or call 1-800-368-1019 or TDD 1-800-537-7697.

Transition to the Postdoctoral Career Development K00 Phase

The F99/K00 award is intended to facilitate successful transition to the postdoctoral career stage. Consequently, a requirement for initiation of the K00 phase is successful completion of the Ph.D. degree. Applicants are encouraged to apply for postdoctoral positions at departments and institutions different from where they conducted their doctoral research. It is important for all applicants, but especially so for applicants who intend to stay at the predoctoral phase institution for the postdoctoral phase, to provide a plan by which they will separate scientifically from their Ph.D. sponsor.

The transition from the predoctoral phase to the postdoctoral phase is intended to be continuous in time and, except in unusual circumstances, the NIH Blueprint will not extend the F99 phase. Transition from the predoctoral (F99) phase to the postdoctoral (K00) phase is not automatic. To activate the K00 phase of the grant, individuals must have been offered and accepted a full-time postdoctoral position to carry out neuroscience-focused research. Upon starting the K00 phase of the award, the F99 phase of the award is terminated.

Prospective applicants are strongly encouraged to contact their Program Official as soon as a plan to assume a postdoctoral position develops, and not later than 6 months prior to the proposed start date of the K00 award. At that time, individuals should discuss plans for transition to, and application for, the K00 phase with their NIH program official.

The K00 postdoctoral phase institution must submit the materials on behalf of the candidate for the K00 award, no later than 3 months prior to the proposed start date of the K00 award. The institution's Authorized Organizational Representative will email the application in PDF format to the NIH Blueprint Scientific/Research Contacts listed in Section VII. The K00 application will be evaluated by NIH Blueprint program staff for completeness and responsiveness to the program.

An eligible K00 institution must have appropriate infrastructure to support the proposed research program and a history of external research funding. Foreign institutions are not eligible. Applicants may apply for neuroscience-focused postdoctoral positions within the NIH intramural research program (IRP). However, should the individual accept such a position in the IRP, the postdoctoral phase of the award will not be activated. This is because NIH intramural scientists are supported directly by NIH intramural funds and are not eligible for NIH extramural grant awards. F99 fellows who accept a postdoctoral position in the IRP will be required to submit a final progress report and a final evaluation statement by the primary F99 mentor instead of a K00 application.

Applicants who are approved to transition will receive a Notice of Award reflecting the new K00 activity code, the dollar amount, and the new grantee organization (if applicable). Candidates who are not approved to transition will receive written notification from the NIH awarding component communicating the rationale for the disapproval. This notification typically will be sent within 60 days of receipt of the K00 application.

Although the financial plans of NINDS provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds.

Instructions for the K00 Transition Award

F99 awardees wishing to submit a K00 transition application must follow the Career Development (K) Instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise, as described below:

The K00 Transition Application will include the following components:

- A new cover page signed by the K00 phase institutional representative;
- · A Final Progress Report for the F99 phase;
- A final evaluation statement by the F99 primary sponsor;
- Updated K00 Project Summary and Abstract, Project Narrative, Bibliography & References Cited, Facilities & Other Resources, and Equipment sections;
- · Biographical sketches
- Mentor's personal statement should include a description of their past and current mentoring and training philosophy, including commitment to diversity and inclusion in their training environments:
- Detailed budget pages for a non-modular budget: K00 budgets consist of salary and fringe benefits, other program related expenses, and indirect costs, as
 described in Part II, Section II of this funding opportunity announcement. Other costs are not allowed;
- Updated sections of the PHS Career Development Award Supplemental Form, which should include:
- · A new Candidate Section
 - In addition to the K application instructions, describe the applicant's current and long-term research and career objectives.
 - Present a scientific history that shows a logical progression from the applicant's prior research and training experiences (including the F99 phase) to the
 training and research experiences proposed for the K00 phase of the award, which will ultimately lead to an independent research career.
 - Describe how the applicant plans to separate scientifically from his/her F99 and K00 sponsors.
 - Timeline with milestones for the research and career development experiences proposed.
 - Describe how the research training in the K00 phase of the award, combined with all previous research training and experiences, will provide the tools,
 skills and knowledge necessary to subsequently pursue an independent research career.
- An updated Research Plan section: The Specific Aims should be updated to reflect current plans for the K00 phase and the updated Research Strategy should be described in less than 6 pages:
- A new Mentor, Co-Mentor, Consultant, Collaborators Section that includes a plan for fostering the candidate's research career independence and transitioning the candidate to the next stage of his/her career by the end of the project award period. The mentor(s) should describe previous experience as a mentor, including the career levels of mentees (e.g., graduate students, career development awardees, postdoctoral students), number of individuals mentored, and their career outcomes. The role of each mentor, co-mentor, consultant and collaborator (as applicable) in the K00 and commitment to the candidate should be clearly described. Expand on efforts by the mentor/co-mentor to enhance diversity and promote inclusion through an environment that promotes the success of individuals with a wide variety of backgrounds and perspectives. It is acceptable to take a position with a mentor that has limited training experience, but in this case the candidate should integrate a co-mentor with a strong, successful track record as a mentor into his/her research training;
 - If the candidate is proposing to gain experience in a clinical trial as part of his or her research training, the mentor or co-mentor must include a statement
 to document leadership of the clinical trial including source of funding, NCT# and appropriate expertise to guide the candidate in any proposed clinical
 trials research experience.

An updated Environment and Institutional Commitment to the Candidate Section:

- Provide a statement of commitment to the applicant and his/her career goal of developing into a productive, independent neuroscience-focused research investigator, i.e., conducting the proposed mentored neuroscience research and career development activities during the K00 phase.
- Provide assurance that the candidate will be able to devote a minimum of 9 person-months (75% of full-time professional effort) to the development of his/her research program. The remaining effort should be devoted to activities related to the development of the candidate's career as an independent scientist.
- Provide assurance that the research facilities, resources, and training opportunities will be available for the applicant's planned career development and research programs during the K00 award period.
- Provide assurance that appropriate time and support for any proposed mentor(s) and/or other staff consistent with the career development plan will be
 available during the K00 award period.
- Describe efforts by the institution to enhance diversity and promote inclusion through an environment that promotes the success of individuals with a wide
 variety of backgrounds and perspectives (i.e. institutional and departmental environments in which trainees from all backgrounds feel integrated into and
 supported by the biomedical community).
- · Updated Protections for Human Subjects and Inclusion of Women, Minorities and Individuals Across the Lifespan (as appropriate);
- Updated Other Research Plan Sections (as appropriate), including:
 - Vertebrate Animals;
 - Select Agent Research;
 - · Resource Sharing Plans;
 - · Authentication of Key Biological and/or Chemical Resources; and
 - Updated Biohazards
 - Responsible Conduct of Research.

Termination of the F99 award phase

If the transition from the F99 phase to the K00 phase at an extramural institution occurs prior to the scheduled end date of the F99 award phase, then a revised Notice of Award will be issued to terminate the F99 phase award. Institutional Allowances: Carry-over of unspent funds from a partially completed year in the F99 phase into the K00 phase is not permitted.

Leave Policies

D-SPAN awardees follow the policies as outlined in NOT-OD-18-154 Summary of Leave, Part-Time and Extension Policies Available to Ruth L. Kirschstein National Research Service Awards (NRSA) Trainees and Fellows.

Cooperative Agreement Terms and Conditions of Award

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

F99 Phase 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.

K00 Phase Awardees must complete the "Inventions and Patents" section when submitting the Research Performance Progress Report (RPPR) for the K00 application renewal.

3. Reporting

When multiple years are involved, awardees will be required to submit the <u>Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm)</u> 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.
- · At the conclusion of a fellowship, the fellow must submit a Termination Notice (PHS 416-7) via pdf through email to the NIH within 30 days of termination.

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.

Within ten years of making awards under this program, NIH will assess the program's overall outcomes, gauge its effectiveness in enhancing diversity, and consider whether there is a continuing need for the program. Upon the completion of this evaluation, NIH will determine whether to (a) continue the program as currently configured, (b) continue the program with modifications, or (c) discontinue the program.

The overall evaluation of the program will be based on metrics that will include, but are not limited to, the following:

For the F99 phase (graduate students):

- Successful completion of a STEM graduate program
- Subsequent participation in a formal research training or career development program in a STEM field
- Subsequent participation in research or employment in a STEM field
- · Authorship of scientific publications in a STEM field
- Subsequent independent research grant support from NIH or another source
- Transition to the K00 phase

For the K00 phase (postdoctorates):

- Subsequent participation in a formal research training or career development program in a STEM field
- Subsequent participation in research or employment in a STEM field
- · Authorship of scientific publications in a STEM field
- · Subsequent independent research grant support from NIH or another source

Section VII. Agency Contacts

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

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/ (//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: <u>GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov)</u> (preferred method of contact)

Telephone: 301-637-3015

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)

Michelle Jones-London, PhD

National Institute of Neurological Disorders and Stroke (NINDS)

Telephone: 301-451-7966

Email: jonesmiche@ninds.nih.gov (mailto:jonesmiche@ninds.nih.gov)

Lauren Ullrich, PhD

National Institute of Neurological Disorders and Stroke (NINDS)

Telephone: 301-451-7964

Email: <u>lauren.ullrich@nih.gov (mailto:lauren.ullrich@nih.gov)</u>

Peer Review Contact(s)

Chief, Scientific Review Branch

National Institute of Neurological Disorders and Stroke (NINDS)

Telephone: 301-496-9223

Email: nindsreview.nih.gov@mail.nih.gov (mailto:nindsreview.nih.gov@mail.nih.gov)

Financial/Grants Management Contact(s)

Chief Grants Management Officer

National Institute of Neurological Disorders and Stroke (NINDS)

Email: ChiefGrantsManagementOfficer@ninds.nih.gov (mailto:ChiefGrantsManagementOfficer@ninds.nih.gov)

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 awards are encouraged to consider applying for an extramural LRP award.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 63A and 45 CFR Part 75.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?04-23-21)

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).