Part 1. Overview Information

National Institutes of Health (NIH (http://www.nih.gov)) Participating Organization(s) **Components of Participating Organizations** National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/) **Funding Opportunity Title** NIDDK Research Education Program Utilizing Stimulating Peripheral Activity to Relieve Conditions (SPARC) - Generated Resources (R25 Clinical Trial Not Allowed) R25 (//grants.nih.gov/grants/funding/ac search results.htm? **Activity Code** text curr=r25&Search.x=0&Search.y=0&Search Type=Activity) Education Projects New **Announcement Type Related Notices** None **Funding Opportunity Announcement (FOA)** RFA-DK-20-020 Number None **Companion Funding Opportunity Number of Applications** See Section III. 3. Additional Information on Eligibility. 93.847 **Catalog of Federal Domestic Assistance** (CFDA) Number(s) **Funding Opportunity Purpose**

The NIH Research Education Program (R25) supports research education activities in the mission areas of the NIH. The overarching goal of this R25 program is to support educational activities that complement and/or enhance the training of a workforce to meet the nation's biomedical, behavioral and clinical research needs.

To accomplish the stated over-arching goal, this FOA will support creative educational activities with a primary focus on:

- Research Experiences
- · Courses for Skills Development

This Funding Opportunity Announcement (FOA) invites applications to establish research programs for qualified graduate students, post-doctoral fellows, medicalresidents, biomedical engineers, and clinical fellows to engage in neuroscience research experiences relevant to the mission of NIDDK and its partnership with the Common Fund program, Stimulating Peripheral Activity to Relieve Conditions (SPARC). The intent is to leverage this partnership to provide resources for short-term research experiences that would necessarily use SPARC-generated resources (datasets/maps/models) as the foundation for the research experience in conjunction with educational activities that may be combined with hands-on computational or 'wet lab' projects. The goal is that the research experiences will be impactful and ideally develop new skills and produce new knowledge that could sustain future NIDDK-funded research careers.

Key Dates

Posted Date	October 19, 2020
Open Date (Earliest Submission Date)	November 22, 2020
Letter of Intent Due Date(s)	November 22, 2020, October 9, 2021, and October 9, 2022.
Application Due Date(s)	December 22, 2020, November 9, 2021, and November 9, 2022.
	All applications are due by 5:00 PM local time of applicant organization. All <u>types of non-AIDS</u> <u>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	February-March 2021, February-March 2022, and February-March 2023.
Advisory Council Review	May 2021, May 2022, and May 2023.
Earliest Start Date	July 2021, July 2022, and July 2023.
Expiration Date	November 10, 2022
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from 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 <u>Section IV</u>. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

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

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

Apply Online Using ASSIST

- 2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
- 3. Use <u>Grants.gov (https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-DK-20-020)</u>
 Workspace to prepare and submit your application and <u>eRA Commons (http://public.era.nih.gov/commons/)</u> to track your application.

Table of Contents

Part 1. Overview Information

Key Dates

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Section II. Award Information
Other Award Budget Information

Section III. Eligibility Information

Section IV. Application and Submission Information

Section V. Application Review Information

Section VI. Award Administration Information

Section VII. Agency Contacts
Section VIII. Other Information

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The NIH Research Education Program (R25) supports research educational activities that complement other formal training programs in the mission areas of the NIH Institutes and Centers. The overarching goals of the NIH R25 program are to: (1) complement and/or enhance the training of a workforce to meet the nation's biomedical, behavioral and clinical research needs; (2) encourage individuals from diverse backgrounds, including those from groups underrepresented in the biomedical and behavioral sciences, to pursue further studies or careers in research; (3) help recruit individuals with specific specialty or disciplinary backgrounds to research careers in biomedical, behavioral and clinical sciences; and (4) foster a better understanding of biomedical, behavioral and clinical research and its implications.

The overarching goal of this R25 program is to support educational activities that complement and/or enhance the training of a workforce to meet the nation's biomedical, behavioral and clinical research needs.

To accomplish the stated over-arching goal, this FOA will support creative educational activities with a primary focus on

- Courses for Skills Development: In computational methodologies relevant to NIDDK areas of interest.
- Research Experiences: For graduate students, postdoctoral fellows, medical residents, biomedical engineers, and clinical fellows to provide new knowledge for NIDDK-funded research careers

The objective of this FOA is to provide exposure to computational methodologies in order to attract individuals to research in computational modeling of the anatomy and physiology of tissues and organs that manifest conditions and diseases relevant to the missions of the NIDDK. This FOA encourages applications from organizations that propose creative and innovative research education programs of interest to the NIDDK. The over-arching goal of this NIDDK R25 program is to leverage NIDDK's current partnership with SPARC to support short term research experiences and accompanying educational activities incomputational/physiological/anatomical neurobiology to graduate students, postdoctoral fellows, medical residents, biomedical engineers, and clinical fellows who are: 1) already conducting NIDDK-related research, though not necessarily neurobiology, and 2) trained neurobiologists who would be new to NIDDK research space. Explicit in this concept is the requirement that SPARC resources (datasets/maps/models) would be foundational to proposed research experiences and accompanying educational activities and only applications relating to structures of interest to NIDDK, such as stomach, colon, pancreas, adipose tissue or organs in the urinary tract, would be considered responsive. The SPARC-generated resources are available through a portal (http://sparc.science/() that contains curated data sets of anatomical, physiological, and gene expression data for NIDDK-relevant organs and tissues that span species. The portal also features an online computing platform that hosts computational models developed by SPARC teams and enables sharing, execution, and coupling of the models to facilitate in silico studies. Provided examples range from the use of machine learning to predict compound action potentials to an electrophysiological simulation of enteric neurons. Information on funded SPARC projects can be found at: https://commonfun

- The program must include demonstrable exposure to computational methodologies in the form of didactic lectures, seminars, and/or small group discussions, supplemented by individual tutorials, where appropriate. The goal of the educational exposure is enhance the likelihood that the short-term research experiences using the SPARC resources as educational tools will yield impactful outcomes. The resources available through the SPARC portal include a collection of 2D and 3D maps that transform the data into interactive visualizations revealing the anatomy and functional relationships of the autonomic nerves and the organs that they innervate to facilitate analysis of retrospectively or prospectively collected in vivo or in vitro experimental data. The portal also features an online computing platform, o2S2PARC (https://osparc.io/), which hosts computational models developed by SPARC teams and enables sharing, execution, and coupling of the models to facilitate in silico studies. To view a webinar introducing the o2S2PARC platform https://www.youtube.com/watch?v=vrdVealYydE (https://www.youtube.com/watch?v=vrdVealYydE (https://www.youtube.com/watch?v=vrdVealYydE). Documentation on o2S2PARC is available here: https://docs.osparc.io (https://docs.osparc.io/) and information to set up a SPARC account can be requested by emailing support@osparc.io (mailto:support@osparc.io).
- The projects can also be combined with laboratory experiences, in silico prediction algorithms, or existing databases, data repositories, or knowledgebases. As an example, faculty with relevant experience in peripheral nervous system neuroanatomy/neurophysiology of the gastrointestinal or urinary tract could develop a short-term research experience involving faculty with expertise in computational biology to interrogate sex-specific variabilities in the neural circuitry of the gastrointestinal or urinary tract related to visceral pain or, to model responses to interventional neuromodulation in NIDDK-relevant diseases or conditions. The research experience may be collaborative among individuals or team-based and participants will have the opportunity to submit datasets to SPARC for curation to be made available to the public.

Research education programs may complement ongoing research training and education occurring at the applicant institution, but the proposed educational experiences must be distinct from those training and education programs currently receiving Federal support. R25 programs may augment institutional research training programs (e.g., T32, T90) but cannot be used to replace or circumvent Ruth L. Kirschstein National Research Service Award (NRSA) programs.

See <u>Section VIII. Other Information</u> for award authorities and regulations.

Section II. Award Information

Funding Instrument	Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
Application Types Allowed	New Resubmission The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.
Clinical Trial?	Not Allowed: Only accepting applications that do not propose clinical trial(s). 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	NIDDK intends to commit \$260,000 in FY2021 to fund 2 awards.
Award Budget	Budgets are limited to \$120,000 per year in direct costs.
Award Project Period	The maximum project period is 5 years.

Other Award Budget Information

Personnel Costs

Individuals designing, directing, and implementing the research education program may request salary and fringe benefits appropriate for the person months devoted to the program. Salaries requested may not exceed the levels commensurate with the institution's policy for similar positions and may not exceed the congressionally mandated cap. (If mentoring interactions and other activities with participants are considered a regular part of an individual's academic duties, then any costs associated with the mentoring and other interactions with participants are not allowable costs from grant funds).

https://grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-020.html

Participant Costs

Participants may be paid if specifically required for the proposed research education program and sufficiently justified. Participant costs must be itemized in the proposed budget.

Allowable participant costs depend on the educational level/career status of the individuals to be selected to participate in the program.

While generally not an allowable cost, with strong justification, participants in the research education program may receive per diem unless such costs are furnished as part of the registration fee. Participants may also receive funds to defray partial tuition and other education-related expenses.

Expenses for foreign travel must be exceptionally well justified.

Individuals supported by NIH training and career development mechanisms (K, T, or F awards) may receive, and indeed are encouraged to receive, educational experiences supported by an R25 program, as participants, but may not receive salary or stipend supplementation from a research education program.

Because the R25 program is not intended as a substitute for an NRSA institutional training program (e.g., T32), costs to support full-time participants (supported for 40 hours/week for a continuous, 12-month period) are not allowable.

Other Program-Related Expenses

Consultant costs, equipment, supplies, travel for key persons, and other program-related expenses may be included in the proposed budget. These expenses must be justified as specifically required by the proposed program and must not duplicate items generally available at the applicant institution.

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees and expenditures for equipment), rather than on the basis of a negotiated rate agreement.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
 In this (Nation American Tribe)
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and educational resources that can contribute to the planned program.

Institutions with existing Ruth L. Kirschstein National Research Service Award (NRSA) institutional training grants (e.g., T32) or other Federally funded training programs may apply for a research education grant provided that the proposed educational experiences are distinct from those training programs receiving federal support. In many cases, it is anticipated that the proposed research education program will complement ongoing research training occurring at the applicant institution.

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 <u>defined in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11118)</u>, **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.
- <u>System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/)</u> 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 (http://www.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.

RFA-DK-20-020: NIDDK Research Education Program Utilizing Stimulating Peripheral Activity to Relieve Conditions (SPARC) - Generated Resources (R25 Clinical Trial Not Allowed)

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

The PD/PI should be an established investigator in the scientific area in which the application is targeted and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. The PD/PI will be expected to monitor and assess the program and submit all documents and reports as required.

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

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

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)).

Program Faculty

Researchers from diverse backgrounds, including racial and ethnic minorities, persons with disabilities, and women are encouraged to participate as preceptors/mentors. Mentors should have research expertise and experience relevant to the proposed program. Mentors must be committed to continue their involvement throughout the total period of the mentee's participation in this award.

Participants

Unless strongly justified on the basis of exceptional relevance to NIH, research education programs should be used primarily for the education of U.S. citizens and permanent residents.

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 instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide

(//grants.nih.gov/grants/guide/url_redirect.htm?id=12000) 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 will not be reviewed.

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 applicants 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 other key personnel
- Participating institution(s)
 Number and title of this full
- Number and title of this funding opportunity

The letter of intent should be sent to

John Connaughton, Ph.D.

Chief, Scientific Review Branch

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Telephone: 301-594-7797

Email: NIDDKLetterofintent@mail.nih.gov (mailto:NIDDKLetterofintent@mail.nih.gov?subject=RFA-DK-20-020)

Page Limitations All page limitations describe

All page limitations described in the SF424 Application Guide and the <u>Table of Page Limits (https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm#train)</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

Follow all instructions provided in the SF424 (R&R) Application Guide.

SF424(R&R) Project/Performance Site Locations

Follow all instructions provided in the SF424 (R&R) Application Guide.

SF424(R&R) Other Project Information Component

Follow all instructions provided in the SF424 (R&R) Application Guide with the following additional modifications:

Facilities & Other Resources. Describe the educational environment, including the facilities, laboratories, participating departments, computer services, and any other resources to be used in the development and implementation of the proposed program. List all thematically related sources of support for research training and education following the format for Current and Pending Support.

Other Attachments: Advisory_Committee.pdf Please name your file "Advisory_Committee.pdf". An Advisory Committee is not a required component of a Research Education program. However, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory Committee to monitor progress of the research education program. The composition, roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will evaluate the overall effectiveness of the program. Proposed Advisory Committee members should be named in the application if they have been invited to participate at the time the application is submitted.

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

Follow all instructions provided in the SF424 (R&R) Application Guide.

R&R Budget

Follow all instructions provided in the SF424 (R&R) Application Guide with the following additional modifications:

- Include all personnel other than the PD(s)/PI(s) in the Other Personnel section, including clerical and administrative staff.
- Use the section on Participant Support Costs to include all allowable categories of funds requested to support participants in the program.

PHS 398 Cover Page Supplement

Follow all instructions provided in the SF424 (R&R) Application Guide.

PHS 398 Research Plan

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

Research Strategy

The **Research Strategy** section must be used to upload the **Research Education Program Plan**, which must include the following components described below:

- Proposed Research Education Program
- Program Director/Principal Investigator
- Program Faculty
- Program Participants
- Institutional Environment and Commitment

RFA-DK-20-020: NIDDK Research Education Program Utilizing Stimulating Peripheral Activity to Relieve Conditions (SPARC) - Generated Resources (R25 Clinical Trial Not Allowed)

- Diversity Recruitment Plan
- Plan for Instruction in the Responsible Conduct of Research
- Evaluation Plan
- Dissemination Plan

Research Education Program Plan

Proposed Research Education Program. While the proposed research education program may complement ongoing research training and education occurring at the applicant institution, the proposed educational experiences must be distinct from those research training and research education programs currently receiving federal support. When research training programs are on-going in the same department, the applicant organization should clearly distinguish between the activities in the proposed research education program and the research training supported by the training program.

Applicants should identify any special activities that are dedicated to participants, including seminars; formal presentations by participants of their research results; informal opportunities for participants to interact with other participants and faculty; workshops; etc. Provide details of overall program administration. For the purposes of this FOA, the development or implementation of hands-on training in computational methodologies that use SPARC generated resources must be described in the application. The required educational activities accompanying the research experiences may include didactic lectures, seminars, and small group discussions, supplemented by individual tutorials, where appropriate. Explain how the development and implementation of the research experiences and accompanying educational activities are linked to the purpose and objectives of the program and to the potential research career development of enrolled participants in computational neurobiology.

Program Director/Principal Investigator. Describe arrangements for administration of the program. Provide evidence that the Program Director/Principal Investigator is actively engaged in research and/or teaching in an area related to the mission of NIH, and can organize, administer, monitor, and evaluate the research education program. For programs proposing multiple PDs/PIs, describe the complementary and integrated expertise of the PDs/PIs, their leadership approach, and governance appropriate for the planned project.

Program Faculty. Researchers from diverse backgrounds, including racial and ethnic minorities, persons with disabilities, and women are encouraged to participate as program faculty. Faculty should have research expertise and experience relevant to the proposed program and demonstrate a history of, or the potential for, their intended roles. Participating institution(s) should have faculty with established research programs who are interested and willing to provide mentorship to students.

Program Participants. Applications must describe the intended participants, and the eligibility criteria and/or specific educational background characteristics that are essential for participation in the proposed research education program. Identify the career levels for which the proposed program is planned. Provide details about the pool of expected participants, their qualifications, recruitment strategies and sources of applicant pool, etc. Graduate students, postdoctoral fellows, medical residents, biomedical engineers, and clinical fellowswho are open to considering a career in basic or clinical NIDDK-related neuroscience or from scientific disciplines such as engineering, informatics, computer science, and computational sciences that could be applied to NIDDK areas of interest should be targeted. Include information on any advertising strategies to be used. Indicate which of these participant groups will be targeted. Comment on the size of the candidate pool expected, note any other institutional programs that might compete for this pool, and describe strategies for addressing this competition.

Institutional Environment and Commitment. Describe the institutional environment, reiterating the availability of facilities and educational resources (described separately under "Facilities & Other Resources"), that can contribute to the planned Research Education Program. Evidence of institutional commitment to the research educational program is required. A letter of institutional commitment must be attached as part of Letters of Support (see below). Appropriate institutional commitment should include the provision of adequate staff, facilities, and educational resources that can contribute to the planned research education program.

Recruitment Plan to Enhance Diversity (NOT-OD-20-031 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)): Every facet of the United States scientific research enterprise—from basic laboratory research to clinical and translational research to policy formation—requires superior intellect, creativity and a wide range of skill sets and viewpoints . NIH's ability to help ensure that the nation remains a global leader in scientific discovery and innovation is dependent upon a pool of highly talented scientists from diverse backgrounds who will help to further NIH's mission.

Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and participants from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust.

In spite of tremendous advancements in scientific research, information, educational and research opportunities are not equally available to all. NIH encourages institutions to diversify their student and faculty populations to enhance the participation of individuals from groups that are underrepresented in the biomedical, clinical, behavioral and social sciences, 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 (http://www.nsf.gov/statistics/showpub.cfm?TopID=28">http://www.nsf.gov/s

(http://www.nsf.gov/statistics/women/)). 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 this program. 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)).

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 <u>Americans with Disabilities Act of 1990, as amended (http://www.ada.gov/pubs/adastatute08.htm)</u>. 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

- 1. Were or currently are homeless, as defined by the McKinney-Vento Homeless Assistance Act (Definition: https://nche.ed.gov/mckinney-vento/);
- 2. 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-quidelines));
- 4. Have/had no parents or legal guardians who completed a bachelor's degree (see https://nces.ed.gov/pubs2018/2018009.pdf (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 (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 (<a href="https://data.hr
- (https://www.qhpcertification.cms.gov/s/LowIncomeandHPSAZipCodeListingPY2020.xlsx?v=1) (qualifying zipcodes are included in the file). Only one of the two possibilities in #7 can be used as a criterion for the disadvantaged background definition.

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), and are subsequently less likely to be represented in biomedical research. For background see

Department of Education data at, https://nces.ed.gov/ (https://nces.ed.gov/programs/coe/indicator_tva.asp (https://nces.ed.gov/pro

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/ (<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PM

New applications must include a description of plans to enhance recruitment, including the strategies that will be used to enhance the recruitment of <u>prospective participants</u> from underrepresented backgrounds and may wish to include data in support of past accomplishments.

Applications lacking a diversity recruitment plan will not be reviewed.

Plan for Instruction in the Responsible Conduct of Research. All applications must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). The plan must address the five, required instructional components outlined in the NIH policy: 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 program faculty in the instruction; 4) Duration of Instruction - the number of contact hours of instruction, taking into consideration the duration of the program; and 5) Frequency of Instruction - instruction must occur during each career stage and at least once every four years. See also NOT-OD-10-019

(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html). The plan should be appropriate and reasonable for the nature and duration of the proposed program. Renewal (Type 2) applications must, in addition, describe any changes in formal instruction over the past project period and plans to address any weaknesses in the current instruction plan. All participating faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period must be named in the application.

RFA-DK-20-020: NIDDK Research Education Program Utilizing Stimulating Peripheral Activity to Relieve Conditions (SPARC) - Generated Resources (R25 Clinical Trial Not Allowed)

Applications lacking a plan for instruction in responsible conduct of research will not be reviewed.

Evaluation Plan. Applications must include a plan for evaluating the activities supported by the award. The application must specify baseline metrics (e.g., numbers, educational levels, and demographic characteristics of participants), as well as measures to gauge the short or long-term success of the research education award in achieving its objectives. Wherever appropriate, applicants are encouraged to obtain feedback from participants to help identify weaknesses and to provide suggestions for improvements.

Dissemination Plan. A specific plan must be provided to disseminate nationally any findings resulting from or materials developed under the auspices of the research education program, e.g., sharing course curricula and related materials via web postings, presentations at scientific meetings, workshops.

Letters of Support: A letter of institutional commitment must be attached as part of the Letters of Support (see above): "Institutional Environment and Commitment".

Resource Sharing Plans

Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The following modifications also apply: resource sharing includes datasets submitted to the SPARC portal and or models submitted to the online computing platform, <u>o2S2PARC (https://osparc.io/)</u>, which hosts computational models developed by SPARC teams and enables sharing, execution, and coupling of the models to facilitate in silico studies.

When relevant, applications are expected to include a software dissemination plan if support for development, maintenance, or enhancement of software is requested in the application. There is no prescribed single license for software produced. However, the software dissemination plan should address, as appropriate, the following goals:

- Software source code should be freely available to biomedical researchers and educators in the non-profit sector, such as institutions of
 education, research institutions, and government laboratories. Users should be permitted to modify the code and share their
 modifications with others.
- The terms of software availability should permit the commercialization of enhanced or customized versions of the software, or incorporation of the software or pieces of it into other software packages.
- To preserve utility to the community, the software should be transferable such that another individual or team can continue development in the event that the original investigators are unwilling or unable to do so.

Appendix

Only limited Appendix materials are allowed. Follow the instructions for the Appendix as described in the SF424 (R&R) Application Guide.

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.

Delayed Onset Study

Note: <u>Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy)</u> 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.

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

<u>Part I. Overview Information</u> 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 <u>Federal holiday (https://www.opm.gov/policy-data-oversight/snow-dismissal-procedures/federal-holidays/)</u>, 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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123)</u>, NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

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

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

5. Intergovernmental Review (E.O. 12372)

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

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url redirect.htm?id=11120).

Pre-award costs are allowable only as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11143).

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. <u>Section III. Eligibility Information</u> contains information about registration.

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

Important reminders:

All PD(s)/PI(s) 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 <u>components of participating organizations</u>, 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:

RFA-DK-20-020: NIDDK Research Education Program Utilizing Stimulating Peripheral Activity to Relieve Conditions (SPARC) - Generated Resources (R25 Clinical Trial Not Allowed)

The goal of this R25 program is to support educational activities that establish research programs for qualified graduate students, post-doctoral fellows, medical residents, biomedical engineers, and clinical fellows to engage computational neuroscience research experiences relevant to the mission of NIDDK and its partnership with the Common Fund program, Stimulating Peripheral Activity to Relieve Conditions (SPARC). The intent is to leverage this partnership to provide resources for short-term research training experiences that would necessarily use SPARC-generated resources

(datasets/maps/models) as a foundation for the research experiences, but may be combined with hands-on computational or wet lab projects.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to strongly advance research education by fulfilling the goal of this R25 Education Program, in consideration of the following review criteria and additional review criteria, as applicable for the project proposed.

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.

Significance

Does the proposed program address a key audience and an important aspect or important need in research education? Is there convincing evidence in the application that the proposed program will significantly advance the stated goal of the program?

Specific to this FOA: If the aims of the program are achieved, will it significantly influence participants' skills in applying computational methodologies to SPARC generated resources relevant to NIDDK areas of interest?

Investigator(s)

Is the PD/PI capable of providing both administrative and scientific leadership to the development and implementation of the proposed program? Is there evidence that an appropriate level of effort will be devoted by the program leadership to ensure the program's intended goal is accomplished? If applicable, is there evidence that the participating faculty have experience in mentoring students and teaching science? If applicable, are the faculty good role models for the participants by nature of their scientific accomplishments? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Specific to this FOA: If applicable, does the participating faculty have expertise and experience relevant to the proposed program and the mission of NIDDK? Is the makeup of the Advisory Committee suitable? Are the named members committed to providing oversight and input, and to monitoring and evaluating the overall effectiveness of the program? Is there evidence that the participating faculty will provide quality educational experiences?

Innovation

Taking into consideration the nature of the proposed research education program, does the applicant make a strong case for this program effectively reaching an audience in need of the program's offerings? Where appropriate, is the proposed program developing or utilizing innovative approaches and latest best practices to improve the knowledge and/or skills of the intended audience?

Specific to this FOA: Does this proposed program enhance or expand existing research education, training and/or career development activities currently supported at the applicant institution or available elsewhere? Adaptations of existing research education programs may be considered innovative under special circumstances, e.g. the addition of unique components and/or a proposal to determine portability of an existing program. Will activities be dedicated to the program recipients, such as forums for presenting research plans and of accomplished work at the end of the program? Are unique activities proposed to enhance the research experiences of the participants?

Approach

Does the proposed program clearly state its goals and objectives, including the educational level of the audience to be reached, the content to be conveyed, and the intended outcome? Is there evidence that the program is based on a sound rationale, as well as sound educational concepts and principles? Is the plan for evaluation sound and likely to provide information on the effectiveness of the program? If the proposed program will recruit participants, are the planned recruitment, retention, and follow-up (if applicable) activities adequate to ensure a highly qualified participant pool?

Specific to this FOA: Is there a plan to ensure that the participants research education is appropriate for impactful use of SPARC-generated resources? Will the participants have ample opportunities to interact with other participants and faculty?

Environment

Will the scientific and educational environment of the proposed program contribute to its intended goals? Is there a plan to take advantage of this environment to enhance the educational value of the program? Is there tangible evidence of institutional commitment? Is there evidence that the faculty have sufficient institutional support to create a sound educational environment for the participants? Where appropriate, is there evidence of collaboration and buy-in among participating programs, departments, and institutions?

Additional Review Criteria

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

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (///grants.nih.gov/grants/guide/url redirect.htm?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (//grants.nih.gov/grants/guide/url_redirect.htm? id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Revisions

Not Applicable

Renewals

Not Applicable

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.

Recruitment Plan to Enhance Diversity

Peer reviewers will separately evaluate the recruitment plan to enhance diversity after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment of prospective participants from underrepresented groups. The review panel's evaluation will be included in the summary statement. Plans will be rated as **acceptable** or **unacceptable**, and the summary statement will provide the consensus of the review committee.

Training in the Responsible Conduct of Research

RFA-DK-20-020: NIDDK Research Education Program Utilizing Stimulating Peripheral Activity to Relieve Conditions (SPARC) - Generated Resources (R25 Clinical Trial Not Allowed)

Taking into account the specific characteristics of the proposed research education program, the level of participant experience, 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 program faculty in the instruction; 4) **Duration of Instruction** - The number of contact hours of instruction, taking into consideration the duration of the program; and 5) **Frequency of Instruction** - Instruction must occur during each career stage and at least once every four years. See also: NOT-OD-10-019 (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html). The review panel's evaluation will be included in the summary statement. Plans will be rated as acceptable or unacceptable, and

Applications from Foreign Organizations

the summary statement will provide the consensus of the review committee.

Not Applicable

Select Agent Research

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

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 (//grants.nih.gov/grants/guide/url redirect.htm?id=11153): 1) Data Sharing Plan (//grants.nih.gov/grants/guide/url redirect.htm?id=11151); 2) Sharing Model Organisms (//grants.nih.gov/grants/guide/url redirect.htm?id=11152); and 3) Genomic Data Sharing Plan (//grants.nih.gov/grants/guide/url redirect.htm?id=11153).

If support for development, maintenance, or enhancement of software is requested in the application, the reviewers will comment on the proposed software dissemination plan.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by NIDDK, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a 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.
- Will receive a written critique.

<u>Appeals (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html)</u> 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 Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKDAC). 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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123)</u>. Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

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

Section VI. Award Administration Information

1. Award Notices

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

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

Awardees must comply with any funding restrictions described in <u>Section IV.6. 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.

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</u> <u>Grants (//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.

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, Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158).</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-provider-obligations/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.

http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html (http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html).

- 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/ (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? (<a href="h
- 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/undex.html (http://www.html (htt
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see
 https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html
 https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf
 For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm).

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.

RFA-DK-20-020: NIDDK Research Education Program Utilizing Stimulating Peripheral Activity to Relieve Conditions (SPARC) - Generated Resources (R25 Clinical Trial Not Allowed)
In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009
(Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and

3. Reporting

cooperative agreements except fellowships.

When multiple years are involved, awardees will be required to submit the <u>Research Performance Progress Report (RPPR)</u>
(//grants.nih.gov/grants/rppr/index.htm) annually. Continuation support will not be provided until the required forms are submitted and accepted.

Programs that involve participants should report on education in the responsible conduct of research and complete a Participant Diversity Report (//grants.nih.gov/grants/guide/url redirect.htm?id=61198), in accordance with the RPPR Instruction Guide (//grants.nih.gov/grants/rppr/rppr instruction guide.pdf).

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 https://www.fsrs.gov (//grants.nih.gov/grants/guide/url redirect.htm?id=11171) for additional information on this reporting requirement.

Failure by the grantee institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the award.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Other Reporting Requirements

- The institution must submit a completed Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.htm?id=61189)) for each participant appointed full time for eight weeks or more or the equivalent. Grantees must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//grants.nih.gov/grants/guide/url_redirect.htm?id=41183). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.
- Participant Termination Notice: Within 30 days of the end of the total support period for each participant, the institution must submit a Termination Notice (PHS Form 416-7 (//grants.nih.gov/grants/guide/url redirect.htm?id=41179)) via xTrain (//grants.nih.gov/grants/guide/url redirect.htm?id=41183) for each participant appointed full time for eight weeks or more, or the equivalent.

A final RPPR and the expenditure data portion of the Federal Financial Report are required for closeout of an award as described in the <u>NIH Grants</u> <u>Policy Statement (//grants.nih.gov/grants/guide/url redirect.htm?id=11161)</u>.

4. Evaluation

In carrying out its stewardship of human resource-related programs, the NIH or its Institutes and Centers will periodically evaluate their R25 research education programs, employing the measures identified below. In assessing the effectiveness of its research education investments, NIH may request information from databases, PD/PIs, and from participants themselves. Where necessary, PD/PIs and participants may be contacted after the completion of a research education experience for periodic updates on participants' subsequent educational or employment history and professional activities.

Upon the completion of a program evaluation, NIH and its ICs will determine whether to (a) continue a program as currently configured, (b) continue a program with modifications, or (c) discontinue a program.

In evaluating this research education program NIDDK expects to use the following evaluation measures:

For Courses for Skills Development:

- Educational level of participants
- Content
- Participants' feedback on the program
- New knowledge or skills acquired

For Research Experience and Mentoring Programs Involving the Following Groups:

Graduate Students:

- Subsequent educational/career progress of participants, including:
 - 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
 - Subsequent employment in a research or research-related field
 - Subsequent authorship of scientific publications in a STEM fieldSubsequent independent research grant support from NIH or another source
- Ideal and a sea of Fed. On a selection grant support from Military

Postdoctorates and Early Career Investigators:

- Subsequent educational/career progress of participants, including:
 Subsequent participation in research
 - Subsequent participation in research
 Subsequent employment in a research
 - Subsequent employment in a research or research-related field
 Subsequent authorship of acceptific publications in a STEM field
 - Subsequent authorship of scientific publications in a STEM field
 Subsequent independent research great support from NIII or on

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 applicants.

Application Submission Contacts

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

Finding Help Online: http://grants.nih.gov/support/ (//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</u> (<u>mailto:GrantsInfo@nih.gov</u>) (preferred method of contact) Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)

Contact Center Telephone: 800-518-4726 Email: <u>support@grants.gov</u> (<u>mailto:support@grants.gov</u>)

SBA Company Registry (Questions regarding required registration at the SBA Company Registry and for technical questions or issues)
Website to Email: http://sbir.gov/feedback?type=reg (http://sbir.gov/feedback?type=reg (http://sbir.gov/feedback?type=reg)

Scientific/Research Contact(s)

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Peer Review Contact(s)

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Telephone: 301-594-7797

 $\textbf{Email:} \ \underline{connaughtonj@nih.gov} \ \underline{(mailto:connaughtonj@nih.gov)}$

Financial/Grants Management Contact(s)

RFA-DK-20-020: NIDDK Research Education Program Utilizing Stimulating Peripheral Activity to Relieve Conditions (SPARC) - Generated Resources (R25 Clinical Trial Not Allowed)

Jeni Smits

National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK)

Telephone: 301-827-4020

Email: jeni.smits@nih.gov (mailto:jeni.smits@nih.gov)

Section VIII. Other Information

Recently issued trans-NIH <u>policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163)</u> may affect your application submission. A full list of policy notices published by NIH is provided in the <u>NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164)</u>. All awards are subject to the terms and conditions, cost principles, and other considerations described in the <u>NIH Grants Policy Statement</u> (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

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 Part 52 and 45 CFR Part 75.

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









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