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

Funding Opportunity Title

Transition to Independent Environmental Health Research (TIEHR) Career Award (K01 Independent Basic Experimental Studies with Humans Required)

Activity Code

K01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k01&Search.x=0&Search.y=0&Search_Type=Activity) Research Scientist Development Award - Research & Training

Announcement Type

Reissue of PAR-19-225 (https://grants.nih.gov/grants/guide/pa-files/PAR-19-225.html)- Transition to Independent Environmental Health Research (TIEHR) Career Award (K01 Independent Basic Experimental Studies with Humans Required)

Related Notices

- NOT-OD-23-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html) Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available
- 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)

Funding Opportunity Announcement (FOA) Number

PAR-21-170

Companion Funding Opportunity

PAR-21-171 (//grants.nih.gov/grants/guide/pa-files/PAR-21-171.html) - Transition to Independent Environmental Health Research (TIEHR) Career Award (K01 Clinical Trial Required)

PAR-21-172 (//grants.nih.gov/grants/guide/pa-files/PAR-21-172.html) - Transition to Independent Environmental Health Research (TIEHR) Career Award (K01 Clinical Trial Not Allowed)

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.113

Funding Opportunity Purpose

The Transition to Independent Environmental Health (TIEHR) Career Award is a 3-year bridge scholar development program for newly independent faculty who intend to pursue research careers in environmental health sciences. At the conclusion of the career development period the candidates are expected to demonstrate they can successfully compete for research funding in the environmental health sciences.

This Funding Opportunity Announcement is for basic science experimental studies involving humans, referred to in NOT-OD-18-212 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-212.html) as “prospective basic science studies involving human participants.” These studies fall within the NIH definition of a clinical trial and also meet the definition of basic research. Types of studies that should be submitted under this FOA include studies that prospectively assign human participants to conditions (i.e., experimentally manipulate independent variables) and that assess biomedical or behavioral outcomes in humans for the purpose of understanding the fundamental aspects of phenomena without specific application towards processes or products in mind. Applicants not planning an independent clinical trial or basic experimental study with humans, or proposing to gain research experience in a clinical trial or basic experimental study with humans led by another investigator, must apply to the 'Independent Clinical Trial Not Allowed' companion FOA.

The proposed project must be related to the programmatic interests of one or more of the participating NIH Institutes and Centers (ICs) based on their scientific missions.

This Funding Opportunity Announcement (FOA) is designed specifically for applicants proposing to serve as the lead investigator of an independent clinical trial, a clinical trial feasibility study, or a separate ancillary study to an existing trial, as part of their research and career development. Applicants planning independent clinical trials with specific application towards processes or with products in mind, must apply to the companion FOA, PAR-21-171 (https://grants.nih.gov/grants/guide/pa-files/PAR-21-171.html). Applicants not planning an independent clinical trial, or proposing to gain research experience in a clinical trial led by another investigator, must apply to companion FOA, PAR-21-172 (//grants.nih.gov/grants/guide/pa-files/PAR-21-172.html).

Key Dates

Posted Date

March 15, 2021

Open Date (Earliest Submission Date)

May 12, 2021

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11111) apply, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates.

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

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply

Advisory Council Review

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply

Earliest Start Date

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply

Expiration Date

May 08, 2024

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Career Development (K) 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 the NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced.

Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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

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

   Apply Online Using ASSIST

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

3. Use Grants.gov (https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-21-170) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall goal of the NIH Research Career Development program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. NIH Institutes and Centers (ICs) support a variety of mentored and non-mentored career development award programs designed to foster the transition of new investigators to research independence and to support established investigators in achieving specific objectives. Candidates should review the different career development (K) award programs to determine the best program to support their goals. More information about Career programs may be found at the NIH Extramural Training Mechanisms (//grants.nih.gov/grants/guide/url_redirect.htm?id=41159) website.

The objective of the NIH Mentored Research Scientist Development Award (K01) is to provide salary and research support for a sustained period of "protected time" (3-5 years) for intensive research career development, under the guidance of an experienced mentor, or sponsor in the biomedical, behavioral or clinical sciences leading to research independence. The expectation is that, through this sustained period of research career development and training, awardees will launch independent research careers and become competitive for new research project grant (e.g., R01) funding.

The Transition to Independent Environmental Health Research (TIEHR) Career Award (K01) is targeted to investigators who are within the first three years of their first independent faculty appointment.

Candidates must name a mentor who is not the postdoctoral mentor and who has active NIEHS grant support or a substantial history of NIEHS funded research grant support. The role of the mentor for the TIEHR candidate is to provide appropriate guidance, advice and expertise to broaden the research skills of the candidate and assist in the formation of an advisory committee to the candidate and the candidate's research.

Research projects and career development activities proposed for this FOA are expected to contribute to the mission of the NIEHS, which is to discover how the environment affects people in order to promote healthier lives.

Candidates to the TIEHR program are expected to be drawn from a variety of scientific backgrounds, including basic, mechanistic, clinical, epidemiological, computational, engineering, and/or health risk communication research. Applications submitted to the NIEHS are characterized by a research focus on exposure-health related responses from environmental agents within the mission interest of the NIEHS.

Environmental agents which are considered of primary interest for NIEHS include: industrial chemicals or manufacturing byproducts, metals, pesticides, herbicides, air pollutants and other inhaled toxicants, particulates or fibers, fungal, and bacterial or biologically derived toxins. NIEHS also supports research which is aimed at defining health effects of the exposome, or the totality of a person's environmental exposure, and the study of the health effects of mixtures or co-exposures with agents generally outside of NIEHS mission responsibility, if the primary goal of the study is on an exposure within the NIEHS mission interest. Applicants are strongly encouraged to contact NIEHS Scientific/Research staff prior to submission to determine if their project meets the goals of the TIEHR.

Applications Not Responsive to this FOA

The following types of studies are not responsive to this FOA. Applications proposing such studies will be considered non-responsive and will not be reviewed and will be withdrawn:

- Studies primarily focused on agents that are considered outside the primary mission responsibility of the NIEHS including, but not limited to: alcohol, chemotherapeutic agents, radiation that is not a result of an ambient environmental exposure, smoking, except when considered as a secondary smoke exposure as a component in the indoor environment (particularly in children), drugs of abuse, pharmaceuticals, dietary nutrients, and infectious or parasitic agents.
- Studies which do not focus directly on a human health or disease endpoint.

All applications submitted to this Funding Opportunity Announcement must propose basic science experimental studies involving humans, otherwise referred to in NOT-OD-18-212 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-212.html) as "prospective basic science studies involving human participants," that fall within the NIH definition of a clinical trial and also meet the definition of basic research.

NIH defines basic research consistent with the definition of basic research in federal code, "the systematic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind." (32 CFR 272.3 (https://gov.ecfr.io/cgi-bin/text-idx?SID=362ab86854e9b354eb3404a020a43519&mc=true&node=se32.2.272_13&rgn=div8)).

NIH defines a clinical trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." (NOT-OD-15-015 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html)).

Types of studies that should submit under this FOA include studies that prospectively assign human participants to conditions (i.e., experimentally manipulate independent variables) and that assess biomedical or behavioral outcomes in humans for the purpose of understanding the fundamental aspects of phenomena without specific application towards processes or products in mind.

For the purposes of this FOA, “specific application towards processes or products” refers to the application of biomedical or behavioral products, procedures, or services intended to affect a health-related outcome of the individual or a group of individuals either by better understanding the mechanism of action of an intervention or a measurable improvement in health.

Basic experimental studies in which participants are prospectively assigned to experimental conditions and receive an intervention or experimental manipulation where the effect will be assessed for the purpose of understanding fundamental aspects of phenomena may submit under this FOA.

Please refer to the table comparing Funding Opportunity Types by Clinical Trial Allowability (https://grants.nih.gov/grants/Comparison-of-FOA-Types-Clinical-Trials.pdf) for additional guidance on the most appropriate FOA for the type of study.

Prospective studies with humans conducted with specific applications towards processes or products in mind, including FDA Phase 0 or 1 studies, mechanistic clinical trials (e.g., those that examine the mechanisms by which an intervention works or the processes that account for an intervention's effects on clinical outcome), and safety and efficacy studies should submit under the a 'Clinical Trials Required' or Clinical Trial Optional’ FOA, but not under this FOA.

Observational studies involving humans should submit under the ‘Clinical Trials Not Allowed’ FOA.
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.

Clinical Trial?

Required - Basic Experimental Studies with Humans: Only accepting applications that propose independent clinical trial(s) that also meet the definition of basic research.

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

Funds Available and Anticipated Number of Awards

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

Award Budget

Award budgets are composed of salary and other program-related expenses, as described below.

Award Project Period

The total project period may not exceed 3 years.

Other Award Budget Information

Salary

NIEHS will contribute up to $75,000 per year toward the salary of the career award recipient. Further guidance on budgeting for career development salaries is provided in the SF424 (R&R) Application Guide. See also NOT-OD-17-094 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-094.html)

The total NIH contribution to salary may not exceed the legislatively mandated salary cap. See: http://grants.nih.gov/grants/policy/salcap_summary.htm (//grants.nih.gov/grants/policy/salcap_summary.htm).

Other Program-Related Expenses

NIH will contribute $50,000 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.

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

Indirect Costs

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 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)

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.

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

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

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any candidate 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 mentor and organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. Multiple PDs/PIs are not allowed.

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

551, or other legal verification of such status).
Candidates must be within 3 years of their appointment to their first independent faculty position at the time of submission (receipt date) of the application. Criteria to address in determining whether the position is considered independent are listed below. Candidates whose position is not tenure track must demonstrate institutional commitment and include documentation from the institution that the candidate has independent laboratory and/or other space, as further described in the Institutional Support section below. Criteria for independent faculty positions generally include, but are not limited to, that the position:1) qualifies the candidate to hire postdoctoral fellows and be the responsible supervisor of graduate students; 2) allows the candidate to attend and participate in faculty meetings; 3) allows the candidate to apply for independent research funding as the principal investigator of an NIH R01 or equivalent research grant; and 4) is not contingent on the award of this grant application. Postdoctoral appointments and other appointments such as research assistant or instructor are generally not eligible.

Applications from newly appointed faculty who have received start-up packages from their institution, which includes institutional salary support, are eligible and encouraged to apply.

Current and former PDs/PIs on NIH research project (R01), program project (P01), center grants (P50), Project Leads of program project (P01), or center grants (P50), other major individual career development awards (e.g., K01, K07, K08, K22, K23, K25, K76, K99/R00), or the equivalent are not eligible. Current and former PDs/PIs of an NIH Small Grant (R03), Exploratory/Developmental Grant (R21), Planning Grant (R34/U34), Dissertation Award (R36), or SBIR/STTR (R41, R42, R43, R44) remain eligible, as do PD/PIs of Transition Scholar (K38) awards and individuals appointed to institutional K programs (K12, KL2).

Candidates for the K01 award must have a research or health-professional doctoral degree.

2. Cost Sharing

This FOA does not require cost sharing as defined in the (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126)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, and each is from a different candidate.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. An individual may not have two or more competing NIH career development applications pending review concurrently. In addition, 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)).

Candidates may submit research project grant (RPG) applications concurrently with the K application. However, any concurrent RPG application may not have substantial scientific and/or budgetary overlap with the career award application. K award recipients are encouraged to obtain funding from NIH or other Federal sources either as a PD/PI on a competing research grant award or cooperative agreement, or as project leader on a competing multi-project award as described in NOT-OD-08-065 (//grants.nih.gov/grants/guide/url_redirect.htm?id=51126).

Level of Effort

At the time of award, the candidate must have a “full-time” appointment at the academic institution. Candidates are required to commit a minimum of 75% of full-time professional effort (i.e., a minimum of 9 person-months) to their program of career development. Candidates may engage in other duties as part of the remaining 25% of their full-time

professional effort not covered by this award, as long as such duties do not interfere with or detract from the proposed career development program.

Candidates who have VA appointments may not consider part of the VA effort toward satisfying the full time requirement at the applicant institution. Candidates with VA appointments should contact the staff person in the relevant Institute or Center prior to preparing an application to discuss their eligibility.

After the receipt of the award, adjustments to the required level of effort may be made in certain circumstances. See NOT-OD-09-036 (https://grants.nih.gov/grants/guide/url_redirect.htm?id=51125) for more details.

Mentor(s)

Before submitting the application, the candidate must identify a mentor who will supervise the proposed career development and research experience. The mentor should be an active investigator in the Environmental Health Sciences (i.e., active NIEHS grant support or a substantial history of NIEHS R01, P50 or P01 grant support) and be committed both to the career development of the candidate and to the direct supervision of the candidate's research. The candidate's previous postdoctoral mentor may not be named as the mentor for the candidate on the TIEHR award. The mentor may be at the same or different institution than the candidate. Where feasible, women, individuals from diverse racial and ethnic groups, and individuals with disabilities should be involved as mentors to serve as role models. The mentor, or a member of the team of mentors, should have a successful track record of mentoring. Candidates are encouraged to identify more than one mentor, i.e., a team of mentors, if this is deemed advantageous for providing expert advice in all aspects of the research career development program. In such cases, one individual must be identified as the principal mentor who will coordinate the candidate's career development experience. The candidate must work with the mentor(s) in preparing the TIEHR application and the subsequent R01 application. The principal mentor should also agree to: (1) assist in the establishment of an advisory committee with appropriate research expertise for the candidate; (2) attend at least two meetings of the advisory committee, including one to provide feedback on an R01 draft of a grant submission; and (3) sponsor the candidate at meetings largely attended by other NIEHS grantees. The mentor(s) or mentoring team must demonstrate appropriate expertise, experience, and ability to guide the applicant in the organization, management and implementation of the proposed research and clinical trial.

Institutional Environment

The applicant institution must have a strong, well-established record of research and career development activities and faculty qualified to serve as mentors in biomedical, behavioral, or clinical research.

Section IV. Application and Submission Information

1. Requesting an Application Package

Buttons to access the online ASSIST system or to download application forms are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Career Development (K) 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 may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications (//grants.nih.gov/grants/guide/url_redirect.htm?id=41137).

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed.

Instructions for Application Submission

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing (DMS) Plan will be attached in the Other Plan(s) attachment in FORMS-H and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

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.

Project Summary/Abstract

Include a description of your current research, the research you propose during three year TIEHR career development award, and a summary of the proposed career development activities.

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

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

R&R Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Career Development Award Supplemental Form

Other Plan(s):

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

The PHS 398 Career Development Award Supplemental Form is comprised of the following sections:

- Candidate
- Research Plan
- Other Candidate Information
- Mentor, Co-Mentor, Consultant, Collaborators
- Environment & Institutional
- Commitment to the Candidate
- Other Research Plan Sections
- Appendix

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

Candidate Section

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

Candidate Information and Goals for Career Development

Candidate's Background

- Describe the candidate's commitment to a health-related research career. Describe all the candidate's professional responsibilities in the recipient institution and elsewhere and describe their relationship to the proposed activities on the career award.
- Describe prior training and how it relates to the objectives and long-term career plans of the candidate.
- Describe the candidate's research efforts to this point in his/her research career, including any publications, prior research interests and experience.
- Provide evidence of the candidate's potential to develop into an independent investigator.

Career Goals and Objectives?

- Describe a systematic plan: (1) that shows a logical progression from prior research and training experiences to the research and career development experiences that will occur during the career award period and then to independent investigator status; and (2) that justifies the need for further career development to become an independent investigator.
- The candidate must demonstrate they have received training or will participate in courses such as: data management, epidemiology, study design (including statistics), hypothesis development, drug development, etc., as well as the legal and ethical issues associated with research on human subjects and clinical trials.

Candidate's Plan for Career Development/Training Activities During Award Period

- The candidate and the mentor(s) are jointly responsible for the preparation of the career development plan. A career development timeline is often helpful.
- The didactic (if any) and the research aspects of the plan must be designed to develop the necessary knowledge and research skills in scientific areas relevant to the candidate's career goals.
- Describe the professional responsibilities/activities including other research projects beyond the minimum required 9 person-months (75% full-time professional effort) commitment to the career award. Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator.

Research Plan Section

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

Research Strategy

- A sound research project that is consistent with the candidate's level of research development and objectives of his/her career development plan must be provided. The research description should demonstrate the quality of the candidate's research thus far and also the novelty, significance, creativity and approach, as well as the ability of the candidate to carry out the research.
- The application must also describe the relationship between the mentor's research and the candidate's proposed research plan.
- If the candidate is at the same institution as the former postdoctoral or other research mentor, the application must also describe the relationship between the former mentor's research and the candidate's proposed research plan. Independence must be demonstrated, and the proposed mentor should be scientifically independent of the previous mentor.
- The application should describe how the research plan carried out during the 3-year transition phase will be used to develop a research grant submission. It is expected that an R01 research grant submission will be an outcome of the career development plan in the third year.

- If the applicant is proposing to gain experience in a clinical trial, ancillary study to a clinical trial or a clinical trial feasibility study as part of his or her research career development, describe the relationship of the proposed research project to the clinical trial.
- Applicants proposing a clinical trial, ancillary or feasibility study should describe the planned analyses and statistical approach and how the expected analytical approach is suited to the available resources, proposed study design, scope of the project, and methods used to assign trial participants and deliver interventions.
- If proposing an ancillary study to an ongoing clinical trial, provide a brief description of its relationship to the larger clinical trial.
- If proposing a feasibility study, to begin to address a clinical question, provide justification why this is warranted and how it will contribute to the overall goals of the research project including planning and preliminary data for future, larger scale clinical trials.
- Describe the proposed timelines for the proposed clinical trial, feasibility or ancillary study, including any potential challenges and solutions (e.g., enrollment shortfalls or inability to attribute causal inference to the results of an intervention when performing a small feasibility study).
- Describe how the proposed clinical trial or ancillary study will test the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy (This would not apply to a feasibility study).

Training 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). See SF424 (R&R) Application Guide for instructions.

Mentor, Co-Mentor, Consultant, Collaborators Section

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

Plans and Statements of Mentor and Co-mentor(s)

- The candidate must name a primary mentor who, together with the candidate, is responsible for the planning, directing, monitoring, and executing the proposed program. The candidate may also nominate co-mentors as appropriate to the goals of the program.
- The mentor should have sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award.
- Include a statement that the candidate will commit at least 9 person-months (75% of full-time professional effort) to the career development program and related career development activities.
- The application must include a statement from the mentor providing: 1) information on his/her research qualifications and previous experience as a research supervisor; 2) a plan that describes the nature of the supervision and mentoring that will occur during the proposed award period; 3) a plan for career progression for the candidate to move from the mentored stage of his/her career to independent research investigator status during the project period of the award; and 4) a plan for monitoring the candidate's research, publications, and progression towards independence.
- Similar information must be provided by any co-mentor. If more than one co-mentor is proposed, the respective areas of expertise and responsibility of each should be described. Co-mentors should clearly describe how they will coordinate the mentoring of the candidate. If any co-mentor is not located at the sponsoring institution, a statement should be provided describing the mechanism(s) and frequency of communication with the candidate, including the frequency of face-to-face meetings.
- The mentor must agree to provide annual evaluations of the candidate's progress as required in the annual progress report.
- The research expertise to be sought in the Advisory Committee should be described, but the members should not be named in the application. The names should be submitted as part of the just in time information. Advisory Committee members may be established faculty at either the candidate's

institution or at another institution. Members should be chosen for their expertise in the research project proposed by the candidate. This Advisory Committee should meet formally 6 months after the issuance of the award to assess progress, and 18 months after the award to provide feedback on the draft of a research project grant submission.

- The mentor or mentoring team must provide evidence of expertise, experience, and ability to guide the applicant in the organization, management and implementation of the proposed clinical trial, ancillary or feasibility study and help him/her to meet timelines.

Letters of Support from Collaborators, Contributors and Consultants

- Signed statements must be provided by all collaborators and/or consultants confirming their participation in the project and describing their specific roles. Unless also listed as senior/key personnel, collaborators and consultants do not need to provide their biographical sketches. However, information should be provided clearly documenting the appropriate expertise in the proposed areas of consulting/collaboration.

Environmental and Institutional Commitment to the Candidate

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

Description of Institutional Environment

- The sponsoring institution must document a strong, well-established research and career development program related to the candidate's area of interest, including a high-quality research environment with key faculty members and other investigators capable of productive collaboration with the candidate.
- Describe how the institutional research environment is particularly suited for the development of the candidate's research career and the pursuit of the proposed research plan.
- Describe the resources and facilities that will be available to the candidate, including any clinical trial-related resources, such as specialized administrative, data coordinating, enrollment, and laboratory/testing support. If applicable, include a description of the resources and facilities available at international sites.

Institutional Commitment to the Candidate's Research Career Development

- The sponsoring institution must provide a statement of commitment to the candidate's development into a productive, independent investigator and to meeting the requirements of this award. It should be clear that the institutional commitment to the candidate is not contingent upon receipt of this career award.
- Provide assurances that the candidate will be able to devote the required effort to activities under this award. The remaining effort should be devoted to activities related to the development of the candidate's career as an independent scientist.
- Provide assurances that the candidate will have access to appropriate office and laboratory space, equipment, and other resources and facilities (including access to clinical and/or other research populations, as applicable) to carry out the proposed research plan.
- Provide assurance that appropriate time and support will be available for any proposed mentor(s) and/or other staff consistent with the career development plan.

Appendix:

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

PHS Human Subjects and Clinical Trials Information

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

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **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

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

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).

PHS Assignment Request Form

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

Reference Letters

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

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

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

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to (//grants.nih.gov/grants/guide/url_redirect.htm?id=11142)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. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (//grants.nih.gov/grants/guide/url_redirect.htm?id=11144). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Guidelines for Applicants Experiencing System Issues (//grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines). For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) 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. See Section III of this FOA for information on registration requirements.

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. 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 the National Institute of Environmental Health Sciences, 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

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review.

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.

In addition, for applications involving clinical trials:

The reviewers will consider that the clinical trial may include study design, methods, and interventions that are not by themselves innovative, but address important questions or unmet needs. Reviewers should also consider the scope

of the clinical trial relative to the available resources, including the possibility that research support provided through K awards may be sufficient to support only small feasibility studies.

Overall Impact

Reviewers should provide their assessment of the likelihood that the proposed career development and research plan will enhance the candidate's potential for a productive, independent scientific research career in a health-related field, taking into consideration the criteria below in determining the overall impact score.

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.

Candidate

- Does the candidate have the potential to develop as an independent and productive researcher?
- Are the candidate's prior training and research experience appropriate for this award?
- Is the candidate's academic, clinical (if relevant), and research record of high quality?
- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator in research?
- Do the reference letters address the above review criteria, and do they provide evidence that the candidate has a high potential for becoming an independent investigator?
- Does the candidate have the potential to organize, manage, and implement the proposed clinical trial, feasibility or ancillary study?
- Does the candidate have training (or plans to receive training) in data management and statistics including those relevant to clinical trials?

Career Development Plan/Career Goals and Objectives/Plan to Provide Mentoring

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate?
- Are the candidate's prior training and research experience appropriate for this award?
- Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?

Research Plan

- Is the prior research that serves as the key support for the proposed project rigorous?
- Has the candidate included plans to address weaknesses in the rigor of prior research that serves as the key support of the proposed project?
- Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Has the candidate presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- Are the proposed research question, design, and methodology of significant scientific and technical merit?
- Is the research plan relevant to the candidate's research career objectives?
- Are the scientific rationale and need for a clinical trial, feasibility or ancillary study well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms?
- If proposing a small feasibility study, is the study warranted and will it contribute to planning and preliminary data needed for design of future larger scale clinical trials?
- Is the clinical trial or ancillary study necessary for testing the safety, efficacy or effectiveness of an intervention, or in the case of a feasibility study necessary to establish feasibility of future clinical trial?

- Is the study design justified and relevant to the clinical, biological, and statistical hypothesis(es) being tested
- Are the plans to standardize, assure quality of, and monitor adherence to, the protocol and data collection or distribution guidelines appropriate?
- Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions, if interventions are delivered? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)

- Are the qualifications of the mentor(s) in the area of the proposed research appropriate?
- Does the mentor(s) adequately address the candidate's potential and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is there evidence of the mentor's current research productivity and peer-reviewed support?
- Is active/pending support for the proposed research project appropriate and adequate?
- Does the mentor or mentoring team have the expertise, experience, and ability to guide the applicant in the organization, management and implementation of the proposed clinical trial, ancillary, or feasibility study and help him/her to meet timelines?

Environment & Institutional Commitment to the Candidate

- Is there clear commitment of the sponsoring institution to ensure that a minimum of 9 person-months (75% of the candidate's full-time professional effort) will be devoted directly to the research and career development activities described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?
- Is the institutional commitment to the career development of the candidate appropriately strong?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for the candidate's scientific and professional development of high quality?
- Is there assurance that the institution intends the candidate to be an integral part of its research program as an independent investigator?
- Are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?
- Does the application adequately address the capability and ability to conduct the trial feasibility or ancillary study at the proposed site(s) or centers? If applicable, are there plans to add or drop enrollment centers, as needed, appropriate?
- If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

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.

Study Timeline for Clinical Trials

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

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

Additional Review Considerations

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review.

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.

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) Sharing Model Organisms (//grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) Genomic Data Sharing Plan (GDS) (//grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

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 mentor(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).

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).

Authentication of Key Biological and/or Chemical Resources

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

Budget and Period of Support

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

2. Review and Selection Process

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

As part of the scientific peer review, all applications 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.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer

review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board.

The following will be considered in making funding decisions:

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

3. Anticipated Announcement and Award Dates

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

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

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

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration and Results System Information Website (https://register.clinicaltrials.gov). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that all 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.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under

a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, 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). More specifically, for K Awards, visit the Research Career Development ("K") Awardees section of the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=51164).

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

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and https://www.lep.gov (https://www.lep.gov). For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).
- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html).
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html); https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html; and https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf (https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals

supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).

- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

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 theFederal 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 cooperative agreements except fellowships.

Data Management and Sharing

Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023.

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120). The Supplemental Instructions for Individual Career Development (K) RPPRs must be followed. The Mentor's Report must include an annual evaluation statement of the candidate's progress.

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

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.

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.

4. Evaluation

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

Section VII. Agency Contacts

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

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Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten on-time submission, 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 processes and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (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)

Carol Shreffler, PhD
National Institute of Environmental Health Sciences (NIEHS)
Telephone: 984-287-3322
Email: shreffl1@niehs.nih.go (mailto:shreffl1@niehs.nih.gov)v

Peer Review Contact(s)

Varsha Shukla, PhD
National Institute of Environmental Health Sciences (NIEHS)

Telephone: 984.287.3288
Email: varsha.shukla@nih.gov (mailto:varsha.shukla@nih.gov)

Financial/Grants Management Contact(s)

Latavia Miller
National Institute of Environmental Health Sciences (NIEHS)
Telephone: 984-287-4525
Email: latavia.miller@nih.go (mailto:latavia.miller@nih.gov)v

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) 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 career development 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 Part 52 and 45 CFR Part 75.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?03-19-21)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

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