Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (<u>NIH</u>) Centers for Disease Control and Prevention (<u>CDC</u>)
	Division of Program Coordination, Planning and Strategic Initiatives, Sexual & Gender Minority Research Office (<u>SGMRO</u>)

	Office of Research Infrastructure Programs (ORIP) Office of Strategic Coordination (Common Fund) Office of Data Science Strategy (ODSS) All of Us Research Program, Office of the Director, National Institutes of Health (PRECMED) CDC Components: Agency for Toxic Substances and Disease Registry (ATSDR) Center for Global Health (CGH/CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID/CDC) National Center for Immunization and Respiratory Diseases (NCIRD/CDC) National Center for HIV, Viral Hepatitis, STDs and Tuberculosis Prevention (NCHHSTP/CDC) National Center for Injury Prevention and Control (NCIPC/CDC) National Center for Environmental Health (NCEH/CDC) National Institute for Occupational Safety and Health (NIOSH/CDC) All applications to this notice of funding opportunity should fall within the mission of the Institutes/Centers listed above.
Funding Opportunity Title	Research Supplements to Promote Diversity in Health- Related Research (Admin Supp - Clinical Trial Not Allowed)

P40 Animal (Mammalian and Nonmammalian) Model, and Animal and Biological Material Resource Grants P41 Biotechnology Resource Grants P50 Specialized Center P51 Primate Research Center Grants P60 Comprehensive Center PM1 Program Project or Center with Complex Structure **PN2** Research Development Center **R00** Research Transition Award R01 Research Project Grant R03 Small Grant Program <u>R15</u> Academic Research Enhancement Award (AREA) R16 Research Excellence Award <u>R18</u> Research Demonstration and Disseminations Projects R21 Exploratory/Developmental Research Grant Award R21/R33 Phased Innovation Award R24 Resource-Related Research Projects R33 Exploratory/Developmental Grants Phase II R34 Clinical Trial Planning Grant Program R35 Outstanding Investigator Award R37 Method to Extend Research in Time (MERIT) Award R41 Small Business Technology Transfer (STTR) Grant - Phase I only R41/R42 Small Business Technology Transfer (STTR) Grant - Phase I, Phase II, and Fast-Track R41/R42 Small Business Technology Transfer (STTR) Grant - Phase I and Phase II R42 Small Business Technology Transfer (STTR) Grant - Phase II only R43 Small Business Innovation Research (SBIR) Grant - Phase I only R43/R44 Small Business Innovation Research (SBIR) Grant - Phase I, Phase II, and Fast-Track R43/R44 Small Business Innovation Research (SBIR) Grant - Phase I and Phase II R44 Small Business Innovation Research (SBIR) Grant - Phase II only R49 Injury Control Research and Demonstration Projects and Injury Prevention Research Centers <u>R61/R33</u> Exploratory/Developmental Phased Award RC1 NIH Challenge Grants and Partnerships Program Phase I RC2 High Impact Research and Research Infrastructure Programs RC3 Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-

SPAN) Program
RC4 High Impact Research and Research
Infrastructure Programs Multi-Yr Funding
RF1 Multi-Year Funded Research Project
RL1 Linked Research Project Grant
RM1 Research Project with Complex Structure
SC1 Research-Enhancement Award
SC2 Pilot Research Project
SC3 Research Continuance Award
S06 Minority Biomedical Research Support
Cooperative Agreements
UL1 Linked Specialized Center Cooperative
Agreement
U01 Research Project Cooperative Agreements
U10 Cooperative Clinical Research Cooperative
Agreements
U18 Research Demonstration Cooperative
Agreements
U19 Research Program Cooperative Agreements
U24 Resource-Related Research Projects Cooperative
Agreements
U34 Clinical Planning Grant Cooperative Agreement
U2C Resource-Related Research Multi-Component
Projects & Centers
Cooperative Agreements
<u>U41</u> Biotechnology Resource Cooperative Agreements
U42 Animal (Mammalian and Nonmammalian) Model,
and Animal and Biological Materials Resource
Cooperative Agreements
<u>U44</u> Small Business Innovation Research (SBIR)
Cooperative Agreements - Phase II
<u>U54</u> Specialized Center- Cooperative Agreements
<u>U56</u> Exploratory Grants Cooperative Agreements
<u>U60</u> Cooperative Agreements in Occupational Safety
and Health Research, Demonstrations, Evaluation and Education Research, Demonstrations, Evaluation and
Education Research, Demonstrations, Evaluation and Education
UC2 High Impact Research and Research
Infrastructure Cooperative Agreement Programs
UC4 High Impact Research and Research
Infrastructure - Cooperative Agreement Programs
<u>UF1</u> Multi-Year Funded Research Project Cooperative
Agreement
UG1 Clinical Research Cooperative Agreements -
Single Project
<u>UG3/UH3</u> Exploratory/Developmental Phased Award
Cooperative Agreement
UH2 Exploratory/Developmental Cooperative
Agreement Phase I
UH2/UH3 Phase Innovation Awards Cooperative

Announcement Type	Agreement <u>UH3</u> Exploratory/Developmental Cooperative Agreement Phase II <u>UM1</u> Multi-Component Research Project Cooperative Agreements <u>UM2</u> Program Project or Center with Complex Structure Cooperative Agreement Reissue of <u>PA-21-071</u> - Research Supplements to Promote Diversity in Health-Related Research (Admin Supp - Clinical Trial Not Allowed)
Related Notices	 April 1, 2024 - Notice of Information Encouraging Submission of Research Supplements to Promote Diversity in Tobacco Regulatory Science through PA-23-189 - Research Supplements to Promote Diversity in Health- Related Research (Admin Supp - Clinical Trial Not Allowed). See Notice NOT-OD-24-074 January 12, 2024 - Notice of Participation of the All of Us Research Program in PA-23-189. See Notice NOT-PM-24-002 See Notices of Special Interest associated with this funding opportunity October 12, 2023 - Notice of Clarification to NIEHS' Participation on PA-23-189, "Research Supplements to Promote Diversity in Health- Related Research (Admin Supp - Clinical Trial Not Allowed)". See Notice NOT-ES-23-015. September 28, 2023 - Notice of Information Regarding NIGMS' Expanded Program Eligibility for PA-23-189 Research Supplements to Promote Diversity in Health- Related Research (Admin Supp - Clinical Trial Not Allowed)". See Notice NOT-ES-23-015. September 28, 2023 - Notice of Information Regarding NIGMS' Expanded Program Eligibility for PA-23-189 Research Supplements to Promote Diversity in Health- Related Research (Admin Supp - Clinical Trial Not Allowed)". See Notice NOT-GM-24-003. August 8, 2022 - New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023. See Notice NOT-OD-22-195. October 1, 2020 - Requirement for Trainee Diversity Report to be submitted Electronically for Institutional Research Training, Career Development, and Research

	1
Notice of Funding Opportunity (NOFO) Number	PA-23-189
Companion Notice of Funding Opportunity	None
Number of Applications	See <u>Section III. 3. Additional Information on</u> <u>Eligibility</u> .
Assistance Listing Number(s)	93.113, 93.121, 93.172, 93.173, 93.213, 93.242, 93.273, 93.279, 93.286, 93.307, 93.310, 93.350, 93.351, 93.361, 93.398, 93.837, 93.839, 93.838, 93.233, 93.840, 93.846, 93.847, 93.853, 93.859, 93.865, 93.866, 93.867, 93.879, 93.989, 93.061, 93.070, 93.083, 93.084, 93.136, 93.262, 93.326, 93.143, 93.368
Funding Opportunity Purpose	The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention hereby notify Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) whose research is supported by specific types of research grants (activity codes listed above) that funds are available for administrative supplements to enhance the diversity of the research workforce by recruiting, mentoring, and supporting high school, undergraduate and graduate/clinical students, postbaccalaureate and post Masters individuals, postdoctoral researchers (including health professionals), and eligible investigators from diverse backgrounds, including those from groups that have been shown to be underrepresented in health-related research. This supplement opportunity is also available to support PD(s)/PI(s) of research grants who are or become disabled and need additional support to accommodate their disability in order to continue to work on the research project. The activities proposed in the supplement application must fall within the scope of the parent grant, and simultaneously advance the objectives of the parent grant and support the research training and professional development of the supplement candidate. This Notice of Funding Opportunity (NOFO) is designed specifically for applicants proposing

	research that does not involve leading an independent clinical trial, a clinical trial feasibility study, or an ancillary clinical trial. Applicants to this NOFO are permitted to propose research experience in a clinical trial led by a mentor or co-mentor.
Key Dates	
Posted Date	June 29, 2023
Open Date (Earliest Submission Date)	Submission dates vary by awarding IC. See <u>Table of</u> <u>IC-Specific Information, Requirements and Staff</u> <u>Contacts</u> for more details.
Letter of Intent Due Date(s)	Not Applicable
Application Due Date(s)	Due dates vary by awarding IC. 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	Not Applicable
Advisory Council Review	Not Applicable
Earliest Start Date	Start dates vary by awarding IC. See <u>Table of IC-</u> <u>Specific Information, Requirements and Staff Contacts</u> for more details.
Expiration Date	May 8, 2026
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions It is critical that applicants follow the instructions in the Application Guide (<u>SF424</u> (R&R) Application Guide, and eRA Commons Administrative Supplement User

<u>Guide</u>, as appropriate) except where instructed to do otherwise (in this NOFO or in a Notice from the <u>NIH Guide for Grants and Contracts</u>). Conformance to all requirements (both in the Application Guide and the NOFO) 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 <u>eRA</u> <u>Commons</u> to track your application. Check with your institutional officials regarding availability.
- 3. Use <u>Grants.gov</u> Workspace to prepare and submit your application and <u>eRA</u> <u>Commons</u> to track your application.

Table of Contents

 Part 1. Overview Information

 Part 2. Full Text of the Announcement

 Section I. Notice of Funding Opportunity Description

 Section II. Award 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. Notice of Funding Opportunity Description

The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) hereby notify all Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) holding research grants with activity codes listed in "Part 1 Overview

Information" that funds are available for administrative supplements to recruit and support high school, undergraduate and graduate/clinical students, postbaccalaureate and post Masters individuals, postdoctoral researchers (including health professionals), and eligible investigators. Administrative supplements must

support work within the scope of the original project.

The NIH and CDC currently provide multiple opportunities to develop research careers and enhance participation for individuals from diverse backgrounds, including those from groups demonstrated to be underrepresented in the biomedical, behavioral, clinical and social sciences. Nevertheless, reports from the National Science Foundation (NSF; see http://www.nsf.gov/statistics/wmpd/) and others provide strong evidence that underrepresentation remains an important problem that the entire research enterprise must actively address.

This administrative supplement is designed to provide support for research experiences for individuals from diverse backgrounds from high school to the faculty level. Continuation of this program in the future will depend on the evaluation of the career outcomes of the supported individuals as well as continuing assessments of the diversity of the scientific workforce.

In all cases, the proposed research experience must be an integral part of the approved, ongoing research of the parent award, and it must have the potential to contribute significantly to the research career development of the candidate. **Enhancing Diversity**

Fostering diversity in the scientific research workforce is a key component of the NIH strategy to identify, develop, support and maintain the quality of our scientific human capital NOT-OD-20-031.

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, including those from underrepresented groups, 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 trainees 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, postdoctoral researchers 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 NSF to be underrepresented in health-related sciences on a national basis (see data at <u>http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27</u>) and

the report Women, Minorities, and Persons with Disabilities in Science and

<u>Engineering</u>). 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 (<u>https://www.govinfo.gov/content/pkg/FR-1997-10-30/html/97-28653.htm</u>).

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</u>. See NSF data at <u>http://www.nsf.gov/statistics/wmpd/2013/pdf/tab7-</u>

<u>5 updated 2014 10.pdf</u>.

C. Individuals from disadvantaged backgrounds, defined as those who meet two or more of the following criteria:

 Were or currently are homeless, as defined by the McKinney-Vento Homeless Assistance Act (Definition: <u>https://nche.ed.gov/mckinney-vento/</u>);

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);

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-eligibilityguidelines);

4. Have/had no parents or legal guardians who completed a bachelor's degree (see

https://nces.ed.gov/pubs2018/2018009.pdf);

5. Were or currently are eligible for Federal Pell grants (Definition: https://www2.ed.gov/programs/fpg/eligibility.html);

6. Received support from the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) as a parent or child (Definition: <u>https://www.fns.usda.gov/wic/wic-eligibility-requirements</u>).

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), or b) a <u>Centers for</u> <u>Medicare and Medicaid Services-designated Low-Income and</u> <u>Health Professional Shortage Areas (qualifying zipcodes are</u> 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 <u>https://nces.ed.gov/programs/coe/indicator tva.asp</u>), and are subsequently less likely to be represented in biomedical research. For background see Department of Education data at,<u>https://nces.ed.gov/;</u> https://nces.ed.gov/programs/coe/indicator_tva.asp; https://www2.ed.gov/rschstat/research/pubs/advancing-diversity-inclusion.pdf.

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/).

Women have been shown to be underrepresented in doctorate-granting research institutions at senior faculty levels in most biomedical-relevant disciplines, and may also be underrepresented at other faculty levels in some scientific disciplines (See data from the National Science Foundation National Center for Science and Engineering Statistics: Women, Minorities, and Persons with Disabilities in Science and Engineering, special report available at https://www.nsf.gov/statistics/2017/nsf17310/, especially Table 9-23, describing science, engineering, and health doctorate holders employed in universities and 4-year colleges, by broad occupation, sex, years since doctorate, and faculty rank).

Upon review of NSF data, and scientific discipline or field related data, NIH encourages institutions to consider women for faculty-level, diversity-targeted programs to address faculty recruitment, appointment, retention or advancement.

For the purpose of this announcement, institutions are encouraged to identify candidates who will enhance diversity on a national basis. 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.

Note: This NOFO is designed specifically for applicants proposing research that does not involve leading an independent clinical trial, a clinical trial feasibility study, or an ancillary clinical trial. Applicants to this NOFO are permitted to propose research experience in a clinical trial led by a mentor or co-mentor.

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

Section II. Award Information

Funding Instrument	The funding instrument will be the same as the parent award. Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
	approved project or activity. Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH or CDC scientific or program staff will assist, guide, coordinate, or

	participate in project activities. See Section VI.2 for additional information about the substantial involvement for this NOFO.
Application Types Allowed	Non-competing Administrative Supplements
Clinical Trial?	Not Allowed: Only accepting applications that do not propose clinical trials. <u>Need help determining whether you are doing a clinical trial?</u>
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon NIH or CDC appropriations, as applicable.
Award Budget	Application budgets are limited to no more than the amount of the current parent award and must reflect the actual needs of the proposed project. Direct costs for individual administrative supplements vary from less than \$5,000 to more than \$100,000 depending on the career level of the candidate. Administrative supplements end with the currently funded competitive cycle of the parent grant. Budget requests may also be limited by the awarding IC. See <u>Table of IC-Specific</u> <u>Information, Requirements and Staff Contacts</u> for more details. The funding mechanism being used to support this program, administrative supplements, can be used to cover cost increases that are associated with achieving certain new research objectives, as long as the research objectives are within the original scope of the peer reviewed and approved project, and is in alignment with the career development goals of the supplement candidate.
Award Project Period	The project and budget periods must be within the currently approved project period for the existing parent award., and in alignment with requirements stated in the <u>Table of IC-Specific Information</u> , <u>Requirements and Staff Contacts</u> .

NIH grants policies as described in the <u>NIH Grants Policy Statement</u> will apply to the applications submitted and awards made from this NOFO. CDC grants policies will apply to the applications submitted and awards made from this NOFO to participating CDC components.

Section III. Eligibility Information

1. Eligible Applicants Eligible Organizations

All organizations administering an eligible parent award may apply for a supplement under this announcement.

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 and CDC 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

Indian/Native American Tribal Governments (Federally Recognized)

Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Governments

Eligible Agencies of the Federal Government

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

This announcement is for supplements to existing projects. To be eligible, the parent award must be active and the research proposed in the supplement must be accomplished within the competitive segment. The proposed supplement must be to provide for an increase in costs due to unforeseen circumstances. All additional costs must be within the scope of the peer reviewed and approved project. IMPORTANT: The research proposed by the NIH or CDC recipient in the supplement and the supplement of the provide the provide the supplement of the provide the provide the supplement.

application must be within the original scope of the parent grant that is supported by respective funding organization (e.g., NIH or CDC).

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*</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. Since administrative supplements are made against active grants and cooperative agreements, many of these registrations may already be in place. 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 <u>NIH Policy on Late Submission of Grant</u> <u>Applications</u> states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

<u>System for Award Management (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.

- <u>NATO Commercial and Government Entity (NCAGE) Code</u> Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- O Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- <u>eRA Commons</u> Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; 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.

<u>Grants.gov</u> Applicants must have an active 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)

Individual(s) must hold an active grant or cooperative agreement, and the research proposed in the supplement must be accomplished within the competitive segment of the active award. Individuals are encouraged to work with their organizations to develop applications for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH or CDC support.

For supplements to parent awards that include multiple PDs/PIs, the supplement may be requested by any or all of the PDs/PIs (in accordance with the existing leadership plan) and submitted by the awardee institution of the parent award. Do not use this administrative supplement application to add, delete, or change the PDs/PIs listed on the parent award. Visit the Multiple Program Director/Principal Investigator Policy in the SF424 (R&R) Application Guide for more information. **Established Investigators Who Are or Become Disabled:** Established investigators (PDs/PIs) on an NIH research, program project, or center grant who are or become disabled during the current project period may request funds for reasonable accommodations to permit completion of the currently funded research project. Any currently funded PD(s)/PI(s) on an NIH research project grant, program project grant, or center grant may request support for special equipment, an assistant, or other modifications to facilitate reasonable accommodation to a disabling injury or illness that has occurred during the current project period.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the <u>NIH Grants Policy</u> <u>Statement. For CDC awards, this NOFO does not require cost sharing as defined in</u> <u>the HHS Grants Policy Statement.</u>

3. Additional Information on Eligibility Number of Applications

A parent award may support more than one individual on a supplement; however, each request must be strongly justified and include assurances that each candidate will receive appropriate mentoring. Investigators are encouraged to recruit more than one high school or undergraduate student for support by a supplemental award. Appointment of more than one individual to a single award above the high school or undergraduate level depends on the nature of the parent grant, the circumstances of the request, and the program balance of the NIH or CDC awarding component. Candidates may receive support from only one administrative supplement at a time but may be supported by more than one supplement during the development of their research careers. Support under the supplement is not transferable to another individual or transportable to another parent grant. Requirements may vary by awarding IC. See <u>Table of IC-Specific Information</u>, <u>Requirements and Staff Contacts</u> for more details.

Since applications submitted to this announcement will only receive administrative review by the awarding Institute or Center, and will not receive peer review, the NIH policy on resubmission applications will not apply. However, applications not accepted by the Institute or Center for review, or not funded by the Institute or Center, should not be submitted again without either responding to any written concerns or contacting the awarding Institute or Center for instructions first.

Eligible Candidates for the Supplement Program

The strength of the institution's description of how the candidate furthers the goals of the program in the Candidate Eligibility Statement will be considered, consistent with applicable law, along with all other aspects of the proposed experience (see *Review Criteria in Section V. Application Review Information*).

Supplemental awards under this announcement are limited to citizens or noncitizen nationals of the United States or to individuals who have been lawfully admitted for permanent residence in the United States (i.e., in possession of a Permanent Resident Card, Form I-551). This program may not be used to provide technical support to NIH-supported investigators. *Note:* PD(s)/PI(s) should encourage candidates to submit applications for fellowships, career development awards, research grants, and other sources of independent support before the supplement period ends.

PD(s)/PI(s) are encouraged to consider administrative supplements under this program for candidates at the following career levels:

High School Students: The purpose of this program is to provide high school students who have expressed an interest in the health-related sciences with an opportunity to obtain a meaningful experience in health-related research to stimulate their interest in research careers in biomedical, behavioral, clinical or social sciences. Any eligible high school students who are currently enrolled and in good standing at their high school and are interested in these areas of science are encouraged to participate in this program.

Undergraduate Students: As part of this supplement program, undergraduate students with a demonstrated interest in or desire to pursue research training in health-related sciences, may participate in a research project during the summer months and/or the academic year. This experience is separate from any requirement of the regular academic program. The student may be affiliated with either the applicant institution or another academic institution. Any eligible undergraduate student interested in healthrelated research is encouraged to participate in this program.

Baccalaureate and Master's Degree Holders: This supplement will provide opportunities for baccalaureate or master's degree holders who have demonstrated an interest in and wish to pursue research training in healthrelated sciences while applying for admission to graduate or medical school. The duration of the program is normally 1 year, but the research experience can be extended for an additional year if evidence is provided to show that the candidate is actively pursuing entry into a graduate or a health professions school. Students who plan to attend medical, dental or other professional schools are encouraged to use this program to gain research experience.

Graduate (Predoctoral) and Health Professional Students: The objective of this program is to support graduate/health professional (e.g., PhD, MD, DDS, DVM, etc.) students in biomedical, behavioral, clinical or social sciences, and health professional students who wish to develop their research capabilities. However, because this program is not intended to provide an alternative or additional means of supporting individuals who receive support from an NIH research grant, a Ruth L. Kirschstein National Research Service Award (Kirschstein-NRSA), or any other PHS funding mechanism, students who are supported by an institutional Kirschstein-NRSA may not be transferred to supplemental support prior to completion of the expected period of training on the program. In addition, individuals may not be transferred to a supplement to increase the availability of funds to the parent grant for other uses. Individuals may be supported by the parent grant for short periods, at the recipient's risk, pending Institute/Center decision on the supplement application. (See Pre-Award (Pre-Agreement) Costs in the Section 7.9.1 of the NIH Grants Policy Statement for further information).

Individuals in Postdoctoral Training: These supplements support individuals in the postdoctoral research phase of their training who wish to participate as researchers in ongoing research projects and career development experiences in preparation for an independent career in healthrelated research. This experience must serve as a means of assisting the postdoctoral researcher's development into a productive researcher in healthrelated science. Because this program is not intended to provide an alternative or additional means of supporting individuals who receive support from PHS funding mechanisms, individuals in postdoctoral training who are supported by an institutional Kirschstein-NRSA may not be transferred to supplemental support prior to the completion of their expected period of training in the program. In addition, individuals may not be transferred to a supplement to increase the availability of funds to the parent grant for other uses. Individuals may be supported by the parent grant for short periods, at the recipient's risk, pending Institute/Center decision on the supplement application. (See Pre-Award (Pre-Agreement) Costs in the Section 7.9.1 of the NIH Grants Policy Statement for further information). The individual in postdoctoral training may be affiliated with either the applicant institution or some other institution. Only under extraordinary circumstances, which must be well justified in the application, would it be acceptable for the postdoctoral candidate to work with their former predoctoral mentor.

Investigators Developing Independent Research Careers: These supplements provide either short or long-term research support for faculty members who wish to participate in ongoing research projects while further developing their own research potential, to enhance their research skills and establish an independent research career.

1. Short-term Investigator Research Supplement: This supplement provides short-term support for faculty members to conduct full-time research in the biomedical, behavioral, clinical or social sciences for three to five months each year during the summer or another portion of the academic year, over a maximum period of four years. Examples of this may include researchers at teaching-intensive schools who wish to pursue short-term research experiences in ongoing projects while further developing their own research potential, to enhance their research skills and establish an independent research career.

2. Long-term Investigator Research Supplement: This supplement provides long-term research support for faculty members to conduct research in the biomedical, behavioral, clinical or social sciences. Support is usually provided for up to two years at a minimum of 9 person months (equivalent to 75% effort) during each 12-month period. The expectation is that the project will enhance the supplement candidate's ability to compete for independent grant support.

In either case (1 or 2 above), the investigator may be affiliated with the applicant institution or some other institution. The investigator must have a doctoral degree, be beyond the level of a research trainee (post-residency and specialty training), and typically be employed at the junior faculty level (instructor or assistant professor). An individual who has received previous funding from NIH as an independent PD/PI on a research grant (e.g., R01), as the project leader on a component of a program project or center grant (e.g., P01, P50, G12), or as PD/PI on an individual research career development award (e.g., K01, K02, K07, K08, and K23), is not eligible. However, individuals appointed as Scholars on Institutional Career Development Award (K12, KL2) are eligible for this supplement program, following the completion

of their expected career development appointment. Applications for facultylevel supplements must convincingly demonstrate the need for the mentored research experience in establishing the candidate as an independent investigator.

Eligible Awards

For eligible awards, see the listing of Activity Codes under "Part 1. Overview Information." Note however that not all participating components support all the activity codes listed in this NOFO. PD(s)/PI(s) who are supported by an active grant or cooperative agreement may be eligible to work with their institutions to submit a request for an administrative supplement to the awarding component of the parent award. Policies may vary by agency and awarding IC. See <u>Table of IC-Specific</u> <u>Information, Requirements and Staff Contacts</u> for more details.

At the time of a supplemental award, the parent award must have support remaining for a reasonable period (usually two years or more).

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must prepare applications using current forms in accordance with the Application Guide.

The application forms package specific to this opportunity must be accessed through <u>ASSIST</u>, <u>Grants.gov Workspace</u> or an institutional system-to-system solution. Applicants are encouraged to contact the administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

All forms must be completed for the supplemental activities **only** and must not reflect funding or activities for the previously awarded parent award. It is critical that applicants follow the instructions for their submission option (SF424 (R&R) Application Guide) except where instructed in this notice of funding opportunity announcement to do otherwise. Conformance to documented requirements is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations applicable to the parent award as described in the Application Guide and the <u>Table of Page Limits</u> for the activity code of the parent award must be followed, with the following exceptions or additional requirements:

Application Submission

Administrative supplement requests must be submitted through Grants.gov using electronic submission processes.

Instructions for Electronic Application Submission through Grants.gov

Use the Apply button(s) in Part I of this announcement to access the application forms package posted at Grants.gov. If presented with more than one form package, use the Competition ID and Competition Titles provided to determine the most appropriate application forms package for your situation.

Prepare applications using the SF424 (R&R) forms associated with the chosen package. Please note that some forms marked optional in the application package are required for submission of applications for this announcement. Follow all instructions in the <u>SF424 (R&R) Application Guide</u> to ensure you complete all appropriate required and optional forms, with the following additional guidance:

R&R Cover form: Select Revision in the Type of Application field.

Research Plan form: The Research Strategy section should be completed and must include a summary or abstract of the funded parent award or project. Applications for supplements must include a description of how the candidate's proposed research activities relate to one or more aims of the parent project. In addition, they should incorporate a plan for the candidate to interact with other individuals on the parent grant, to contribute intellectually to the research, and to enhance their research skills and knowledge regarding the selected area of biomedical, behavioral, clinical or social sciences science. It must also provide evidence of a focus on the enhancement of the research capability of the supplement candidate and that the research experience is intended to provide opportunities for career development as a productive researcher. Applications should include a description of how the mentored research experience will contribute to the competitiveness of the candidate to transition into the next level in the biomedical, behavioral, clinical, or social sciences research pathway. Finally, it must demonstrate that the PD(s)/PI(s) is willing to provide active and individualized mentorship and has developed a mentoring plan to facilitate the research and career development of the candidate. Co-mentoring approaches and mentoring committees are encouraged, especially when the primary mentor is an early-stage faculty member. Applications must include a description of stage-appropriate opportunities for developing the skills required to conduct responsible, safe, and rigorous research. Provide a timeline for the Research Experience Plan that is appropriate for career stage of the candidate.

Career Development and Mentorship Plan:

An appropriate career development and mentorship plan for the candidate must be included in the application. The expectation is that the PI will prepare a tailored career development and mentorship plan that will include objectives and associated timelines for helping the candidate make the transition to the next stage of his/her research career. Required components of the career development and mentorship plan include:

A detailed description of proposed research and professional development activities specific to the candidate to expand and foster their research capabilities and skills to successfully move towards their short- and long-term career goals.

Details of mentor-candidate interactions. The plan should go well beyond simple laboratory assignments and supervision plans or stating that the candidate will attend seminars or lab meetings. The career development and mentorship plan should be structured, specific and stage-appropriate for the candidate and include parameters such as the frequency of meetings, topics to be discussed, and how progress will be monitored.

A projected timeline delineating specific research milestones and professional development activities that will be made to secure independent research funding (i.e., anticipated publications, grantsmanship workshops, timeframe for grant submissions and type of independent research support the candidate seeks).

A description of how the PI will assist the candidate in achieving the objectives and goals they have described in their candidate statement (see below). The plan should take into account the typical barriers and impediments encountered by all trainees, and may also address the unique challenges in gaining entry and progressing in the biomedical workforce that may be encountered by individuals from underrepresented groups, including but not limited to individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds.

Project/Performance Site Locations form: Include the primary site where the proposed supplement activities will be performed. If a portion of the proposed supplement activities will be performed at any other site(s), identify the locations in the fields provided.

Senior/Key Personnel Profile (Expanded) form:

- List the PD/PI as the first person (regardless of his or her role on the supplement activities).
- List the candidate to be supported through this supplement as the second person. Select Other for the Project Role and enter Candidate in the Other Project Role Category.
- List and identify any other individuals directly involved in activities related to the supplement, including mentor, technician, etc. If individuals other than the PD/PI will be serving as the candidate's mentor or co-mentor or are expected to be directly involved in activities related to the supplement, list and identify them as additional Senior/Key Persons. Select Other for the Project Role and enter Mentor, co-Mentor, or other role as appropriate.
- Do not include other Sr/Key persons from the parent project unless they are directly involved in the candidate's research directly involved in the candidate's research or training experience.
- If the institution would like to request support for multiple individuals, it must submit a separate application for each.
- $_{\odot}$ Candidates for supplement support must have an eRA Commons account and the candidate's Commons Username must be entered in the Credential field.
- $_{\odot}$ Under the Degree field, designate the candidate's current
 - educational/career level using one of the abbreviations from the bulleted list below (e.g., Grad for a predoctoral candidate). Enter the relevant abbreviation and no additional text.
- Because a candidate's compensation level is determined by his or her current educational/career level, this information is required.
 - o HS High School
 - UG Undergraduate
 - PB Postbaccalaureate
 - PM Post-master s
 - o Grad Predoctorate
 - PD Postdoctoral researcher
 - ∘ Fac Faculty
- In keeping with NIH's goal of gaining a better understanding of the size and characteristics of the biomedical research workforce, described in <u>NOT-OD-13-097</u>, diversity supplement candidates are encouraged to

provide demographic and educational or applicable degree information in their eRA Commons Personal Profiles.

- Biographical Sketch: Include a biosketch for all individuals listed on the Senior/Key Personnel profile, including the PD/PI, supplement candidate, and any other individuals directly involved in activities related to the supplement, including mentors, technicians, etc. Biosketches of mentors and other senior and key persons should provide evidence of past mentoring and training experience. Mentors should describe commitment topromoting inclusive and supportive scientific environments.
- The personal statement of the candidate's biographical sketch should address:
 - Evidence of scientific achievement or interest.
 - Any source(s) of current funding.
 - A statement from the candidate outlining their short- and longterm research objectives and career goals. The candidate must describe how the planned activities in the diversity supplement proposal are related to or will facilitate achievement of their career goals.
 - If the PI has previously received support from a research supplement award(s), they must describe: a) the outcome of the previous supplement(s) including the current status of the candidate(s) (i.e., title of current position and name of institution); b) the outcomes of the prior development/mentorship plan; c) any unexpected positive or negative occurrences that affected specific aspects of the development/mentorship plan or success of the candidate(s); and d) how these prior experiences influenced the development/mentorship plan proposed for the current candidate(s).
- **Budget forms** (e.g., *R&R Budget, PHS 398 Training Budget*): Only include funds requested for the additional supplement activities

R&R Other Project Information form:

- Assurances: If applicable, attach PDF documents in the Other Attachments field indicating that the proposed research experience was approved by the Institutional Animal Care and Use Committee (IACUC) or human subjects Institutional Review Board (IRB) at the grantee institution. Name the documents IACUC Documentation.pdf and/or IRB Documentation.pdf . Adherence to the NIH and CDC, respective policies for including individuals across the lifespan and minorities in clinical studies must also be ensured, if additional human subjects involvement is planned for the supplement.
- Candidate Eligibility Statement: A signed statement from an institutional official establishing the eligibility of the candidate for support under this program. The statement must include clearly presented information on citizenship of the candidate and a description of how the appointment of this specific candidate would further the goals of this funding opportunity, consistent with the Notice of NIH's Interest in Diversity (<u>NOT-OD-20-031</u>). Name the document Candidate Eligibility

Statement.pdf . The strength of this statement will be considered by the NIH or CDC administrative review committee, as applicable, along with all other material provided.

- Home Institution Approval: Under unusual circumstances where the applicant and mentor would be at a site other than the grantee institution, an appropriately signed letter from the institution where the research is to be conducted must also be submitted. The request must be signed by the PD/PI, the candidate, and the appropriate institutional business official.
- Sub-recipient Approval: Under unusual circumstances where any of the research is to be conducted at an organization other than the grantee institution, an appropriately signed letter from the institution where the research is to be conducted must be submitted. The request must be signed by the candidate, the PD/PI, and the appropriate institutional business official.
- PHS Human Subjects and Clinical Trials Information form: Only include a new or revised human subjects study record if these items do not change the scope of the approved project (e.g., new clinical trials cannot be added through an administrative supplement). If new recruitment or use of an additional existing dataset or resource is proposed in the supplement application, Section 2.4 should be revised and new Inclusion Enrollment Reports created, as appropriate.

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 electronic 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</u> <u>holiday</u>, the application deadline is automatically extended to the next business day.

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

For electronic application 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.

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the <u>NIH Grants Policy Statement</u>. For CDC awards, all CDC awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Pre-award costs are allowable only as described in the <u>NIH Grants Policy</u> <u>Statement</u>.

Awards are based on the current programmatic needs of the NIH or CDC awarding component, therefore investigators must contact their program officials at the NIH before applying (see <u>Table of IC-Specific Information, Requirements and Staff</u> Contacts).

Supplements for Established Investigators Who Are or Become Disabled Support will be limited to items that will permit the investigator to complete the remaining years of a currently funded research project. This might include salary support for an individual who can assist the Established Investigator in meeting the goals of the research project, specialized equipment, or modifications of the working environment. In all cases, the requested support must be consistent with the type of disability and the nature of the approved research. The total amount of support requested under this supplement must be reasonable in relationship to the direct costs of the parent award and the Established Investigator's role and effort on the project. In future competing applications, funds for continuation of the accommodations provided under this supplement must be requested in the parent grant application and may NOT be requested as a research supplement.

Reasonable Accommodations: As part of these awards, funds may be requested to make changes or adjustments to the research setting that will make it possible for a qualified individual with a disability to perform the essential functions associated with his/her role on the project. The accommodations requested under this program must be directly related to the performance of the proposed role on the research project and must be appropriate to the disabilities of the individual. Some types of accommodations that might be provided under these awards include: specialized equipment, assistive devices, and personnel such as readers, interpreters, or assistants. In all cases, the total funds for accommodations requested from the supplement must be reasonable in relationship to the direct costs of the parent grant and the nature of the supplement award. See, Auxiliary Aids and Services for Postsecondary Students with Disabilities: Higher Education's Obligations Under Section 504 and Title II of the ADA,

<u>https://www2.ed.gov/about/offices/list/ocr/docs/auxaids.html</u>; see also, Protecting Students With Disabilities: Frequently Asked Questions About Section 504 and the Education of Children with Disabilities,

https://www2.ed.gov/about/offices/list/ocr/504faq.html.

High School Students: The salary for a high school student, whether full- or parttime, should be consistent with institutional salary policies. Institutional salary rates for high school students that exceed the hourly minimum wage must be justified. Students are expected to devote sufficient effort to the research project and related activities during the period of support to gain insight into the process of scientific discovery. Support for at least three months is encouraged during any one year. This may include a combination of full-time summer experience and parttime experience during the school year. PD(s)/PI(s) are encouraged to seek high school students who will devote at least two years to this program (i.e., equivalent to two three-month, full-time periods). Exceptions to the latter will be considered, depending on the circumstances of the applicant, the parent grant, and the specific request.

Undergraduate Students: The salary for an undergraduate student should be consistent with institutional salary policies. Institutional rates for undergraduate salary that exceed \$12 per hour must be justified. An additional amount of \$200

per month for supplies and travel may also be requested. Students are expected to devote the equivalent of at least three months of full-time effort to the research project and related activities in any one year; in most cases, the period of support for any individual should last at least two years. Exceptions to these requirements will be considered, depending on the circumstances of the applicant, the parent grant, and the specific request.

Baccalaureate and Master's Degree Holders: The salary for baccalaureate and master's degree holders should be reasonable and consistent with the institutional salary policies and cannot exceed the compensation allowed for graduate students. Additional funds up to \$3,000 per year may be requested to support supplies and travel for the candidate.

Graduate (Predoctoral) and Health Professional Students: The NIH will provide salary support in addition to other necessary expenses, such as supplies and travel, to enable the individual to participate as a graduate research assistant in a funded research project. The NIH will provide compensation that (1) conforms to the established, consistently applied salary and wage policies of the institution and (2) reflects the percentage of time devoted to the PHS-funded project. For graduate students this compensation may include tuition remission paid as, or in lieu of, wages provided that the student is in a bona fide employer-employee relationship with the institution for the work performed, and payment is made explicitly for performance of necessary work. The total amount requested for salary, tuition and fringe benefits cannot exceed the amount allowable for a first year postdoctoral researcher (i.e., level zero) at the same institution performing comparable work (see NIH Guide announcement,

<u>http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html</u>). Additional funds up to \$4,000 per year may be requested to support supplies and travel for the candidate.

Individuals in Postdoctoral Training: The NIH will provide support for salary and fringe benefits in addition to other necessary expenses, such as travel and supplies, to enable the candidate to participate as a postdoctoral research associate on the funded research project. The requested annual salary must be in accordance with the salary structure of the grantee institution, consistent with the level of effort. Requested salary may not exceed the maximum allowable NRSA stipend level for postdoctoral fellows (with comparable levels of experience) in effect at the time of appointment (see: https://grants.nih.gov/training/nrsa.htm). Fringe benefits are provided in addition to salary and should be in accordance with the fringe benefits provided to other postdoctoral researchers at the awardee institution. The supplement budget may include up to \$6,000 per year to support supplies and travel for the candidate.

Investigators Developing Independent Research Careers: The requested salary and fringe benefits for an investigator should be consistent with the level of support provided by NIH Career Development Awards. Participating NIH Institutes and Centers have varying salary caps (see <u>Table of IC-Specific Information</u>, <u>Requirements and Staff Contacts</u>). Salary and fringe benefits must be in accordance with the salary structure of the grantee institution and must be consistent with the level of effort. Additional funds of up to \$10,000 per year may be requested for supplies and travel for the candidate. Equipment may be purchased but requires prior approval of the NIH awarding component. The maximum period of support for any investigator is usually two years. **Initial and Continued Funding**

In most cases, during the first budget period for the supplement, funds will be provided as an administrative supplement to the parent grant. In subsequent years, continued funding for the supplement is contingent on continued funding of the parent grant and cannot extend beyond the current competitive segment of the parent grant and the availability of funds.

In Renewal (Type 2) applications, funds for continuation of support of the supplemental award will depend on the successful renewal of the parent grant and will be handled as follows:

- Funds for the continuation of support for students must be requested as a new diversity supplement. The request must be submitted promptly in anticipation of a renewal award to avoid an interruption of support. Additional time may be considered for individuals with disabilities but must be well justified.
- Funds for continued support for a postdoctoral researcher or an investigator must be requested by name in the parent grant application at the time of renewal and may not be requested as a research supplement. Postdoctoral researchers and investigators are expected to be fully integrated in the research laboratory when considered for continuation of support.

7. Other Submission Requirements and Information

Applications must be submitted using the instructions specified above. **Applicants must complete all required registrations prior to submission.** <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 <u>How to Apply Application Guide</u>. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the <u>Dealing with System</u> <u>Issues guidance</u>. For assistance with application submission contact the Application Submission Contacts in <u>Section VII</u>.

Important reminders:

For applications submitted electronically on the SF424 (R&R) Application forms, all PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form. Failure to register in the eRA 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 unique entity identifier provided on the application is the same identifier 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.

Post Submission Materials

Not Applicable

Section V. Application Review Information 1. Criteria

Administrative Supplements do not receive peer review. Instead, the administrative criteria described below will be considered in the administrative evaluation process. The staff of the NIH or CDC awarding component, as applicable, will evaluate requests for a supplement consistent with applicable law to determine its overall merit. The following general criteria will be used:

Budget and Period of Support

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

Overall Impact

NIH staff will consider the ability of the proposed supplement activities to increase or preserve the parent award's overall impact within the original scope of award as well as the potential for the supplement to advance the training and career development of the candidate. Factors to be considered include:

- The qualifications of the candidate including career goals, prior research training, research potential, and any relevant experience.
- Evidence of educational achievement and interest in science (if the candidate is a student).
- The strength of the description of how this appointment would further the goals of this funding opportunity, consistent with the Notice of NIH's Interest in Diversity (<u>NOT-OD-20-031</u>).
- The plan and timeline for the proposed research and career development experiences in the supplemental request and their relationship to the parent grant.
- Evidence that the proposed experience will expand and foster the research capabilities, knowledge, and/or skills of the candidate.
- Evidence that the activities of the candidate will be an integral part of the project.
- $_{\odot}$ Evidence of adequate mentoring experience and success.
- Evidence that the candidate will receive high quality research career mentoring.

In addition, each of the following criteria will be evaluated as applicable for the proposed supplement.

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, NIH staff 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, NIH staff 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.

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.

Vertebrate Animals

NIH staff will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: (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 <u>Worksheet for Review of the Vertebrate Animal Section</u>.

Biohazards

NIH staff 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.

2. Review and Selection Process

Administrative supplement requests will undergo an administrative evaluation by NIH staff, but not a full peer review. Applications submitted for this funding opportunity will be assigned to the awarding component for the parent award and will be administratively evaluated using the criteria shown above, consistent with applicable law.

3. Anticipated Announcement and Award Dates Not Applicable

Section VI. Award Administration Information

1. Award Notices

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. This may be as an NoA for the supplemental activities only; alternatively, it may be as either a revision to the current year NoA or included as part of a future year NoA. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions described in <u>Section IV.5.</u> <u>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 NOFO will be subject to terms and conditions found on the <u>Award Conditions and Information for NIH Grants</u> website or the <u>CDC General Terms and Conditions for Research Awards</u> website, as applicable. This includes any recent legislation and policy applicable to awards that is highlighted on this website. When calculating the award for additional funds, NIH or CDC will 1) prorate funding if the requested budget period is adjusted at the time of award, and 2) use the institution's current F&A rate; i.e., the rate in effect when the new funding is provided.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the <u>NIH Grants Policy</u> <u>Statement</u> as part of the NoA. For these terms of award, see the <u>NIH Grants Policy</u> <u>Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General</u> and <u>Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and</u> <u>Conditions for Specific Types of Grants, Recipients, and Activities</u>, including of note, but not limited to:

Federalwide Research Terms and Conditions

Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment

Acknowledgment of Federal Funding

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which the recipient agrees, as a condition of receiving the grant, to administer programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity, The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/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 NOFO.

- For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals see <u>https://www.hhs.gov/civil-rights/for-individuals/special-</u> <u>topics/limited-english-proficiency/fact-sheet-guidance/index.html</u> and <u>https://www.lep.gov</u>.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including reasonable accommodations and making services accessible to them, see see

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, see https://www.hhs.gov/civilrights/for-individuals/sex-discrimination/index.html. 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.
- For guidance on administering programs in compliance with applicable federal conscience protection and associated anti-discrimination laws see <u>https://www.hhs.gov/conscience/conscience-protections/index.html</u> and 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 <u>https://www.hhs.gov/ocr/about-us/contact-us/index.html</u> 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 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 and 2 CFR Part 200.206 Federal awarding agency review of risk posed by applicants. This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

Any supplements to Cooperative Agreements will be subject to the same Cooperative Agreement terms and conditions as the parent award.

3. Data Management and Sharing

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

Any supplements will be subject to the same data management and sharing requirements as the parent award.

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 <u>NIH</u> <u>Grants Policy Statement</u>. Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. Reporting

Reporting requirements will be specified in the terms and conditions of award as applicable to the supplemental activities. In most non-competing continuation applications, the progress report and budget for the supplement must be included with, but clearly delineated from, the progress report and budget for the parent award. The progress report must include information about the activities supported by the supplement even if support for future years is not requested. Continuation of support for the supplement activities in the remaining years of the competitive segment of the grant will depend upon satisfactory review by the NIH awarding component of progress for both the parent award and the supplement project, the research proposed for the next budget period, and the appropriateness of the proposed budget for the proposed effort. This information is submitted with the <u>Research Performance Progress Report (RPPR)</u> and financial statements as required in the <u>NIH Grants Policy Statement</u>. NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR 200.301

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at <u>www.fsrs.gov</u> on all subawards over the threshold. See the <u>NIH Grants Policy Statement</u> for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, 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 and 2 CFR Part 200 Award Term and Condition for Recipient Integrity and Performance Matters.

5. Evaluation

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

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

currently configured, (b) continue the program with modifications, or (c) discontinue the program.

In evaluating this program, NIH expects to use the following evaluation measures: **High School Students:**

Aggregate number and demographic characteristics of participants Subsequent educational/career progress, including:

- Successful completion of a high school degree
- $_{\odot}\,\textsc{Enrollment}$ in an undergraduate program in a STEM field

Undergraduate Students:

Aggregate number and demographic characteristics of participants Subsequent educational/career progress, including:

- $_{\odot}\,$ Successful completion of an undergraduate degree in a STEM field
- $_{\odot}$ Enrollment in an advanced degree program in a STEM field

Postbaccalaureate and Post Masters Individuals:

Aggregate number and demographic characteristics of participants Subsequent educational/career progress, including:

- Application to an advanced degree program in a STEM field
- Enrollment in an advanced degree program in a STEM field

Graduate Students:

Aggregate number and demographic characteristics of participants Subsequent educational/career progress of participants, including:

- $_{\odot}\,\text{Successful completion}$ of a STEM graduate program
- $_{\odot}$ Subsequent participation in a formal research training or career development program in a STEM field
- \circ Subsequent participation in research
- o Subsequent employment in a research or research-related field
- $_{\odot}$ Subsequent authorship of scientific publications in a STEM field
- $_{\odot}$ Subsequent independent research grant support from NIH or another source

Postdoctoral Researchers and Early Career Investigators:

Aggregate number and demographic characteristics of participants Subsequent educational/career progress of participants, including:

- \circ Subsequent participation in research
- \circ Subsequent employment in a research or research-related field
- $_{\rm O}$ Subsequent authorship of scientific publications in a STEM field
- Subsequent independent research grant support from NIH or another source.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential 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: <u>https://www.era.nih.gov/need-help</u> (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> (preferred method of contact) Telephone: 301-480-7075 Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace) Contact Center Telephone: 800-518-4726 Email: <u>support@grants.gov</u> **Scientific/Research Contact(s)** See <u>Table of IC-Specific Information, Requirements and Staff Contacts</u> **Peer Review Contact(s)**

Not Applicable

Financial/Grants Management Contact(s)

See Table of IC-Specific Information, Requirements and Staff Contacts

Section VIII. Other Information

Recently issued trans-NIH <u>policy notices</u> may affect your application submission. A full list of policy notices published by NIH is provided in the <u>NIH Guide for Grants</u> <u>and Contracts</u>. All awards are subject to the terms and conditions, cost principles, and other considerations described in the <u>NIH Grants Policy Statement</u>. For CDC awards, all awards are subject to the terms and conditions, cost principles, and other considerations described in the <u>HHS Grants Policy Statement</u>.

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.





NIH... Turning Discovery Into Health®

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see <u>Help</u> <u>Downloading Files</u>.