Attachment 5:

RFA-RM-18-005

Coordination & Evaluation Center Phase II

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

This Funding Opportunity Announcement (FOA) is developed as a Common Fund initiative (http://commonfund.nih.gov/ (http://commonfund.nih.gov/ (http://commonfund.nih.gov/ (http://commonfund.nih.gov/ (<a href="http://commonfund.nih.gov/ (<a href="http://commonfund.nih.gov/ (<a href="http://commonfund.nih.gov/ (<a href="http://commonfund.nih.gov/). All NIH Institutes and Centers participate in Common Fund initiatives. The FOA will be administered by the National Institute of General Medical Sciences (NIGMS) (https://www.nigms.nih.gov/Pages/default.aspx)) on behalf of the NIH.

Funding Opportunity Title

Limited Competition: NIH Coordination and Evaluation Center for Enhancing the Diversity of the NIH-Funded Workforce Program (U54 - Clinical Trial Not Allowed)

Activity Code

<u>U54 (//grants.nih.gov/grants/funding/ac_search_results.htm?</u> text_curr=u54&Search.x=0&Search_y=0&Search_Type=Activity) Specialized Center- Cooperative Agreements

Announcement Type

Reissue of RFA-RM-13-015 (https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-13-015.html)

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-RM-18-005

Companion Funding Opportunity

RFA-RM-18-006 (https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-18-006.html), U54 Specialized Center-Cooperative Agreements

RFA-RM-18-002 (https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-18-002.html), U24

(//grants.nih.gov/grants/funding/ac search results.htm?

text_curr=u24&Search.x=0&Search.y=0&sort=ac&Search_Type=Activity&text_prev=) Resource-Related Research

Projects - Cooperative Agreements

RFA-RM-18-003 (https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-18-003.html), U24 (//grants.nih.gov/grants/funding/ac search results.htm?

<u>text_curr=u24&Search.x=0&Search.y=0&sort=ac&Search_Type=Activity&text_prev=)</u> Resource-Related Research Projects – Cooperative Agreements

RFA-RM-18-004 (https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-18-004.html), U01 (//grants.nih.gov/grants/funding/ac_search_results.htm?

text_curr=u01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project - Cooperative Agreements

RFA-RM-19-003 (https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-19-003.html), U01 (https://grants.nih.gov/grants/funding/ac_search_results.htm?

text curr=u01&Search.x=0&Search_y=0&Search_Type=Activity) Research Project - Cooperative Agreements

Number of Applications

Only one application is allowed, as defined in Section III. 3. Additional Information on Eligibility. <u>Section III. 3.</u> <u>Additional Information on Eligibility</u>.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.310

Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) invites an application from the Program Directors/Principal Investigators of the Coordination and Evaluation Center (CEC), which is currently supporting the research being performed for the Enhancing the Diversity of the NIH-Funded Workforce Program. This program, known as the Diversity Program Consortium (DPC), consists of three integrated initiatives: Building Infrastructure Leading to Diversity (BUILD), the National Research Mentoring Network (NRMN) and the CEC. The CEC will continue to organize the activities required for the attainment of program-wide goals and to measure the agreed upon hallmarks of success (hallmarks of success (hallmarks at the student, faculty, and institutional level. The CEC will employ and refine the processes developed in the previous funding period to assess the impact of BUILD and NRMN activities on attainment of the hallmarks. The CEC will coordinate the collection of data from the DPC, assess the data in an ongoing way, provide feedback, and facilitate an iterative process of program adjustment to maximize the research of BUILD and NRMN. The CEC should also focus on the dissemination of effective strategies for enhancing the diversity of the biomedical research workforce and for transitioning into a sustainable model beyond the funding cycle.

Key Dates

Posted Date

February 22, 2018

Open Date (Earliest Submission Date)

May 11, 2018

Letter of Intent Due Date(s)

30 days prior to the application due date

Application Due Date(s)

June 11, 2018, by 5:00 PM local time of applicant organization. All <u>types of non-AIDS applications</u> allowed for this funding opportunity announcement are due on this date.

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

October - November 2018 (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward)

Advisory Council Review

January 2019

Earliest Start Date

July 2019

Expiration Date

June 12, 2018

Due Dates for E.O. 12372

Not Applicable

** ELECTRONIC APPLICATION SUBMISSION REQUIRED**

NIH's new Application Submission System & Interface for Submission Tracking (ASSIST) is available for the electronic preparation and submission of multi-project applications through Grants.gov to NIH. Applications to this FOA must be submitted electronically using ASSIST or an institutional system-to-system solution; paper applications will not be accepted. ASSIST replaces the Grants.gov downloadable forms currently used with most NIH opportunities and provides many features to enable electronic multi-project application submission and improve data quality, including: pre-population of organization and PD/PI data, pre-submission validation of many agency business rules and the generation of data summaries in the application image used for review.

Required Application Instructions

It is critical that applicants follow the Multi-Project (M) 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/)) and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. 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.

Table of Contents

Part 1. Overview Information

Part 2. Full Text of the Announcement

Section I. 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. Funding Opportunity Description

Background

The NIH recognizes the need to diversify the scientific workforce by enhancing the participation of individuals from diverse backgrounds, including those from groups identified as underrepresented
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) in the biomedical, clinical, behavioral and social sciences workforce because scientists and trainees from different backgrounds bring a variety of perspectives, creativity, and individual enterprise to address complex scientific problems. A diverse NIH-supported scientific workforce will also improve global competitiveness, contribute to robust learning environments, and enhance public trust.

The United States has seen an increase in the number of Ph.D. degrees in the biomedical sciences earned by scientists from backgrounds and groups traditionally underrepresented in the biomedical sciences (Gibbs, et al., 2016, eLife 2016;5:e21393); however, the attrition of scientists from underrepresented groups from biomedical research pathways continues to be an issue (Valantine, Lund & Gammie, CBE-Life Sciences Education, 2016, 15:fe4, 1-5).

With the recognized need to enhance diversity in the biomedical research workforce, the NIH Director requested input from the NIH Advisory Committee to the Director (ACD) regarding actions that the NIH should take to make transformative progress in this area. In 2012, the ACD Working Group on Diversity in the Biomedical Research Workforce explored ways to improve the recruitment of individuals from diverse backgrounds, including those from groups underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) in biomedical research careers. The Working Group provided recommendations, endorsed by the ACD, about ways to develop and support individuals from diverse backgrounds, including those from groups underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) in the biomedical sciences, throughout their research career (from undergraduate study to acquisition of tenure in an academic position or the equivalent in a non-academic setting). In response to these recommendations, the NIH established the Common Fund Program "Enhancing the Diversity of the NIH-Funded Workforce," also known as the Diversity Program Consortium (DPC).

The first phase of the Enhancing the Diversity of the NIH-Funded Workforce Common Fund program allowed for the formation of a national consortium through which awardee institutions, in partnership with the NIH, began implementing and evaluating training and mentoring programs to engage individuals from diverse backgrounds, including those from groups <u>underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html)</u> in the biomedical sciences and help them prepare for and succeed in biomedical research careers. The DPC was

developed in the context of existing programs through which NIH and other entities have made significant investments to engage scientists and institutions using a variety of training, mentoring, and research capacity-building approaches. Although these programs have shown positive outcomes for trainees and participants, data on the specific factors that contribute to successful outcomes is limited. The primary goal of the DPC is to provide robust evidence on effective ways to engage and sustain the interest of individuals from diverse backgrounds, including those from underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) groups in the biomedical research workforce, and to encourage the dissemination of successful interventions to a wide variety of institutions across the United States.

The first phase of the program provided an opportunity to establish the types of interventions and evaluative frameworks needed to begin understanding and addressing multi-dimensional factors that strongly influence success. The DPC implemented interventions and evaluative practices designed to understand effective approaches to mentoring, student engagement, research capacity building, faculty development, and infrastructure development. The interventions were designed around the following questions:

- · What are the hallmarks of a successful biomedical research career at each phase of the training process?
- What motivates students to enter biomedical research career paths, and what factors contribute to their sustained participation?
- What factors influence emerging scientists from diverse backgrounds, including those from <u>underrepresented</u> (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) groups, to enter, exit, or sustain a biomedical research career, and how can these factors be addressed?
- What must happen during different training stages to ensure that trainees from diverse background, including
 those from <u>underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html)</u> groups,
 develop the skills, knowledge, and competencies essential to successful biomedical careers, and careers in the
 NIH-funded biomedical research workforce?
- How do institutional structures and resources facilitate successful research training and professional development activities?

The second, and final, phase of this program will allow the DPC to continue gathering data required to address the questions listed above and to assess the longer-term outcomes. During this phase, grantees are expected to refine their approaches and evaluations and to focus on sustainability and dissemination of successful interventions to enhance diversity in the biomedical research workforce. Additional relevant questions for the final phase include, but are not limited to:

- How can training, mentoring, and research capacity interventions to enhance diversity be institutionalized so that their impact continues beyond the period of funding from the NIH Common Fund?
- How can successful approaches to enhance diversity be widely disseminated to other institutions to provide maximum impact at a national level?

The program consists of three highly integrated initiatives, in which awardees work together as the Diversity Program Consortium. The three components are described below.

The Building Infrastructure Leading to Diversity (BUILD) Initiative:

The BUILD initiative was designed to allow sites to implement and study innovative approaches to engaging and sustaining the interest of trainees from diverse backgrounds, including those from groups underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) in biomedical research, potentially helping them on the pathway to become future contributors to the NIH-funded research enterprise. BUILD sites were also funded to implement interventions at the faculty and institutional levels to maximize opportunities for faculty development and research capacity building. An integral component of the BUILD initiative is the long-term evaluation of the interventions. In the first phase, awardees were selected because they identified needs at their institutions and proposed robust approaches to understanding how certain interventions could enhance the diversity of the biomedical research workforce. In the second phase, awardees demonstrating rigorous preliminary results will continue to evaluate the interventions to understand the longer-term impact of the programs and will continue to focus on building

research capacity to successfully compete for research and training grants. Awardee institutions are also expected to develop sustainability plans and dissemination methods, which will broaden the Diversity Program Consortium's impact to non-BUILD institutions, and provide more institutions with opportunities to increase the persistence of biomedical trainees from diverse backgrounds, including those from groups underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) groups, and enhance the research capacity in biomedical research-related fields.

The National Research Mentoring Network (NRMN) Consortium:

Mentorship is crucial in the development of any scientist's career; however, the ACD Working Group on Diversity noted that the community lacks evidence on how to promote successful mentoring relationships for trainees from diverse backgrounds, including those from groups underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) backgrounds. The NRMN was developed to understand the elements that contribute to productive mentoring relationships for individuals from diverse backgrounds, including those from underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) groups, and to develop mentoring tools and resources across the national community of researchers in the biomedical research workforce.

During the first phase of the program, the NRMN was tasked with developing a highly networked set of motivated and skilled mentors from various disciplines linked to mentees across the country. In addition, the NRMN cores were selected to provide training opportunities for mentors, to facilitate networking and professional opportunities, and to collect data on effective practices for mentoring. As part of the Diversity Program Consortium, the NRMN contributed to the development of hallmarks of success (https://www.nigms.nih.gov/training/dpc/Pages/success.aspx) and participated in data collection in collaboration with the Coordination and Evaluation Center (CEC).

In the second phase of the program, the NRMN initiative will continue to develop mentoring and networking opportunities for biomedical researchers from diverse backgrounds, including those from underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) groups, from undergraduates through early career faculty. To broaden the number of innovative strategies explored and increase the likelihood of impact, sustainability, and dissemination, the NRMN will be organized as a consortium of independent research projects, a Resource Center, and a Coordinating Center. The NRMN Coordinating and Resource Centers will work with the independent research projects to enhance dissemination and to promote synergies to provide evidence and resources for effective mentoring to enhance the diversity of the biomedical research workforce. The NRMN Coordination Center will coordinate data collection and storage with the CEC, and build upon and improve instruments and processes developed in the first funding period.

The Coordination and Evaluation Center (CEC):

The scale of the DPC's scientific approach necessitated a center to coordinate the consortium-wide evaluation and data collection efforts, and to store the vast amount of data collected. During the first phase, the CEC was responsible for coordinating consortium-wide activities and working with the BUILD and NRMN programs to develop site-specific and consortium-wide https://www.nigms.nih.gov/training/dpc/Pages/success.aspx), robust evaluation plans, and the https://www.nigms.nih.gov/training/dpc/Pages/datasharing.aspx). These consortium--wide development activities were established through consensus in Executive Steering Committee meetings (See https://www.nigms.nih.gov/training/dpc/Pages/datasharing.aspx). These consortium--wide development activities were established through consensus in Executive Steering Committee meetings (See https://www.nigms.nih.gov/training/dpc/Pages/datasharing.aspx). These consortium--wide development activities were established through consensus in Executive Steering Committee). The CEC coordinated the clearance through the Office of Management and Budget (OMB) to allow for the secure collection and reporting of data from BUILD and NRMN awardees. The CEC also facilitated consortium-wide working groups, meetings, discussions of approaches, progress, and lessons learned.

The CEC's evaluation activities and coordination responsibilities will continue in the second phase of the program. The consortium-wide hallmarks and consortium-wide evaluation plans will be maintained during the second phase, and the CEC will work closely with BUILD and NRMN awardees to gather data and conduct program evaluations. In addition, the CEC will increase outreach and dissemination of successful interventions.

The long-term impact of this catalytic, trans-NIH program will be in the broad dissemination of effective, evidence-based training and mentoring strategies. The DPC's method of taking a scientific approach to understand training

interventions is an innovative design that is likely to serve as a model for biomedical training programs across the Nation.

Purpose/ Objectives

The objective of this funding opportunity announcement is to invite an application from the Program Directors/Principal Investigators of the CEC, which is currently supporting the research being performed by the members of the DPC. The CEC will continue to coordinate the activities of the consortium to ensure that all BUILD and NRMN awardees address the DPC goals and objectives. The CEC will conduct evaluation activities to confirm that each of the training and mentoring interventions is assessed with respect to agreed-upon principles, that different approaches may be compared, and that lessons learned are disseminated.

The CEC will work collaboratively with DPC awardees to 1) identify fundamental attributes of successful biomedical researchers; 2) identify metrics for site-specific goals; 3) assess the impact of approaches used by each site on the attainment of https://www.nigms.nih.gov/training/dpc/Pages/success.aspx); 4) coordinate data acquisition across sites; and 5) disseminate consortium-endorsed practices and lessons learned to transform training and mentoring programs across the nation. The CEC will also provide administrative support for the Executive Steering Committee and its subcommittees, and coordinate the annual grantees meeting and other consortium-wide activities as required. (See Section VI for details about the Executive Steering Committee.)

The CEC will continue to work collaboratively with DPC awardees to design meaningful ways to assess the impact of approaches tailored toward the individual environments as well as those intended to address consortium-wide goals. The consortium will strive to enhance training and engagement at awardee institutions, modify approaches as needed to increase the overall impact, and support awardee cooperation and sharing of effective practices.

The leadership and key personnel of the CEC are expected to have broad experience working collaboratively to assess and evaluate biomedical research training and mentoring activities, including those involving nationally underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) student groups. The ability to work collaboratively with multiple communities while providing strong leadership in evaluative activities is a requirement. The CEC must also include individuals with expertise in multi-site evaluation as well as in coordination, communication, and consensus-building among diverse groups of stakeholders. The CEC should also include individuals with knowledge and expertise regarding factors that contribute to decisions to pursue, or not to pursue, biomedical research careers and the current evidence base related to training and mentoring practices and approaches to evaluate them.

The CEC will conduct the following activities:

- Maintaining, refining and revising standardized evaluation approaches and data collection protocols for the DPC that include individual and institutional demographic characteristics, nature of participation in the DPC, and achievement of training and career milestones.
- Identifying, refining and developing instruments designed to assess participants' perceptions and attitudes
 towards biomedical research and to assess the attainment of the DPC https://www.nigms.nih.gov/training/dpc/Pages/success.aspx). Participants include undergraduates, graduate
 students, postdoctoral fellows, and faculty.
- Collaborating with DPC awardees to iteratively assess the impact of innovative approaches on participants'
 perceptions and attitudes towards biomedical research careers and the impact of the approaches on attainment
 of https://www.nigms.nih.gov/training/dpc/Pages/success.aspx), providing feedback so
 that approaches may be adjusted to maximize impact.
- Ensuring that evaluation metrics for the DPC are compatible with those of NIH training and scientific research workforce diversity program evaluation efforts.
- Conducting a process evaluation of the DPC sites to assess implementation and ongoing operations.
- Coordinating ongoing data collection, data management, and reporting activities across the DPC sites.
- Conducting outcomes evaluations of the DPC according to consortium-specified metrics, including interim milestones.

- Using effective quantitative or qualitative approaches to detect the unique impact of the DPC programs on
 participant outcomes, with attention to the impact on individuals from nationally <u>underrepresented</u>
 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) groups, using appropriate comparison groups, statistical techniques, or other evaluation strategies.
- Using effective quantitative or qualitative approaches to assess potential higher-level impacts of the DPC activities, such as institutional/organizational operating procedures, resource allocation, or policies.
- Planning and enabling effective communications across the multiple DPC awardees to facilitate data solicitations and coordination.
- Coordinating annual meetings with the DPC awardees to facilitate communication about program progress, preliminary evaluation findings, and the sharing of successes and challenges with all participants.
- Organizing and coordinating Executive Steering Committee Meetings. Assisting the Executive Steering Committee in organizing appropriate subcommittees.
- Facilitating efficient communications between the NIH Program Officials, members of the CEC Steering Committee, and the Executive Steering Committee to allow for consultations, oversight of the project, and setting strategic directions.
- Continuing development and maintenance of the consortium website and portal for sharing information and lessons learned.
- Disseminating evaluation results to relevant stakeholders, including professional societies, research
 organizations, medical and basic science associations, academic institutions, federal agencies, and other
 organizations.
- Collaborating with new sites to implement and evaluate DPC training, mentoring, or research administration capacity interventions that can be sustained beyond the granting period (see NOT-RM-18-007 for more details).

The CEC is expected to implement previously developed evaluation metrics and methods to assess the attainment of hallmarks of career success, including core competencies, by DPC participants at multiple career stages. The CEC will continue to collect the following core data, including, but not limited to:

- Completion of undergraduate, entrance into graduate programs, completion of graduate programs, completion of postdoctoral research training, and transitioning into faculty position in a biomedical field.
- Involvement in biomedical research appropriate to career stage (e.g., ranging from research assistantships for undergraduates to early career faculty participating as investigators)
- Authorship on publications in peer reviewed journals or publications deposited in publicly accessible preprint archives.
- Receipt of NIH or other peer reviewed grants or fellowships.

Examples of additional information collected for evaluation purposes may include, but are not limited to:

- Attainment of consortium defined <u>hallmarks of success</u> (<u>https://www.nigms.nih.gov/training/dpc/Pages/success.aspx</u>), or core competencies.
- Significant enhancement of awareness about biomedical research careers, improved understanding of the requirements and strategies for success in those careers, and measurable enhancement of interest in research.
- Establishment of quality mentor training programs (applicable to in-person and online mentoring strategies) with measurable mentoring outcomes.
- Improved mentoring skills demonstrated by mentors as ascertained by metrics to be determined through the NRMN and CEC collaboration.
- Changes in the biomedical research workforce composition, engagement, or productivity; or changes to institutional/organizational operating procedures or policies.
- · Sustainability of initiative activities.
- Ease of implementation and evaluation of training and mentoring interventions at new sites.

In conducting the overall program evaluation, it is expected that the CEC may also refine its previously identified evaluation questions and metrics as appropriate to assess program outcomes. The questions and data are expected

to apply to the hallmarks of success (https://www.nigms.nih.gov/training/dpc/Pages/success.aspx) at the individual (student and faculty), institutional, and national level as described in the data sharing agreement (https://www.nigms.nih.gov/training/dpc/Pages/datasharing.aspx), particularly related to enhancing diversity in the biomedical research workforce and establishing overall sustainability of successful strategies. The DPC, through its collaborative and inclusive governance structure, will establish and define any additional data elements required to effectively evaluate the activities, including data, intended to measure hallmarks of success (https://www.nigms.nih.gov/training/dpc/Pages/success.aspx) at each career stage. It is anticipated that data may be obtained from various sources (e.g., NIH xTrain/eRA Commons, DPC grantees, federal and private entities when appropriate). The Consortium and/or the CEC will disseminate data collection requirements.

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

Section II. Award Information

Funding Instrument

<u>Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH 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 FOA.</u>

Application Types Allowed

Renewal

The <u>OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116)</u> and the SF424 (R&R) Application Guide provide details on these application types.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials

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

NIH intends to fund one award, corresponding to \$4,400,000 per year. Future year amounts will depend on annual appropriations.

Award Budget

Application budgets need to reflect the actual needs of the proposed project.

Award Project Period

The maximum project period is 5 years.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Eligibility is limited to the current awardee of the Coordination and Evaluation Center for the Enhancing the Diversity of the NIH-Funded Workforce Program, funded through RFA-RM-13-015 (https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-13-015.html).

Foreign Institutions

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

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

Foreign components, as <u>defined in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?</u> <u>id=11118</u>), **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- <u>Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform)</u> All registrations
 require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both
 SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as
 on the grant application.
- <u>System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/)</u> (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.
- <u>eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123)</u> 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.
- <u>Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300)</u> 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 individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an

application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

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

2. Cost Sharing

This FOA does not require cost sharing as defined in the <u>NIH Grants Policy Statement</u>. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

Only one application (normally identified by having a unique DUNS number or NIH IPF number) is allowed.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

Section IV. Application and Submission Information

1. Requesting an Application Package

A button to access the online ASSIST system is available in <u>Part 1</u> of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

Most applicants will use NIH's ASSIST system to prepare and submit applications through Grants.gov to NIH. Applications prepared and submitted using applicant systems capable of submitting electronic multi-project applications to Grants.gov will also be accepted.

2. Content and Form of Application Submission

It is critical that applicants follow the Multi-Project (M) 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 and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. 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 <u>Frequently Asked Questions – Application Guide</u>, <u>Electronic Submission of Grant Applications (//grants.nih.gov/grants/guide/url_redirect.htm?id=41137)</u>.

Page Limitations

Component Types Available in ASSIST	Research Strategy/Program Plan Page Limits
Overall	12
Admin Core (use for Administrative Core)	12

Component Types Available in ASSIST	Research Strategy/Program Plan Page Limits
Data Coordination (use for Data Coordination Center)	12
Evaluation Core	12
Comm and Dissem Core (use for Communications and Dissemination Core)	12

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

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in the SF424 (R&R) Application Guide, and should be used for preparing a multi-component application.

The application should consist of the following components:

- Overall: required, 1 maximum
- · Administrative Core: required, 1 maximum
- Data Coordination Core: required, 1 maximum
- · Evaluation Core: required, 1 maximum
- Communications and Dissemination Core: required, 1 maximum

Overall Component

When preparing your application in ASSIST, use Component Type 'Overall'.

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

SF424 (R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

Note: Human Embryonic Stem Cell lines from other components should be repeated in cell line table in Overall component.

Research & Related Other Project Information (Overall)

Follow standard instructions.

Project/Performance Site Location(s) (Overall)

Enter primary site only.

A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components will be generated upon submission.

Research & Related Senior/Key Person Profile (Overall)

Include only the Project Director/Principal Investigator (PD/PI) and any multi-PDs/PIs (if applicable to this FOA) for the entire application.

A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall section of the assembled application image in eRA Commons will be generated upon submission.

Budget (Overall)

The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover.

A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.

PHS 398 Research Plan (Overall)

Specific Aims: This section should include the overall CEC aims.

Research Strategy: Describe the overall coordination model for the CEC and the plans to continue to gather data to test site-specific and consortium-wide interventions. Summarize the strengths of the CEC, including expertise and knowledge in understanding factors that contribute to decisions to pursue biomedical research careers, in assessing and evaluating biomedical research training and mentoring activities, in working collaboratively and building consensus with diverse stakeholder groups, and finally, in coordinating multi-site evaluation activities. The research strategy should also provide the plans to disseminate effective and transferable strategies for enhancing the diversity of the biomedical research workforce with the aim of having a lasting national impact. Additionally, the strategy should include a description of plans for transitioning into a sustainable national model for evaluating the Diversity Program Consortium outcomes beyond the funding period. Within this section, the applicant should provide a timeline for the proposed activities.

Resource Sharing Plan: Not Applicable to this component. The Resource Sharing Plan for the entire application is included in the Administrative Core.

Appendix:

Do not use the Appendix to circumvent page limits.. 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 (Overall)

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

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, there must be at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record within the application. The study record(s) must be included in the component(s) where the work is being done, unless the same study spans multiple components. To avoid the creation of duplicate study records, a single study record with sufficient information for all involved components must be included in the Overall component when the same study spans multiple components.

PHS Assignment Request Form (Overall)

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

Administrative Core

When preparing your application in ASSIST, use Component Type 'Admin Core.'

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

SF424 (R&R) Cover (Administrative Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Administrative Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Administrative Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Administrative Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Administrative Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Administrative Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Administrative Core)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Administrative Core)

Specific Aims: This section should include specific aims of the Administrative Core and how they relate to the overall CEC aims

Research Strategy: Provide a description of the current structure and evolving plans to communicate within the consortium and the frequency with which coordinating calls and meetings will occur. Describe the progress and plans regarding the consortium website and other communications tools to convey information to the consortium members. Include a description of the CEC's organizational and governance structure and explain the roles and responsibilities of Administrative Core personnel. Include a management plan that describes the composition and roles of any committees that help manage or oversee CEC activities, including the required Executive Steering Committee (roles and composition defined by the NIH in Section VI). Provide details on the processes to be used to allocate and prioritize fiscal and other resources. Describe plans to support the members of the consortium as they disseminate the site-specific findings and implement sustainable programs for enhancing the diversity of the scientific workforce beyond the funding period. New dissemination and sustainability activities (e.g., co-hosting intervention workshops, hosting leadership training activities for the PD/PIs and organizing meetings for institutional leaders) should be described.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:

To achieve the goals of this funding initiative, the collection of certain data is critical. Accordingly, consistent with achieving the goals of this program, the applicant, regardless of the amount of direct costs requested for any one year, is expected to use the Data Sharing requirements set forth in "Diversity Program Consortium Data Sharing Policy." A copy of this policy can be found at: https://www.nigms.nih.gov/training/dpc/Pages/datasharing.aspx (https://www.nigms.nih.gov/training/dpc/Pages/datasharing.aspx).

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

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

Appendix:

Do not use the Appendix to circumvent page limits. 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 (Administrative Core)

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

Data Coordination Core

When preparing your application in ASSIST, use Component Type 'Data Coordination.'

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

SF424 (R&R) Cover (Data Coordination Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Data Coordination Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Data Coordination Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Data Coordination Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Data Coordination Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Data Coordination Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Data Coordination Core)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Data Coordination Core)

Specific Aims: This section should include specific aims of the Data Coordination Core and how they relate to the overall CEC aims.

Research Strategy: Describe the framework or conceptual model for the coordination of data collection activities across BUILD sites and the NRMN. Describe the current and future strategies and processes to promote standardization or harmonization of data collection across BUILD sites and the NRMN. Describe the approach to successfully collect, store, and manage data across the DPC programs. Describe monitoring or oversight mechanisms to maximize data quality and minimize missing data. Describe how implementation or operational difficulties regarding data collection by individual sites will be addressed. Describe procedures to ensure privacy and security of coded data obtained from DPC sites. Identify planned committees or workgroups to guide, support, or implement data coordination activities. Finally, describe plans for data collection and storage beyond the funding period.

Resource Sharing Plan: Not Applicable. The Resource Sharing Plan for the entire application is included in the Administrative Core.

Appendix: Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information (Data Coordination Core)

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

Evaluation Core

When preparing your application in ASSIST, use Component Type 'Evaluation Core.'

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

SF424 (R&R) Cover (Evaluation Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Evaluation Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Evaluation Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Evaluation Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Evaluation Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Evaluation Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components,

the Biographical Sketch can be included in any one component.

• If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Evaluation Core)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Evaluation Core)

Specific Aims: This section should include specific aims of the Evaluation Core and how they relate to the overall CEC aims.

Research Strategy: Describe the theoretical models and conceptual frameworks that guide evaluation activities. Include a description of the factors that contribute to decisions to pursue, or not to pursue, biomedical research careers and how approaches that seek to enhance student engagement, interest, and achievement are evaluated. Describe the comparison groups and methods to determine the efficacy of the interventions as they relate to individuals from nationally underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) groups. Describe approaches that are used to determine whether individual approaches used by DPC are enhancing the ability of trainees and participants to achieve the career hallmarks of success (https://www.nigms.nih.gov/training/dpc/Pages/success.aspx). Describe approaches to analyze data across consortium components to yield fundamental insights about factors that determine whether individuals select biomedical research careers, whether their interest is sustained, and whether they ultimately excel in these careers. Describe additional evaluation strategies to identify the unique impact of the DPC programs on participant outcomes as well as higher-level impacts on institutions, organizations, and the biomedical research workforce. Identify planned committees or workgroups to guide, support, or implement evaluation activities. While describing these activities and strategies, include examples of preliminary data on achieving site-specific or consortium-wide hallmarks of success (https://www.nigms.nih.gov/training/dpc/Pages/success.aspx) at the student, faculty, or institutional level.

Resource Sharing Plan: Not Applicable. The Resource Sharing Plan for the entire application is included in the Administrative Core.

Appendix: Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information (Evaluation Core)

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

Communications and Dissemination Core

When preparing your application in ASSIST, use Component Type 'Comm and Dissem Core.'

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

SF424 (R&R) Cover (Communications and Dissemination Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Communications and Dissemination Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Communications and Dissemination Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Communications and Dissemination Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Communications and Dissemination Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Communications and Dissemination Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Communications and Dissemination Core)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Communications and Dissemination Core)

Specific Aims: Describe the aims and objectives that will be pursued to support the communication and dissemination of mentoring, training, or research capacity building interventions proven to be effective in enhancing the diversity of the biomedical research workforce.

Research Strategy: The application should describe how the core leadership will provide expertise in communications. As part of the communications efforts, describe the strategies to keep various stakeholders informed about the results from intervention projects. The application should provide plans to use the Diversity Program Consortium research findings to promote the adoption of effective, sustainable interventions to a broad spectrum of institutions.

The core leadership should describe plans to use the knowledge generated through the interventions research to form policies, programs, and practices for dissemination to institutions not part of the current DPC. Dissemination activities may include co-hosting intervention workshops with DPC sites, and facilitating the collaborations with sites within the DPC and institutions outside of the consortium to implement and assess sustainable mentoring, training, or research capacity building interventions and evaluation protocols (see NOT-RM-18-007). Timelines for implementation and data collection protocols for the new DPC Dissemination and Translation Awards (DPC DaTA) should be described.

Resource Sharing Plan: Not Applicable. The Resource Sharing Plan for the entire application is included in the Administrative Core.

Appendix: Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information (Communications and Dissemination Core)

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov.

4. Submission Dates and Times

<u>Part I. Overview Information</u> contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or <u>Federal holiday</u> (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to <u>Grants.gov</u> (<u>//grants.nih.gov/grants/guide/url_redirect.htm?id=11128</u>) (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 <u>eRA Commons</u> (<u>//grants.nih.gov/grants/guide/url_redirect.htm?id=11123</u>), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

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

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

5. Intergovernmental Review (E.O. 12372)

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

6. Funding Restrictions

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

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

For information on how your application will be automatically assembled for review and funding consideration after submission go to: http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf (//grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf).

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

(<u>//grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines</u>). For assistance with application submission, contact the Application Submission Contacts in <u>Section VII</u>.

Important reminders:

All PD(s)/PI(s) and component Project Leads must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM).

Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by the NIGMS. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299). Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact - Overall

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the CEC to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the Center proposed).

Scored Review Criteria - Overall

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. For example, a Center that by its nature is not innovative may be essential to advance a field.

Significance

Does the proposed Center address the needs of the research consortium that it will coordinate? Is the scope of activities proposed for the Center appropriate to meet those needs? Will successful completion of the aims bring unique advantages or capabilities to the research consortium?

Are the overall plans for coordination and evaluation likely to foster a collaborative environment across the consortium? Are the research infrastructure, available resources, and institutional collaborations in place and adequate to support the overall mission of the CEC? Are the communications and dissemination plans likely to have a national influence?

Investigator(s)

Are the PD(s)/PI(s) and other personnel well suited to their roles in the Center? Do they have appropriate experience and training, and have they demonstrated experience and an ongoing record of accomplishments in managing research? If the Center is multi-PD/PI, do the investigators have complementary and integrated expertise and skills; are their leadership approach, governance, plans for conflict resolution, and organizational structure appropriate for the Center? Does the applicant have experience overseeing selection and management of subawards, if needed?

Have the PD(s)/PI(s) demonstrated the ability to coordinate complex consortia to establish and implement joint goals? Are the PD(s)/PI(s) experienced with programs that focus on diverse participant populations? Have the PD(s)/PI(s) demonstrated sufficient leadership in coordinating data collection and evaluation activities across multiple sites? Do the investigators have the necessary experience and scientific/technical expertise to manage and analyze types of data that will be collected from the DPC programs? Do the investigators have expert

facilitation skills to support solution and consensus building in collaborative environments? Do the investigators have experience disseminating evaluation findings to diverse stakeholders?

Innovation

Does the application propose novel organizational concepts, management strategies, or instrumentation in coordinating the research consortium the Center will serve? Are the concepts, strategies, or instrumentation novel to one type of research program or applicable in a broad sense? Is a refinement, improvement, or new application of organizational concepts, management strategies or instrumentation proposed?

Does the application include innovative quantitative or qualitative approaches, methodologies, or study designs to evaluate the effectiveness or impact of programs designed to enhance the diversity of the biomedical research workforce?

Approach

Are the overall strategy, operational plan, and organizational structure well-reasoned and appropriate to accomplish the goals of the research consortium the Center will serve? Will the investigators promote strategies to ensure a robust and unbiased scientific approach across the consortium, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? Have the investigators presented adequate plans to ensure consideration of biological variables, such as sex, for studies of vertebrate animals or human subjects??

If the Center involves human subjects, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Are the proposed evaluation methods robust and is the vision for comparing across DPC sites compelling? Are activities of the project cores well integrated? Is the project timeline reasonable and likely to be achieved? Are plans for sustainability reasonable and likely to be achieved?

Environment

Will the institutional environment in which the Center will operate contribute to the probability of success in facilitating the research consortium it serves? Are the institutional support, equipment and other physical resources available to the investigators adequate? Will the Center benefit from unique features of the institutional environment, infrastructure, or personnel? Are resources available within the scientific environment to support electronic information handling?

Is the environment of the awardee institution adequate to support the CEC in accomplishing its goal of managing and evaluating the DPC activities?

Additional Review Criteria - Overall

As applicable for the Centert 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.

Administrative Core

Is there evidence that the CEC has provided coordination across DPC sites and fostered a collaborative environment?

Will the coordination efforts continue to unite the various sites and promote collective goals?

Is a clear and logical organizational and governance structure described?

Are the roles and responsibilities of Administrative Core personnel appropriate and clearly delineated?

Are the processes to be used to allocate and prioritize fiscal and other resources appropriate?

Are the plans to continue the development and refinement of the consortium website and other communications tools to convey information to consortium members appropriate?

Is a reasonable and appropriate plan provided to ensure timely and effective communication across the DPC? Does it appropriately address weaknesses, if any, identified during the previous funding period?

Does the management plan adequately describe the composition and roles of any committees or boards, including the required CEC Steering Committee, proposed to help manage and oversee the CEC? Is the composition of the committee(s) appropriate and reasonable?

Is an adequate infrastructure to support communication and dissemination, data coordination and evaluation activities described?

Are key administrative personnel experienced in the organization of meetings, workshops, and other networking activities, and are there personnel appropriate for record keeping, website development, and other communications tasks?

Data Coordination Core

Is a clear and logical framework or model for the coordination of data collection across the DPC provided?

Are proposed strategies and processes to promote standardization and harmonization of operating procedures across the DPC appropriate? Were the previous strategies successful?

Is the infrastructure to support data collection, storage, and management appropriate and comprehensive and sustainable?

Are data monitoring issues or oversight strategies to ensure data quality and address missing data adequately addressed?

Are strategies to deal with implementation obstacles or operational difficulties regarding data collection by individual program sites adequately addressed? Are reasonable remediation plans proposed for sites that have not adequately participated in data collection?

Are strategies and procedures to ensure data privacy and security of coded data appropriate?

Are the roles of core personnel involved in data coordination activities well described? Is the expertise of core personnel appropriate?

Are planned committees or workgroups involved in data coordination activities appropriate?

Evaluation Core

Is the theoretical model or conceptual framework guiding evaluation activities appropriate? Do they provide adequate evidence that supports the use of the model/framework?

Are the methods to be used to assess efficacy of individual DPC activities compelling?

Are comparison groups described, and are they appropriate for the assessment of approaches being employed by DPC?

Is the evaluation process flexible enough to accommodate various processes to be employed by DPC sites?

Are appropriate data analytic strategies being applied to understand factors associated with entry and success in biomedical research careers?

Are the additional evaluation activities likely to identify the unique impact of DPC programs on participant outcomes and higher-level systems change?

Are the roles of core personnel clearly described? Is their expertise appropriate?

Are planned committees or workgroups involved in data coordination activities appropriate?

Communications and Dissemination

Does the core leadership have expertise in communications?

Is it likely that relevant information about the DPC activities and interventions will reach stakeholders?

Does the leadership have the capacity to use knowledge generated through the interventions research to form policies, programs, and practices for dissemination institutions not currently part of the DPC?

Are the dissemination plans feasible and likely to be sustainable at institutions outside of the consortium?

Are the plans for disseminating the DPC interventions likely to have a national influence?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six 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 six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the <u>Guidelines for the Review of Human Subjects</u> (//grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Children

When the proposed center 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 children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the <u>Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.htm? id=11174)</u>.

Vertebrate Animals

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

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

Not Applicable

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

Revisions

Not Applicable

Additional Review Considerations - Overall

As applicable for the center 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.

Applications from Foreign Organizations

Not Applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) <u>Data Sharing Plan</u>

(//grants.nih.gov/grants/guide/url redirect.htm?id=11151); 2) Sharing Model Organisms

(//grants.nih.gov/grants/guide/url_redirect.htm?id=11152); 3) Genomic Data Sharing Plan

(//grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html); and 4) Software Dissemination Plan.

Authentication of Key Biological and/or Chemical Resources

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

Budget and Period of Support

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

2. Review and Selection Process

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

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

<u>Appeals (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html)</u> of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned 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 submitted in response to this FOA. 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 <u>eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123)</u>. Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

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

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the <u>NIH Grants Policy Statement</u> (<u>//grants.nih.gov/grants/guide/url_redirect.htm?id=11120</u>) as part of the NoA. For these terms of award, see the <u>NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at <u>Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158</u>).</u>

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. 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. HHS provides general 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 http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html

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

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

(http://www.hhs.gov/ocr/civilrights/understanding/index.html). 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). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at

http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html (http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. 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 http://minorityhealth.hbs.gov/omh/browse.aspx?lyl=2&lylid=53 (http://minorityhealth.hbs.gov/omh/browse.aspx?lyl=2&lylid=53 (http://minorityhealth.hbs.gov/omh/browse.aspx?lyl=2&lylid=53 (http://minorityhealth.hbs.gov/omh/browse.aspx?lyl=2&lylid=53 (http://minorityhealth.hbs.gov/omh/browse.aspx?lyl=2&lylid=53 (http://minorityhealth.hbs.gov/omh/browse.aspx?lyl=2&lylid=53 (http://minorityhealth.hbs.gov/omh/browse.aspx?lyl=2&lylid=53 (http://minorityhealth.hbs.gov/omh/browse.aspx?lyl=2&lylid=53 (http://minorityhealth.hbs.gov/omh/browse.aspx?lyl=2&lylid=53 (http://minorityhealth.hbs.gov/omh/browse.aspx?lyl=2&lylid=53 (http://minorityhealth.hbs.gov/omh/browse.aspx?lyl=2&lylid=54 (http://min

http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will continue as a cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated to continue during the performance of the activities during the second phase of the project. Under the cooperative agreement, the NIH purpose remains to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility has been and will remain with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- All aspects of the study, including any modification of project design, conduct of the project, quality control, data analysis and interpretation, preparation of publications, and collaboration with other investigators will be verified, confirmed and established when necessary by the Steering Committee.
- Awardee will agree to the governance of the Steering Committee and, for issues affecting the entire consortium, the Executive Steering Committee.
- Awardee will agree to accept close coordination, cooperation, and participation of the Enhancing the Diversity
 of the NIH-Funded Workforce Working Group in those aspects of scientific and technical management of the
 project as described under "NIH Program Staff Responsibilities."
- Awardee will provide goals and progress toward those goals at regular intervals as requested by the Steering Committee and the Executive Steering Committee.

- Awardee will ensure that resources (e.g. data sets; procedure manuals) developed during both phase I and phase II of this project are made publicly available and that results are published in a timely manner.
- Awardee will adhere to the Executive Steering Committee policies regarding intellectual property, data release
 and other policies that were established during phase I and are still applicable, and any additional policies that
 might be established during the course of this activity that are consistent with applicable NIH policies, laws, and
 regulations.
- Awardee will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies. The members of the DPC will adhere to the DPC Data Sharing Policy
 (https://www.nigms.nih.gov/training/dpc/Pages/datasharing.aspx). All evaluation-related data will be shared with the NIH at the conclusion of the award.

NIH staff will continue to have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- The Project Scientists for the project will serve on the Steering Committee and the Executive Steering Committee. As they have during the first phase of the grant, the Project Scientists may work with the awardees on any issues that come before these Committees.
- The Project Scientists will continue to serve as a liaison between the awardee and the Enhancing the Diversity
 of the NIH-Funded Workforce Working Group. The coordinators of the Enhancing the Diversity of the NIHFunded Workforce Working Group will periodically report progress to the Director of the Division of Program
 Coordination, Planning, and Strategic Initiatives (DPCPSI), and the Chairs of the Working Group.
- The NIH reserves the right to withhold funding or curtail the study (of an individual award) in the event of (a) substantive changes in the agreed-upon work scope with which NIH cannot concur, (b) human subject ethical issues that may dictate a premature termination; or (c) the project is not progressing well.
- Support or other involvement of industry or any other third party in the study (e.g., participation by the third
 party; involvement of project resources or citing the name of the study or NIH support; or special access to
 project results, data, findings, or resources) may be advantageous and appropriate. However, except for
 licensing of patents or copyrights, support or involvement of any third party will occur only following notification
 of and concurrence by NIH.
- Additionally, an NIH Program Official will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

Areas of joint responsibility include:

A Steering Committee will remain as the primary governing board for the cooperative agreement funded under this FOA. The Steering Committee membership will include the NIH Program Official(s); NIH Project Scientist(s); the PD(s)/PI(s) of the awarded cooperative agreement, who will serve as Steering Committee Chair(s); and two external members not involved in the project who are selected by the PD(s)/PI(s). Additional members of the Enhancing the Diversity of the NIH-Funded Workforce Working Group may be appointed to the Steering Committee by the co-chairs of the Working Group, but the total number of NIH votes may not exceed 1/3 of the Steering Committee voting membership. Other government staff may attend the Steering Committee meetings, if their expertise is required for specific discussions.

The Steering Committee will:

- Meet at least annually or as needed, with intermittent conference calls as needed.
- Develop recommendations for the DPC awardees, as needed, to refine the uniform procedures and policies developed during phase I to meet the goals of the FOA and the goals of the Enhancing the Diversity of the NIH-Funded Workforce Program.
- As needed, develop additional recommendations and policies for the DPC awardees to ensure the goals of the FOA and the goals of the Enhancing the Diversity of the NIH-funded Workforce Program continue to be met during phase II.

- Provide input to the PD/PI with respect to the activities of the CEC and its ability to coordinate and evaluate the
 activities of DPC sites, and progress in meeting the goals of the FOA.
- Schedule the time for, and prepare concise (3 to 4 pages) summaries of, the Steering Committee meetings, which will be delivered to members of the group within 30 days after each meeting.
- Provide representation on the Executive Steering Committee (see below) to address issues relevant to the Diversity Program Consortium as a whole.

Dispute Resolution:

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened. The three members will be a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two. In the case of individual disagreement, the first member may be chosen by the individual awardee. This special dispute resolution procedure does not alter the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

Executive Steering Committee:

An Executive Steering Committee (ESC) remains responsible for providing general oversight and guidance to the Diversity Program Consortium awardees. The ESC membership will continue to include one non-NIH member from the Steering Committee of each of the BUILD, NRMN, and CEC awards; the NIH Program Official and/or Project Scientists for each program; and a member of the Enhancing the Diversity of the NIH-Funded Workforce Working Group, who will serve as ESC Chair. The co-chairs of the Enhancing the Diversity of the NIH-Funded Workforce Working Group may appoint additional members from the Working Group to serve as members on the ESC, but the total number of NIH votes may not exceed 1/3 of the Executive Committee voting membership. Awardee members of the ESC will be required to accept and implement policies approved by the ESC. The CEC will be responsible for communicating ESC feedback and guidance to the BUILD, NRMN, and CEC Steering Committees.

The ESC will meet through monthly conference calls and at least once annually in person.

Responsibilities of the ESC include the following:

- Form sub-committees as necessary to work through detailed issues that affect the Diversity Program Consortium as a whole.
- Refine competencies to be targeted through DPC activities.
- Refine <u>hallmarks of success (https://www.nigms.nih.gov/training/dpc/Pages/success.aspx)</u> in biomedical research careers at various career stages, as needed.
- Develop policies for adoption of mentoring standards, building upon those developed during phase I.
- Refine procedures and policies for sharing information between projects and with the wider community that were developed during the first funding phase, and implement dissemination in accordance with the agreed upon procedures and policies.
- Review and consider issues and progress of individual awardees so that lessons learned can be shared, and plans of the Diversity Program Consortium as a whole and of individual projects may be modified to have maximal impact.
- Contribute content and ideas for the CEC-managed program website for the purposes of sharing information both within the consortium and with the wider community.
- Plan for dissemination activities, including development of a public summary of lessons learned across the Program as a whole and applicability of the lessons to the wider community.

3. Reporting

When multiple years are involved, awardees will be required to submit the <u>Research Performance Progress Report</u> (<u>RPPR</u>) (<u>//grants.nih.gov/grants/rppr/index.htm</u>) annually and financial statements as required in the <u>NIH Grants</u> Policy Statement. (<u>//grants.nih.gov/grants/guide/url_redirect.htm?id=11161</u>)

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 <u>NIH Grants Policy Statement</u> (//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.

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 registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

<u>Grants.gov Customer Support (//grants.nih.gov/grants/guide/url_redirect.htm?id=82301)</u> (Questions regarding Grants.gov registration and submission, downloading forms and application packages)

Contact Center Telephone: 800-518-4726

Email: support@grants.gov)

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)

Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)

Telephone: 301-945-7573

Scientific/Research Contact(s)

Michael Sesma, Ph.D.

National Institute of General Medical Sciences (NIGMS)

Telephone: 301-594-3900

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

Peer Review Contact(s)

Stephanie Constant, Ph.D.

National Institute of General Medical Sciences (NIGMS)

Telephone: 301-594-2881

Email: stephanie.constant@nih.gov (mailto:stephanie.constant@nih.gov)

Financial/Grants Management Contact(s)

Kaneisha Akinpelumi, M.S.W.

National Institute of General Medical Sciences (NIGMS)

Telephone: 301-594-3915

Email: kaneisha.akinpelumi@nih.gov (mailto:kaneisha.akinpelumi@nih.gov)

Section VIII. Other Information

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

Authority and Regulations

Awards are made under the authorization of Sections 301, 402 and 405 of the Public Health Service Act as amended (42 USC 241, 282, and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?02-23-18)
NIH Funding Opportunities and Notices (/grants/guide/index.html)







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