Attachment 3: RFA-RM-13-015 (Coordination & Evaluation Center)

Department of Health and Human

Services Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (<u>NIH</u>)
Components of Participating Organizations	This Funding Opportunity Announcement (FOA) is developed as a Common Fund initiative (<u>http://commonfund.nih.gov/</u>) through the NIH Office of the Director, Office of Strategic Coordination (<u>http://dpcpsi.nih.gov/osc/</u>). The FOA will be administered by the National Institute on Minority Health and Health Disparities (<u>NIMHD</u>) on behalf of the NIH.
Funding Opportunity Title	NIH Coordination and Evaluation Center for Enhancing the Diversity of the NIH-Funded Workforce Program (U54)
Activity Code	U54 Specialized Center- Cooperative Agreement
Announcement Type	New
Related Notices	 January 10, 2014 - See Notice NOT-RM-14-005. Notice of Change to Application Due Date. January 3, 2014 - See Notice NOT-RM-14-002. Notice of Technical Assistance Webinar.
Funding Opportunity Announcement (FOA) Number	RFA-RM-13-015
Companion Funding Opportunity	<u>RFA-RM-13-016</u> , <u>U54</u> Specialized Center - Cooperative Agreements <u>RFA-RM-13-017</u> , <u>U54</u> Specialized Center - Cooperative Agreements
Number of Applications	Only one application per institution is allowed, as defined in <u>Section III. 3.</u> <u>Additional Information on Eligibility</u> .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.310
Funding Opportunity Purpose	The purpose of this Funding Opportunity Announcement (FOA) is to encourage institutions with expertise in data coordination and evaluation of research training, career development, and mentoring programs to submit applications for the establishment and operation of the Coordination and Evaluation Center (CEC) for the NIH Enhancing the Diversity of the NIH-Funded Workforce Program. This program will consist of three integrated initiatives: the Building Infrastructure Leading to Diversity (BUILD) initiative, the National Research Mentoring Network (NRMN) and the CEC. Awardees funded through these initiatives will work together as a consortium which will be coordinated by the CEC. The CEC will facilitate the establishment of program-wide goals and agreed upon hallmarks of successful biomedical researchers at multiple career stages. The CEC will

develop appropriate instruments and processes to assess the impact of
BUILD and NRMN activities on attainment of these hallmarks by program
participants. It will coordinate the collection of data from BUILD and NRMN
awardees and other sources, assess the data in an ongoing way, provide
feedback to the consortium and facilitate an iterative process of program
adjustment to maximize the research benefit of BUILD and NRMN activities.

Key Dates

Posted Date	December 19, 2013
Letter of Intent Due Date(s)	(Extended to March 2, 2014 per <u>NOT-RM-14-005</u>), Originally February 18, 2014
Application Due Date(s)	(Extended to April 2, 2014 per <u>NOT-RM-14-005</u>), Originally March 18, 2014
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	June/July 2014
Advisory Council Review	August 2014
Earliest Start Date	September 2014
Expiration Date	(Extended to April 3, 2014 per NOT-RM-14-005), Originally March 19, 2014
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the <u>PHS 398 Application Guide</u> except where instructed to do otherwise (in this FOA or in a Notice from the <u>NIH Guide for Grants and Contracts</u>). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. While some links are provided, applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in <u>Section IV</u>. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

Note: A new version of the paper PHS 398 application form and instructions (revised 8/2012) must now be used. Download the new application form and instructions from http://grants.nih.gov/grants/forms.htm.

Table of Contents

 Part 1. Overview Information

 Part 2. Full Text of 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 VI. Agency Contacts

Section VIII. Other Information

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Background

The NIH recognizes a unique and compelling need to promote diversity in the NIH-funded biomedical, behavioral, clinical, and social sciences (collectively termed "biomedical") research workforce. The NIH expects efforts that diversify the workforce to lead to the recruitment of the most talented researchers from all groups, improve the quality of the training environment, balance and broaden the perspective in setting research priorities, improve the ability to recruit subjects from diverse backgrounds into clinical research protocols, and improve the Nation's capacity to address and eliminate health disparities.

With this need in mind, 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 underrepresented in biomedical research, sustain their interest in, and prepare them for, successful biomedical research careers. (These individuals include persons from underrepresented racial and ethnic groups, people with disabilities, and people from disadvantaged backgrounds; see http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27, and the latest NSF report on Women, Minorities, and Persons with Disabilities in Science and Engineering, http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27, and the latest NSF report on Women, Minorities, and Persons with Disabilities in Science and Engineering, http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27, and the latest NSF report on Women, Minorities, and Persons with Disabilities in Science and Engineering, http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27, and the latest NSF report on Women, Minorities, and Persons with Disabilities in Science and Engineering, http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27, and the latest NSF report on Women, Minorities, and Persons with Disabilities in Science and Engineering, http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27, and the latest NSF report on support individuals from diverse backgrou

This Common Fund program is envisioned as a national collaborative forum through which awardee institutions, in partnership with the NIH, will develop and implement novel and innovative programs to engage individuals from diverse backgrounds and help them prepare for and succeed in biomedical research careers. This program is being developed in the context of existing programs through which NIH and other entities have made significant investments to engage scientists using a variety of training and mentoring approaches. Although existing programs may show positive outcomes for trainees and participants, progress towards achieving a more diverse NIH-funded workforce is still insufficient.

This program provides an opportunity to understand and address multi-dimensional factors (e.g., institutional, social, and individual levels) that strongly influence student success, professional development, and persistence within biomedical research career paths. It will build upon and move beyond existing programs and paradigms to support transformative approaches to student engagement, research training, mentoring, faculty development, and infrastructure development. Transformative approaches are ultimately expected to supplant less effective practices and methods to have a broad and sustained impact on the diversity of the NIH-funded biomedical research workforce.

Relevant questions for this funding opportunity include, but are not limited to:

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 (e.g., institutional, social, and individual) influence emerging scientists, particularly those from underrepresented backgrounds, 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, particularly those from underrepresented backgrounds, 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? How can approaches be designed so that their impact continues beyond the period of NIH funding?

The program will consist of three highly integrated initiatives, in which awardees will work together as the Diversity Program Consortium:

The Building Infrastructure Leading to Diversity (BUILD) Initiative:

Various approaches to increase undergraduate student persistence in the STEM-related fields have been implemented (Graham et al., *Science, 341,* 1455-1456). Student participation in research experiences has been associated with improved academic performance and sustained interest in research careers in the basic and biomedical sciences (for example, see Fechheimer et al., CBE--*Life Sciences Education, 10,* 156-163 and Russell et al., *Science, 316 (5824),* 548-549). Recognizing this approach, BUILD awards should emphasize research opportunities for students in a multi-pronged approach to enhance diversity in the NIH research workforce. Institutions are encouraged to consider additional innovative methods to engage and prepare students for success. Flexibility to innovate is a hallmark of the BUILD initiative. Applicants are encouraged to think creatively about how to address identified needs at their institutions and develop visionary approaches that encompass institutional, social, and individual factors.

The National Research Mentoring Network (NRMN) Initiative:

Lack of adequate mentoring is consistently described as a problem for trainees from all backgrounds. The NRMN initiative will develop a highly networked set of motivated and skilled mentors from various disciplines linked to mentees across the country – both from BUILD institutions and elsewhere – for individuals from the undergraduate to early career faculty level. In addition to linking individuals to mentors, the NRMN will develop best practices for mentoring, providing training opportunities for mentors, and providing networking and professional opportunities for mentees. The NRMN is expected to contribute substantially to attainment of hallmarks of successful research career progression for each career stage.

The Coordination and Evaluation Center (CEC):

The CEC will coordinate consortium-wide activities and evaluate BUILD and NRMN programs. The CEC will facilitate the development of consortium-wide hallmarks, including core competencies, of successful biomedical research career progression and examination of the impact of BUILD and NRMN programs according to these hallmarks. These consortium-wide development activities will be established through consensus in Executive Steering Committee meetings, which will be facilitated by the CEC (See Section VI for details about the Executive Steering Committee). The CEC will coordinate the collection and reporting of data from BUILD and NRMN awardees. The CEC will also facilitate consortium-wide discussions of approaches, progress, and lessons learned, and will serve as the focal point for dissemination of information to the broader research training and mentoring communities.

The overarching goal of the Diversity Program Consortium is to enhance the diversity of well-trained biomedical research scientists who can successfully compete for NIH research funding and/or otherwise contribute to the NIH-funded workforce. The BUILD and NRMN initiatives are not intended to support replication or expansion of existing programs at applicant institutions (for example, simply increasing the number of participants in current NIH-funded research training or mentoring programs would not be responsive to this funding announcement). Promising practices and principles derived from the literature or from pilot programs may be leveraged to inform applicants' approaches and/or expansion of existing efforts in novel ways. These initiatives are intended to allow institutions to develop and pilot novel approaches to biomedical research training and mentoring and disseminate successful approaches.

This FOA addresses the CEC, which will serve a critical organizing function for the consortium as a whole, facilitate the development of consortium-wide goals, design instruments and measures of success toward the individual and consortium-wide goals, and serve as a focal point for communication and dissemination.

Purpose/Objectives

The CEC will coordinate the activities of the consortium to ensure that all BUILD and NRMN awardees address the consortium identified goals and objectives. The activities to be undertaken through the BUILD and NRMN awards will allow transformative approaches to participant engagement and training to be piloted. The CEC will

conduct evaluation activities to ensure that each approach is assessed with respect to agreed-upon principles, that different approaches may be compared, and that lessons learned are disseminated. For the purpose of this FOA, "participants" include undergraduates, graduate students, postdoctoral fellows, and early career faculty who are intended to benefit from BUILD and/or NRMN activities.

The CEC will work collaboratively with BUILD and NRMN awardees to 1) identify fundamental attributes of successful biomedical researchers, i.e., hallmarks of success, including core competencies, for each career stage; 2) identify metrics for site-specific goals; 3) assess the impact of approaches used by each site on the attainment of hallmarks of success by participants; 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.)

To develop hallmarks of success at each career stage, the CEC will facilitate a discussion within the consortium after awards are made. While awardees will maintain goals tailored for their particular environments, each will also work toward consortium-wide goals and hallmarks of success.

The CEC will work collaboratively with BUILD and NRMN 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 as a whole will strive to enhance the way in which program participants are engaged and trained, awardees learn from each other during the course of the program, and approaches are modified based on lessons learned to improve overall impact.

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 diverse 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:

- Establishing standardized evaluation approaches and data collection protocols for the BUILD and NRMN programs that include individual and institutional demographic characteristics, nature of participation in the BUILD and NRMN programs, and achievement of training and career milestones.
- Identifying and/or developing instruments designed to assess participants' perceptions and attitudes towards biomedical research and biomedical research careers and to assess their attainment of hallmarks of success.
- Collaborating with BUILD and NRMN awardees to iteratively assess the impact of new approaches on participants' perception and attitudes towards biomedical research careers and the impact of the approaches on attainment of hallmarks of success, providing feedback so that approaches may be adjusted to maximize impact.
- Working with NIH staff to obtain all necessary federal clearances for data collection from BUILD and NRMN participants.
- Ensuring that evaluation metrics for BUILD and NRMN are compatible with those of trans-NIH training and scientific research workforce diversity program evaluation efforts.
- Coordinating ongoing data collection, data management, and reporting activities across BUILD and NRMN institutions.
- Conducting an outcome evaluation of BUILD and NRMN according to consortium-specified metrics, including an evaluation of interim milestones when applicable.
- Developing novel and innovative quantitative or qualitative approaches to identify the unique impact of BUILD and NRMN programs on participant outcomes, through the use of appropriate comparison groups, statistical techniques, or other evaluation strategies.
- Developing novel and innovative quantitative or qualitative approaches to assess potential higher-level impacts of BUILD and NRMN, such as changes to NIH-funded research workforce composition,

engagement, or productivity; or changes to institutional/organizational operating procedures, resource allocation, or policies.

- Conducting a process evaluation of the BUILD sites and NRMN to assess implementation and ongoing operations and their impact on program outcomes.
- Planning and enabling effective communications across the multiple BUILD and NRMN institutions to facilitate CEC objectives of data solicitations and coordination.
- Coordinating annual meetings with the BUILD and NRMN 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.
- Developing and maintaining a 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.

Note: The coordination among the CEC, BUILD, and NRMN awardees for data collection and evaluation will be established after the awardees for these programs are selected. It is therefore not necessary for CEC applicants to collaborate with specific BUILD or NRMN applicants or planning grant awardees as part of their application.

The CEC is expected to develop evaluation metrics and methods to assess the attainment of hallmarks of career success, including core competencies, by BUILD and NRMN participants at multiple career stages. This effort will include identifying Consortium-wide evaluation questions, and short-, intermediate-, and long-term metrics deemed appropriate for conducting assessments during various timeframes of the award period. While the metrics will be specified collectively by the group after awards are issued, the NIH will also expect the CEC to gather core data.

At a minimum, it is expected that the CEC will establish procedures for data collection and begin to gather the following core data:

- Completion of undergraduate or graduate degree, completion of postdoctoral research training, and entrance into graduate programs, postdoctoral research training of 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, etc.)
- Authorship on publications in peer review journals.
- Receipt of NIH or other peer reviewed grants or fellowships.

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

- Attainment of hallmarks of success, or core competencies, as defined by the consortium.
- 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.
- Potential sustainability of initiative activities.

In conducting the overall program evaluation, it is expected that the CEC may also refine previously identified evaluation questions and metrics as appropriate to assess program outcomes. The questions and data are expected to apply to outcomes at the individual, institutional, and national level as appropriate, particularly related to enhancing diversity in the biomedical research workforce and establishing overall sustainability of

successful strategies. The Diversity Program Consortium, through its collaborative and inclusive governance structure will establish and define any additional data elements required to effectively evaluate the BUILD and NRMN, including data intended to measure hallmarks of success at each career stage. It is anticipated that data may be obtained from various sources (e.g., NIH xTrain/eRA Commons, BUILD and NRMN grantees, federal and private entities when appropriate). The Consortium and/or the CEC will disseminate data collection requirements and obtain OMB clearance and other approvals of recommended data as needed.

Technical Assistance Webinars

Potential applicants are strongly encouraged to participate in one or more pre-application Technical Assistance webinars, which will provide an opportunity to clarify expectations for the FOA so applicant organizations can present their strongest case for support. The webinar is scheduled for January 2014. Additional information will be posted on the Common Fund website at http://commonfund.nih.gov/diversity/.

Funding Instrument	Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH staff will assist, guide, coordinate, or participate in project activities.
Application Types Allowed	New The <u>OER Glossary</u> and the PHS 398 Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	The NIH Common Fund intends to commit \$1.75 Million in FY 2014. A single award is anticipated contingent upon the availability of funds.
Award Budget	Application budgets may not exceed \$1.75 Million in total costs annually.
Award Project Period	The project period is 5 years.

Section II. Award Information

NIH grants policies as described in the <u>NIH Grants Policy Statement</u> will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Governments

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

Other

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

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply. Foreign components, as <u>defined in the *NIH Grants Policy Statement*</u>, **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the PHS 398 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 <u>NIH Policy on Late Submission of Grant Applications</u> 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)</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)</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.
- <u>NATO Commercial and Government Entity (NCAGE) Code</u> Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- <u>eRA Commons</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.

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

All PD(s)/PI(s) must have an eRA Commons account and should work with their organizational officials to either create a new account or to affiliate an existing account with the applicant organization's eRA Commons account. 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 PD(s)/PI(s), visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the PHS 398 Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement.

3. Additional Information on Eligibility

Number of Applications

Only one application per institution, identified by a unique DUNS number, is allowed.

NIH will not accept any application that is essentially the same as one already reviewed within the past thirty-seven months (as described in the *NIH Grants Policy Statement*), except for submission:

- To an RFA of an application that was submitted previously as an investigator-initiated application but not paid;
- Of an investigator-initiated application that was originally submitted to an RFA but not paid; or
- Of an application with a changed grant activity code.

Note: Applicants for BUILD or NRMN awards are eligible to apply to this FOA. However, the CEC awardee may not receive a BUILD or NRMN award or be involved as a collaborating institution on a BUILD or NRMN award.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants are required to prepare applications according to the current PHS 398 application forms in accordance with the PHS 398 Application Guide.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the <u>PHS 398 Application Guide</u>, except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

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

By the date listed in <u>Part 1. Overview Information</u>, prospective applicants are asked to submit a letter of intent that includes the following information:

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

The letter of intent should be sent to:

Pamela L. Thornton, PhD, MSW Common Fund Diversity Initiatives National Institute on Minority Health and Health Disparities (NIMHD) 6707 Democracy Boulevard, Suite 800 Bethesda, MD 20892-5465 Telephone: 301-402-1366 Email: pamela.thornton@nih.gov

Application Submission

Applications must be prepared using the PHS 398 research grant application forms and instructions for preparing a research grant application. Submit a signed, typewritten original of the application, including the checklist, five signed photocopies and all copies of the Appendix files in one package to:

Center for Scientific Review National Institutes of Health 6701 Rockledge Drive, Room 1040, MSC 7710 Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail) Bethesda, MD 20817 (for express/courier service; non-USPS service)

Page Limitations

All page limitations described in the PHS 398 Application Guide and the <u>Table of Page Limits</u> must be followed, in addition to the following page limitations to the Research Strategy section of each component of the application.

- Overall: 12 pages
- Administrative Core: 12 pages
- Data Coordination Core: 12 pages
- Evaluation Core: 12 pages

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in the PHS 398 Application Guide, and should be used for preparing a multi-component application.

The application should consist of the following components:

- Overall: required
- Administrative Core: required, 1 maximum
- Data Coordination Core: required, 1 maximum
- Evaluation Core: required, 1 maximum

Overall Component

All instructions in the PHS398 Application Guide must be followed, with the following additional instructions, as noted.

Face Page (Overall)

All instructions in the PHS 398 Application Guide must be followed.

Description, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, Human Embryonic Stem Cells (Overall)

All instructions in the PHS 398 Application Guide must be followed.

Table of Contents (Overall)

All instructions in the PHS 398 Application Guide must be followed.

Detailed Budget for Initial Budget Period (Overall)

All instructions in the PHS 398 Application Guide must be followed.

Budget for Entire Proposed Period of Support (Overall)

All instructions in the PHS 398 Application Guide must be followed.

Biographical Sketch (Overall)

All instructions in the PHS 398 Application Guide must be followed.

Resources (Overall)

All instructions in the PHS 398 Application Guide must be followed.

Research Plan (Overall)

All instructions in the PHS 398 Application Guide must be followed, with the following additional instructions:

Specific Aims: Describe the specific aims for the overall CEC.

Research Strategy: Describe the overall model for the CEC and a vision for general approaches to assess efficacy of diverse training and mentoring approaches. Identify collaborating institutions and organizations if any, and their role in the CEC. Summarize the strengths of the applicant organization and collaborators, including expertise and knowledge in understanding factors that contribute to decisions to pursue, or not to pursue, biomedical research careers; assessing and evaluating biomedical research training and mentoring activities; working collaboratively and building consensus with diverse stakeholder groups; and coordinating multi-site evaluation activities. Describe a vision for communicating the outcome of the Diversity Program Consortium with the wider community. Describe the integration of all the center cores and provide a project timeline that incorporates activities from each core.

Protection of Human Subjects: Because CEC activities will involve the dissemination of evaluation findings derived from data with personal identifiers from BUILD and NRMN participants, it is expected that the CEC will involve human subjects research. The application should clearly specify the activities that do not involve human subjects research or involve exempt or non-exempt human subjects research and provide a justification for this determination. Appropriate human subjects information should be completed in accordance with PHS 398 instructions for all activities involving exempt or non-exempt human subjects research.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the PHS 398 Application Guide.

Administrative Core

All instructions in the PHS 398 Application Guide must be followed, with the following additional instructions, as

noted.

Face Page (Administrative Core)

All instructions in the PHS 398 Application Guide must be followed.

Description, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, Human Embryonic Stem Cells (Administrative Core)

All instructions in the PHS 398 Application Guide must be followed.

Table of Contents (Administrative Core)

All instructions in the PHS 398 Application Guide must be followed.

Detailed Budget for Initial Budget Period (Administrative Core)

All instructions in the PHS 398 Application Guide must be followed. In addition, funds for the PD(s)/PI(s) to organize and travel to the annual grantees meeting and Executive Steering Committee meetings, held in or near Bethesda, MD, as well as funds for the PD(s)/PI(s) to travel to individual consortium sites should be included in the budget request. The first annual grantees meeting/Executive Steering Committee meeting will take place in October, 2014.

Budget for Entire Proposed Period of Support (Administrative Core)

All instructions in the PHS 398 Application Guide must be followed.

Biographical Sketch (Administrative Core)

All instructions in the PHS 398 Application Guide must be followed.

Resources (Administrative Core)

All instructions in the PHS 398 Application Guide must be followed.

Research Plan (Administrative Core)

All instructions in the PHS 398 Application Guide must be followed, with the following additional instructions:

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

Research Strategy: Describe the plans for bringing all consortium components together to develop consortium agreements pertaining to hallmarks of success and appropriate measures of success at each career stage. Describe plans to communicate within the consortium and the frequency with which coordinating calls and/or meetings are expected to be required. Describe plans for a consortium website and/or other communications tools to convey information to the consortium members and community at large. Describe CEC's organizational and governance structure and explain the roles and responsibilities of Administrative Core personnel. Describe the processes to be used to allocate and prioritize fiscal and other resources. Describe available infrastructure to support the required administrative activities of the CEC. Include a management plan that describes the composition and roles of any committees.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the PHS 398 Application Guide.

Data Coordination Core

All instructions in the PHS 398 Application Guide must be followed, with the following additional instructions, as noted.

Face Page (Data Coordination Core)

All instructions in the PHS 398 Application Guide must be followed.

Description, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, Human Embryonic Stem Cells (Data Coordination Core)

All instructions in the PHS 398 Application Guide must be followed.

Table of Contents (Data Coordination Core)

All instructions in the PHS 398 Application Guide must be followed.

Detailed Budget for Initial Budget Period (Data Coordination Core)

All instructions in the PHS 398 Application Guide must be followed.

Budget for Entire Proposed Period of Support (Data Coordination Core)

All instructions in the PHS 398 Application Guide must be followed.

Biographical Sketch (Data Coordination Core)

All instructions in the PHS 398 Application Guide must be followed.

Resources (Data Coordination Core)

All instructions in the PHS 398 Application Guide must be followed.

Research Plan (Data Coordination Core)

All instructions in the PHS 398 Application Guide must be followed, with the following additional instructions:

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 proposed strategies and processes to promote standardization or harmonization of data collection across BUILD sites and the NRMN. Describe the approach and infrastructure available to successfully collect, store, and manage data across the BUILD and NRMN programs. Describe monitoring or oversight strategies to maximize data quality and minimize missing data. Describe how implementation or operational difficulties regarding data collection by individual sites will be addressed. Describe strategies and procedures to ensure privacy and security of coded data obtained from BUILD and NRMN sites. Identify personnel who will be involved in data coordination activities and their relevant expertise. Identify planned committees or workgroups to guide, support, or implement data coordination activities.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the PHS 398 Application Guide.

Evaluation Core

All instructions in the PHS 398 Application Guide must be followed, with the following additional instructions, as

noted.

Face Page (Evaluation Core)

All instructions in the PHS 398 Application Guide must be followed.

Description, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, Human Embryonic Stem Cells (Evaluation Core)

All instructions in the PHS 398 Application Guide must be followed.

Table of Contents (Evaluation Core)

All instructions in the PHS 398 Application Guide must be followed.

Detailed Budget for Initial Budget Period (Evaluation Core)

All instructions in the PHS 398 Application Guide must be followed.

Budget for Entire Proposed Period of Support (Evaluation Core)

All instructions in the PHS 398 Application Guide must be followed.

Biographical Sketch (Evaluation Core)

All instructions in the PHS 398 Application Guide must be followed.

Resources (Evaluation Core)

All instructions in the PHS 398 Application Guide must be followed.

Research Plan (Evaluation Core)

All instructions in the PHS 398 Application Guide must be followed.

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 model(s) or conceptual framework(s) that will guide evaluation activities. Describe 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 may be evaluated. Describe likely comparison groups and methods to compare efficacy. Describe attributes of successful biomedical researchers that might be identified by the consortium as hallmarks of success at each career stage. Describe approaches that will be used to determine whether individual approaches used by BUILD and NRMN are enhancing the ability of trainees and participants to achieve these career hallmarks. 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 BUILD and NRMN programs on participant outcomes as well as higher-level impacts on institutions, organizations, and the biomedical research workforce. Describe likely comparison groups that will be required for these analyses. Describe proposed components of the process evaluation to assess program implementation and ongoing operations of the BUILD sites and the NRMN. Identify personnel who will be involved in evaluation activities and their relevant expertise. Identify planned committees or workgroups to guide, support, or implement evaluation activities.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as

provided in the PHS 398 Application Guide.

Appendix for the Entire Application

Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix (please note all format requirements) as described in the PHS 398 Application Guide.

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates.

Information on the process of receipt and determining if your application is considered "on-time" is described in detail in the PHS 398 Application Guide.

Applicants may track the status of the application in the <u>eRA Commons</u>, NIH's electronic system for grants administration.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

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

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

6. Other Submission Requirements and Information

Applications must be received on or before the due dates in <u>Part I. Overview Information</u>. If an application is received after that date, it will not be reviewed.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review and responsiveness by <u>components of participating organizations</u>, NIH. Applications that are incomplete and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the <u>NIH mission</u>, 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 center 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 center address an important problem or a critical barrier to progress in the field? If the aims of the center are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

In addition, specific for this FOA: Are the overall plans for coordination and evaluation to be conducted by the CEC 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?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the center? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

In addition, specific for this FOA: Has the PD/PI demonstrated the ability to coordinate complex consortia to establish and implement joint goals? Is the PD/PI experienced with programs that focus on diverse participant populations? Has the PD/PI 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 BUILD and NRMN 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 challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions?

In addition, specific for this FOA: Does the application include innovative quantitative or qualitative approaches, methodologies, or study designs to evaluate the effectiveness or impact of the BUILD and NRMN programs?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the center? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the center involves human subjects and/or NIH-defined clinical research, are there 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 potential proposed evaluation methods robust and is the vision for comparing across BUILD and NRMN

sites compelling? Are activities of the project cores well integrated? Is an achievable project timeline provided?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

In addition, specific for this FOA: Is the environment of the awardee institution adequate to support the CEC in accomplishing its goal of managing and evaluating the diverse BUILD and NMRN activities?

Additional Review Criteria - Overall

As applicable for the center 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

- Does the vision for coordination across BUILD and NRMN sites promote a collaborative environment?
- Will the coordination efforts be likely to unite the various sites and foster 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 as appropriate?
- Are the plans to develop a consortium website and/or other communications tools to convey information to consortium and community members appropriate?
- Is a plan provided to ensure timely and effective communication across project cores and with BUILD sites and the NRMN?
- Is a management plan included that describes 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 infrastructure to support communication, data coordination and evaluation activities described?
- Are key administrative personnel experienced in the organization of meetings, workshops, and other networking activities, and are the personnel appropriate for record keeping, website development, and other communications tasks?

Data Coordination Core

- Is a clear and logical framework or conceptual model for the coordination of data collection across BUILD sites and the NRMN provided?
- Are proposed strategies and processes to promote standardization and harmonization of operating procedures across BUILD sites and NRMN appropriate? Are they likely to be successful?
- Is the described infrastructure to support data collection, storage, and management appropriate and comprehensive?
- 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 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?
- Is the description of the attributes of successful biomedical researchers at each career stage

well-reasoned?

- Are the methods to be used to assess efficacy of individual BUILD and NRMN activities compelling and flexible enough to adapt as the specific plans of BUILD and NRMN awardees become known?
- Are comparison groups described, and are they appropriate for the assessment of approaches to be implemented by BUILD and NRMN?
- Is the process evaluation well-described and flexible enough to accommodate various processes to be employed by BUILD and NRMN sites?
- Are appropriate data analytic strategies proposed to understand factors associated with entry and success in biomedical research careers?
- Are additional evaluation activities described to identify the unique impact of BUILD and NRMN 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?

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>.

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</u>.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the <u>Worksheet for Review</u> of the Vertebrate Animal Section.

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

Not Applicable

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>; 2) <u>Sharing Model Organisms</u>; and 3) <u>Genome Wide Association Studies (GWAS)</u>.

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 the CSR, in accordance with <u>NIH peer review policy and procedures</u>, using the stated <u>review</u> <u>criteria</u>. 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.

Appeals of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned to the appropriate NIH Institute or Center and 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 NIMHD Advisory Council. The following will be considered in making funding decisions:

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

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the <u>eRA Commons</u>.

Information regarding the disposition of applications is available in the <u>NIH Grants Policy Statement</u>.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the <u>NIH Grants Policy Statement</u>.

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 the DUNS, SAM Registration, and Transparency Act requirements as noted on the <u>Award Conditions and Information for NIH Grants</u> website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the <u>NIH Grants Policy Statement</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</u> <u>Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and</u> <u>Conditions for Specific Types of Grants, Grantees, and Activities</u>. More information is provided at <u>Award</u> <u>Conditions and Information for NIH Grants</u>.

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 Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is 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 resides 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 consortium as a whole, of 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 as part 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 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 CEC and consortium will develop plans for data sharing among awardees. All evaluation-related data will be shared with the NIH at the conclusion of the award.

NIH staff 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. The Project Scientists may work with the awardees on any issues that come before these Committees.
- The Project Scientists will 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 NIH-Funded 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; (c) or project 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 serve as the primary governing board for the cooperative agreement funded under this FOA. The Steering Committee membership will include the NIH Program Official, 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 uniform procedures and policies necessary to meet the goals of the FOA and the goals of the Enhancing the Diversity of the NIH-Funded Workforce Program as a whole.
- Provide input to the PD/PI with respect to the activities of the CEC and its ability to coordinate and evaluate the activities of BUILD and NRMN 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) will be responsible for providing general oversight and guidance to the Diversity Program Consortium. The ESC membership will 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 at least once annually, with intermittent conference calls as needed. The first ESC meeting will take place during the Annual Grantees Meeting in October, 2014.

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.
- Define competencies to be targeted through BUILD and NRMN activities.
- Define hallmarks of success in biomedical research careers at various career stages.
- Develop policies for adoption of mentoring standards.
- Develop procedures and policies for sharing information between projects and with the wider community.
- 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 a program website managed by the CEC for the purposes of sharing information.
- Develop 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 Non-Competing Continuation Grant Progress Report (<u>PHS 2590 or RPPR</u>) annually and financial statements as required in the <u>NIH Grants Policy</u> <u>Statement.</u>

A final progress report, 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>.

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 <u>www.fsrs.gov</u> on all subawards over \$25,000. See the <u>NIH Grants Policy Statement</u> for additional information on this reporting requirement.

4. Evaluation

In carrying out its stewardship of research workforce diversity initiatives, the NIH will periodically evaluate the CEC, BUILD and NRMN programs. In assessing the effectiveness of its workforce diversity investments, NIH may request information from the CEC and other databases, PD(s)/PI(s), and from BUILD or NRMN participants themselves. Where necessary, PD(s)/PI(s) and participants may be contacted after the completion of a BUILD or NRMN program for periodic updates on participants' subsequent educational or employment history and professional activities. Evaluation of the BUILD, NRMN and CEC will be carried out continuously over the first five years of the program. The findings of this evaluation will determine whether the initiative will be continued for an additional five years as configured, continued with modifications, or discontinued.

The Diversity Program Consortium, through its collaborative and inclusive governance structure will establish and define any additional data elements required to effectively evaluate the BUILD and NRMN, including data intended to measure hallmarks of success, including core competencies, at each career stage. The Consortium and/or the CEC will disseminate these requirements and obtain OMB clearance of recommended date as needed.

The NIH will conduct an evaluation of the CEC continuously over the first five years of the program. The list below includes, but is not limited to, key metrics the NIH may use to help determine whether the CEC goals or outcomes have been met.

- Effectiveness of organization and oversight of consortia-wide meetings.
- Provision of expert assistance in supporting the development of consortium-wide evaluation protocols and common evaluation measures.
- Demonstration of expertise in developing and maintaining data management systems for the collection of evaluation data.
- Effective promotion of collaborations across program sites to support common constructs and instruments and standard procedures.
- Utilization of strategies to facilitate effective communication consortium-wide.
- Development of high impact ways to disseminate new consortia-wide research findings to key stakeholders.

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 Commons Help Desk (Questions regarding eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues) Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Web ticketing system: <u>https://public.era.nih.gov/commonshelp</u> TTY: 301-451-5939 Email: commons@od.nih.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources) Telephone: 301-435-0714 TTY: 301-451-5936 Email: GrantsInfo@nih.gov

Scientific/Research Contact(s)

Pamela L. Thornton, PhD, MSW National Institute on Minority Health and Health Disparities (NIMHD) Telephone: 301-594-8696 Email: <u>pamela.thornton@nih.gov</u>

Peer Review Contact(s)

Karyl Swartz, PhD Center for Scientific Review (CSR) Telephone: 301-435-1883 Email: <u>swartzkb@mail.nih.gov</u>

Financial/Grants Management Contact(s)

Priscilla Grant, JD National Institute on Minority Health and Health Disparities (NIMHD) Telephone: 301-594-8412 Email: <u>grantp@mail.nih.gov</u>

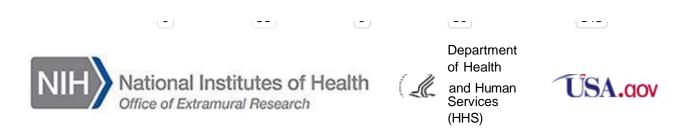
Section VIII. Other Information

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

Authority and Regulations

Awards are made under the authority of sections 301, 402, and 405 of the Public Health Service Act as amended (42 USC 241, 282, and 284) and the Code of Federal Regulations, 42 CFR Parts 52 and 66, and 45 CFR Parts 74 and 92.

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