

OMB #0925-0747

EXP. 11/2019

## Attachment 2:

RFA-RM-18-006 (Building Infrastructure Leading to  
Diversity (BUILD) Initiative Phase II)

# Department of Health and Human Services

## Part 1. Overview Information

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### Participating Organization(s)

National Institutes of Health ([NIH \(http://www.nih.gov/\)](http://www.nih.gov/))

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### Components of Participating Organizations

This Funding Opportunity Announcement (FOA) is developed as a Common Fund initiative (<http://commonfund.nih.gov/> (<http://commonfund.nih.gov/>)) through the NIH Office of the Director, Office of Strategic Coordination (<http://dpcpsi.nih.gov/osc/> (<http://dpcpsi.nih.gov/osc/>)). 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> (<https://www.nigms.nih.gov/Pages/default.aspx>)) on behalf of the NIH.

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### Funding Opportunity Title

**Limited Competition: Building Infrastructure Leading to Diversity (BUILD) Initiative Phase II (U54 – Clinical Trial Not Allowed)**

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### Activity Code

[U54 \(//grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=u54&Search.x=0&Search.y=0&Search\\_Type=Activity\)](https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u54&Search.x=0&Search.y=0&Search_Type=Activity) Specialized Center-Cooperative Agreements

Successful applicants will receive support through the Linked Specialized Center Cooperative agreement mechanism that includes a primary UL1 (Linked Specialized Center Cooperative Agreement) award, a RL5 (Linked Education Project) award and a TL4 (Linked Undergraduate Institutional Training) award.

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### Announcement Type

Reissue of [RFA-RM-13-016 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-13-016.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-13-016.html)

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### Related Notices

- [June 11, 2018 \(//grants.nih.gov/grants/guide/notice-files/NOT-GM-18-035.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-GM-18-035.html) - Notice of Change to Application Due Date in RFA-RM-18-006. See Notice [NOT-GM-18-035 \(//grants.nih.gov/grants/guide/notice-files/NOT-GM-18-035.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-GM-18-035.html).

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### Funding Opportunity Announcement (FOA) Number

**RFA-RM-18-006**

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### Companion Funding Opportunity

[RFA-RM-18-002 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-18-002.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-18-002.html), U24 Resource-Related Research Projects – Cooperative Agreements

[RFA-RM-18-003 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-18-003.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-18-003.html), U24 Resource-Related Research Projects – Cooperative Agreements

[RFA-RM-18-004 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-18-004.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-18-004.html), U01 Research Project – Cooperative Agreements

[RFA-RM-18-005 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-18-005.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-18-005.html), U54 Specialized Center- Cooperative Agreements

[RFA-RM-19-003 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-19-003.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-19-003.html), [U01 \(https://grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=u01&Search.x=0&Search.y=0&Search\\_Type=Activity\)](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

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### Number of Applications

One application per institution is allowed, as defined in [Section III. 3. Additional Information on Eligibility](#).

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

93.310

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**Funding Opportunity Purpose**

This Funding Opportunity Announcement (FOA) invites applications from the Program Directors/Principal Investigators of the current Building Infrastructure Leading to Diversity (BUILD) awards. BUILD is part of the Enhancing the Diversity of the NIH-Funded Workforce Program, also known as the Diversity Program Consortium (DPC). The DPC consists of three integrated initiatives: BUILD, the National Research Mentoring Network (NRMN) and the Coordination and Evaluation Center (CEC). The purpose of the funding opportunity is to allow BUILD sites to continue to implement and evaluate the multi-pronged student, faculty, and institutional interventions to enhance diversity in the NIH biomedical research workforce. In preparation for the second phase of the BUILD initiative, the applicants are expected to provide plans to transition into sustainable models for enhancing diversity in the biomedical research fields at their institutions. Applicants are also expected to develop an effective training, mentoring, or research capacity building intervention that will be disseminated to other institutions to increase the national impact of the initiative.

## Key Dates

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**Posted Date**

April 3, 2018

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**Open Date (Earliest Submission Date)**

May 11, 2018

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**Letter of Intent Due Date(s)**

30 days prior to the application due date

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**Application Due Date(s)**

**New Dates** June 15, 2018, by 5:00 PM local time of applicant organization. All types of non-AIDS applications 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.

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**AIDS Application Due Date(s)**

Not Applicable

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**Scientific Merit Review**

October - November 2018

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**Advisory Council Review**

January 2019

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**Earliest Start Date**

July 2019

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**Expiration Date**

**New Date** June 16, 2018 per issuance of [NOT-GM-18-035 \(//grants.nih.gov/grants/guide/notice-files/NOT-GM-18-035.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-GM-18-035.html). (Original Expiration Date: June 12, 2018)

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**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](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000](https://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](https://grants.nih.gov/grants/guide/) ([//grants.nih.gov/grants/guide/](https://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.**

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## Part 2. Full Text of Announcement

### Section I. Funding Opportunity Description

#### **Background**

The NIH recognizes the need to diversify the scientific workforce by the enhancing the participation of individuals from groups identified as nationally [underrepresented](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html>) in the biomedical, clinical, behavioral and social sciences (collectively termed "biomedical") research workforce. 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 traditionally [underrepresented](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html>) in the biomedical sciences (Gibbs, et al., 2016, eLife 2016;5:e21393); however, the attrition rate of scientists from [underrepresented](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html>) groups 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 backgrounds [underrepresented](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html>) in biomedical research, sustain their interest in, and prepare them for successful biomedical research careers. The Working Group provided recommendations, endorsed by the ACD, about ways to develop and support individuals from groups [underrepresented](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) (<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, including those from groups [underrepresented](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html>) 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 diversity enhancing 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 enhance diversity by engaging and sustaining the interest of individuals in the biomedical research workforce and to encourage the dissemination of successful diversity enhancing 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, particularly those from [underrepresented \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) 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 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) 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?

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. 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 described below.

#### *The Building Infrastructure Leading to Diversity (BUILD) Initiative:*

The initial phase of the BUILD program supported the development of 10 different experiments to test models for enhancing the diversity of the biomedical research workforce. The second and final phase of the BUILD initiative will allow sites that are deemed to have shown significant potential to finish their experiments in order to inform future diversity enhancement efforts at institutions across the country. BUILD sites that compete successfully will be expected to disseminate their models to other institutions. Because this second phase of the program is intended to allow successful BUILD sites to complete their experiments, report outcomes and disseminate successful models, the competition will be limited to the currently funded BUILD awardees.

#### *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 various backgrounds, including those from [underrepresented \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) groups. The NRMN consortium was developed to understand the elements that contribute to productive mentoring relationships, 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 consortium 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 \(https://www.nigms.nih.gov/training/dpc/Pages/success.aspx\)](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 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 [hallmarks of success \(https://www.nigms.nih.gov/training/dpc/Pages/success.aspx\)](https://www.nigms.nih.gov/training/dpc/Pages/success.aspx), robust evaluation plans, and the [data sharing agreement \(https://www.nigms.nih.gov/training/dpc/Pages/datasharing.aspx\)](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 [Section VI](#) for details about the Executive Steering Committee). The CEC coordinated

the clearance through the Office of Management and Budget 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 of this Funding Announcement**

The primary purpose of the second phase of the BUILD initiative (BUILD II) is to provide opportunities and resources to continue conducting and evaluating transformative, broad-based interventions to enhance diversity in the biomedical research workforce. Additionally, the funded sites are expected to disseminate effective diversity enhancing training, mentoring, or research capacity building interventions to institutions not currently part of the DPC. Finally, each funded site will be expected to transition into a sustainable model for enhancing diversity in the biomedical research workforce. Funded sites must have evidence for tangible advances in three key areas: institutional, faculty, and student development to enhance diversity in the biomedical research workforce.

Through the BUILD II initiative, funded institutions will continue to conduct and evaluate biomedical research training for students and faculty and build institutional research capacity that emphasize attainment of the [hallmarks of success](https://www.nigms.nih.gov/training/dpc/Pages/success.aspx) (<https://www.nigms.nih.gov/training/dpc/Pages/success.aspx>). Funded BUILD II institutions are expected to continue to engage participants and offer diversity enhancing research training and mentorship activities to support site-specific and consortium data collection and analysis. As was the case in the first phase, funded institutions may partner with other institutions to broaden the potential pool of participating students and maximize opportunities for research training as well as faculty and staff development. In addition, BUILD II awards will continue to support faculty and staff enrichment in novel ways to further enhance the research training environment. As before, rigorous assessment and evaluation of all activities implemented across the program are expected to be a critical component of all applications.

See [Section VIII. Other Information](#) for award authorities and regulations.

## **Section II. Award Information**

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### **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 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.

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### **Application Types Allowed**

Renewal

The [OER Glossary](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11116](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11116)) and the SF424 (R&R) Application Guide provide details on these application types.

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### **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) ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82370](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370))

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### **Funds Available and Anticipated Number of Awards**

NIH intends to fund up to 10 awards, corresponding to a maximum total of \$40,000,000 total costs in FY2019, \$35,000,000 in FY2020, \$30,000,000 in FY2021, \$25,000,000 in FY2022, and \$20,000,000 in FY2023.

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### **Award Budget**

Application budgets are not limited but need to reflect the actual needs of the proposed project.

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### **Award Project Period**

The maximum project period is five years.

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

## Section III. Eligibility Information

### 1. Eligible Applicants

#### Eligible Organizations

The eligibility to apply to this FOA is limited to the current Primary Institution BUILD awardees of the NIH Enhancing the Diversity of the NIH-Funded Workforce Program funded through [RFA-RM-13-016 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-13-016.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-13-016.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 [defined in the NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11118\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **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 \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System \(DUNS\) \(http://fedgov.dnb.com/webform\)](http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](https://www.sam.gov/portal/public/SAM/) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - [NATO Commercial and Government Entity \(NCAGE\) Code \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11176\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- [Grants.gov \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=82300\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – 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.

##### Participants in the Research Enrichment Core

It is expected that eligibility for BUILD II supported activities will be open to participants at Participating and Partner Institutions, who are, or plan to be, biomedically-related STEM majors. The applicant institution is responsible for selecting participants who will receive BUILD II RL5 financial support. Participants supported through a RL5-linked award must be U.S. citizens or non-citizen nationals or permanent residents and must be enrolled full time at the applicant institution or Pipeline Partner or Graduate Partner institution (if applicable). A non-citizen national is a person who, although not a citizen of the United States, owes permanent allegiance to the U.S. This is generally a person born in a land that is not a state, but that is under U.S. sovereignty, jurisdiction, or administration, e.g., American Samoa. An individual lawfully admitted for permanent residence must possess a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status prior to receiving financial benefit from or employment on the grant. Individuals on temporary visas, those seeking asylum, or refugees are not eligible for support from this program. A limited range of enrichment activities, including research training and participation in research projects, may be offered to high school seniors who are concurrently enrolled in college bridge programs for biomedical sciences at participating institutions, but such students are not eligible to receive financial support from BUILD awards.

##### Trainees in the Training Core

It is expected that eligibility for BUILD II-supported activities will be open to all trainees at Participating Institutions who are, or plan to be, biomedically-related majors. The applicant institution is responsible for selecting trainees who will receive BUILD II TL4 financial support. Student trainees supported through a TL4-linked training award must be at the undergraduate level, U.S. citizens or non-citizen nationals or permanent residents, and must be enrolled full time in academic degree programs in biomedical science fields at the applicant institution. A non-citizen national is a person who, although not a citizen of the United States, owes permanent allegiance to the U.S. This is generally a person born in a land that is not a state, but that is under U.S. sovereignty, jurisdiction, or administration, e.g., American Samoa. An individual lawfully admitted for permanent residence must possess a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status prior to receiving financial benefit from or employment on the grant. Individuals on temporary visas, those seeking asylum, or refugees are not eligible for support from this program.

## 2. Cost Sharing

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement. \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11126\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

## 3. Additional Information on Eligibility

### Number of Applications

Only one application per institution (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 \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html\)](http://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 [Part 1](#) 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000\)](http://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 [Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=41137\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=41137).

### Letter of Intent

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

By the date listed in [Part 1. Overview Information](#), prospective applicants are asked to submit a letter of intent that includes the following information:

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

The letter of intent should be sent to:

Anissa Brown, Ph.D.  
Telephone: 301-594-3900  
Email: [anissa.brown@nih.gov \(mailto:anissa.brown@nih.gov\)](mailto:anissa.brown@nih.gov)

### Page Limitations

<b>Component Types Available in ASSIST</b>	<b>Research Strategy/Program Plan Page Limits</b>
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Component Types Available in ASSIST	Research Strategy/Program Plan Page Limits
Overall	12 pages
Admin Core	6 pages
Inst Dev Core (use for the Institutional Development Core)	12 pages
Research Education (use for the Research Enrichment Core)	12 pages
NRSA Training (use for the Training Core)	25 pages

Additional page limits described in the SF424 Application Guide and the [Table of Page Limits \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11133\)](https://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
- Institutional Development Core: required, 1 maximum
- Research Enrichment Core: required, 1 maximum
- Training Core: required, 1 maximum

Awards issued through this FOA will divide the cores above into three linked awards: a UL1 Linked Specialized Center Cooperative Agreement award will support activities described through the Administrative and Institutional Development Cores; a RL5 Linked Education Project award will support activities described through the Research Enrichment Core; a TL4 Linked Training Award will support activities described through the Training Core.

### 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.

**Facilities and Other Resources:** All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions: applicants are encouraged to use the [Suggested Formats Tables B-D \(https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx\)](https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx) to provide these required data on institutional environment:

- Cumulative Institutional Baseline Data: The reporting period should cover the last five years. An example of how [Table B \(https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx\)](https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx) might be formatted is provided for the applicant to assist with this requirement. See Suggested Format [Table B \(https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx\)](https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx).
- Institutional Faculty Data: Include the data regarding the research activity and diversity of the faculty in the biomedical departments. An example of how [Table C \(https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx\)](https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx) might be formatted is provided for the applicant to assist with this requirement. See Suggested Format [Table C \(https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx\)](https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx).
- Institutional Undergraduate Graduation Data: The reporting period should cover the last five years. The data should include the cumulative number, percent, and diversity of undergraduates that graduated with biomedically relevant degrees. An example of how [Table D \(https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx\)](https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx) might be formatted is provided for the applicant to assist with this requirement. See Suggested Format [Table D \(https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx\)](https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx).

#### 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:** Describe the specific aims for the BUILD II project as a whole. These should not be the same as the specific aims of the individual cores, but should be overarching and should include a vision for how the project will allow participating institutions to: 1. Continue the development and implementation of sustainable approaches to engage students, sustain their interest, and prepare them to pursue doctoral degrees leading to biomedical research careers; 2. Develop appropriate institutional capacity to enable faculty to develop NIH-supported or other extramural supported research programs; and 3. Disseminate interventions and effective practices to institutions currently not a part of the DPC.

**Research Strategy:** Applicants are required to comply with the instructions for the Research Strategy as provided in the SF424 (R&R) Application Guide, with the following modification:

**Approach.** Describe the institution's vision for continuing to reach students who would otherwise be likely to exit the biomedical research training pathway and the vision for successful research career paths, predictors of success at multiple stages, and activities related to student, faculty, and infrastructure development that create an environment that facilitates achievement of student and faculty milestones. The overall structure of the program should be described, including the following specific areas: Partnerships, Student and Faculty Development, Mentoring Infrastructure, Student Training and Financial Support, Evaluation, Sustainability, and Dissemination. Specific items to address in each section are described below.

**Partnerships.** Partnerships involving the Primary Institution and one or more additional institutions among the types described below are encouraged but not required. Applicants should identify proposed partners that have agreed to participate in the BUILD II renewal award. Applicants should provide the rationale for participation of all partner institutions. Each partner institution should contribute substantially to the goals of the program. Describe the leadership plan that will ensure effective communication, data sharing and interaction between partner organizations. Describe how the partnership will operate, the role of faculty or staff from each partner organization, and the vision for student involvement from each.

Building on the information in the Facilities and Other Resources section, applicants should briefly describe existing resources at the Participating and Partner institutions that will be used to support the engagement of students and faculty in biomedical research training and sustain their interest in biomedical research. Describe activities to ensure that the BUILD II award will leverage these existing resources to have synergistic effects, including (if applicable) existing biomedical research workforce diversity programs at participating institutions.

Partnering institutions are defined below:

- **Primary Institutions** – The institution of the contact PD(s)/PI(s). This FOA is a limited competition for the BUILD initiative, which was previously funded under [RFA-RM-13-016 \(https://grants.nih.gov/grants/guide/ifa-files/RFA-RM-13-016.html\)](https://grants.nih.gov/grants/guide/ifa-files/RFA-RM-13-016.html). Only the currently funded BUILD sites are eligible to serve as the primary institution.
- **Participating Institution** – The Primary Institution or an institution of the non-contact PD/PI in a Multi-PD/PI award.
- **Pipeline Partner** – Two- or four-year undergraduate institutions with student populations that will enrich and expand the pool of students engaged in BUILD II activities. Primary Institutions and Pipeline Partners are expected to work collaboratively to implement the training and mentoring activities of BUILD II that enable students to enter the biomedical research career pathway. Funded sites are expected to address institutional, social, and individual-level factors that may influence the sustained interest of participants from the Pipeline Partner institutions.
- **Research Partner** – Research-intensive institutions with investigators who are committed and able to serve as effective mentors. Research Partners are intended to expand training, research, and mentorship opportunities available to participating students, as well as engage faculty at Primary Institutions through collaborations and/or training opportunities. These partner institutions are expected to provide a scientifically rich research environment and a pool of potential research-active faculty mentors. Partnerships may also enhance student interactions between partner institutions through joint courses, shared laboratory or field experiences, or other activities. Partnerships with industry, NIH intramural research laboratories, or other research institutions are encouraged in addition to partnerships with research intensive institutions.
- **Graduate Institution Partner** – Graduate institutions that do not have undergraduate programs but do have research-active faculty and doctoral- and post-doctoral-level trainees engaged in biomedical research, may serve as a partner to a Primary Institution to work collaboratively to establish an accelerated biomedical research graduate program.

**Student and Faculty Development.** BUILD II awards will enable institutions to continue with their approaches to enhance student engagement and biomedical research training and to institutionalize successful piloted training and mentoring interventions to enhance diversity in the biomedical research workforce. BUILD institutions should also continue to provide innovative ways to enhance faculty development and to strengthen institutional research training infrastructure. Specifically, applicants are encouraged to propose professional development, grant writing, and grants management training for faculty and staff to increase institutional research capacity and research administration services.

**Mentoring Infrastructure.** Effective research mentoring is a critical component of successful career progression. Each BUILD II renewal award is expected to include sustainable student and faculty mentorship activities during and beyond the funding cycle. Institutions will have flexibility to

improve existing mentoring strategies with an emphasis on promoting sustainable change at the institutional level. These strategies should focus on enhancing student persistence in biomedical research training pathways, and equipping individuals with the knowledge and skills needed to become successful researchers. BUILD II awardees are encouraged to utilize the National Research Mentoring Network (NRMN) as a resource for mentor training.

*Student Training and Financial Support.* BUILD II awards will continue to afford flexibility to structure and distribute student financial support for research training. Applicants should describe how provision of tuition and paid research experiences may be used most effectively to engage students. The BUILD II initiative specifically seeks to enhance diversity among scientists with doctoral training engaged in NIH-funded biomedical research, but training activities for all aspects of the biomedical research enterprise are encouraged (see <http://commonfund.nih.gov/workforce/> (<http://commonfund.nih.gov/workforce/>) for related discussion of training for multiple career options).

*Evaluation.* Applications must include the plan for evaluating the activities supported by the award. Applicants should describe the methods developed in the first phase of the project to collect data for site-specific interventions and for consortium-wide evaluations according to the established DPC Hallmarks of Success. BUILD II awardees must collaborate with the DPC Coordination and Evaluation Center (CEC) on an ongoing basis throughout the project period to evaluate the efficacy of continued and enhanced training and mentoring interventions. For example, required data may be modified based on recommendations of the DPC Executive Steering Committee that will guide activities across the BUILD II, NRMN and CEC.

*Sustainability.* A primary goal of the BUILD initiative is to lead to sustainable institutional change that enhances the diversity of the biomedical research workforce. For the final phase, applicants must include a sustainability plan for each activity proposed. Primary institutions are expected to develop and include a transition plan in anticipation of the cessation of BUILD II funded student financial, educational, and research support. There is an expectation that sites will transition into a sustainable model for student support. Specifically, the ramp down plan should indicate a decrease in BUILD grant support (e.g., decrease BUILD support 25% in year 2, by 50% in year 3, by 75% in year 4) and a description of planned support to sustain student trainees beyond the funding cycle. Applicants should detail any institutional change, including support for students engaging in biomedical research and faculty reward structures for mentoring students and/or engaging in research activities. It is expected that BUILD II awardees should have increased research capacity because of the first phase of the BUILD awards. Applicants should describe how the enhanced research capacity will be leveraged to sustain faculty research activity. Applicants must provide detailed plans for ongoing or planned recruitment of a diverse faculty, including those from underrepresented groups.

*Dissemination.* BUILD II applicants should describe plans for disseminating tested interventions via outreach, publications, presentations, and collaborations with institutions not currently part of the DPC. The NIH anticipates offering a funding opportunity to non-BUILD institutions seeking to implement successful and sustainable BUILD training, mentoring or research capacity building interventions in collaboration with BUILD II awardees and coordinated by the CEC. Additional details and requirements will be provided in a separate Request for Applications (RFA) for these DPC Dissemination and Translation Awards, DPC DaTA (see [NOT-RM-18-007](https://grants.nih.gov/grants/guide/notice-files/NOT-RM-18-007.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-RM-18-007.html>)). Based on the progress from the first phase, applicants should propose an effective training, mentoring, or research capacity intervention that might be readily implemented and evaluated by institutions across the nation.

*Progress Report.* Applicants are required to comply with the instructions for the Progress Report as provided in the SF424 (R&R) Application Guide, with the following modification:

Describe the past success of the Primary and Partner Institutions (if applicable) in engaging science students into research careers and preparing them to be successful in research. Applicants may use the [Suggested Format Tables A-D](https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx) (<https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx>) to organize the data. Describe site and consortium-wide student outcomes from the previous BUILD funding cycle ([Suggested Format Table A](https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx) (<https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx>)) and compare these outcomes to national statistics and reports on other student development programs, as available. Provide a description of the institutional baseline data for the last five years ([Suggested Format Table B](https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx) (<https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx>)). Provide a description of the diversity of the tenure-track, research-active faculty in biomedical related departments. Describe the site outcomes for faculty support from the previous BUILD funding cycle ([Suggested Format Table C](https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx) (<https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx>)). Include a description the students enrolled at the institution, and undergraduate graduation data and time to degree in BUILD II-relevant sciences for all students and for students from [underrepresented](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html>) backgrounds ([Suggested Format Table D](https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx) (<https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx>)). [Suggested Format Tables B-D](https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx) (<https://www.nigms.nih.gov/training/dpc/Pages/BUILD-Tables-for-Applications.aspx>) may be included in the Facilities and Other Resources section.

**Progress Report Publication List:** Applicants are required to comply with the instructions for the Progress Report Publication List as provided in the SF424 (R&R) Application Guide, with the following modification:

For all applications, provide a list of all publications resulting from the BUILD award during the first funding period. Arrange the publications based on the following categories: 1) Interventions (publications focusing on training or mentoring interventions); 2) Pilot Projects (if applicable list each pilot project and the resulting publications); and 3) Other (BUILD supported research not from pilot projects or interventions research).

**Letters of Support:** Applicants are required to comply with the instructions for the Letters of Support as provided in the SF424 (R&R) Application Guide, with the following modification:

*Institutional Letter.* The application must include a detailed statement from the applicant institution's leadership describing institutional commitment to the transformative concepts proposed and to sustaining BUILD II models of student and faculty engagement and training if they are shown to be effective. Institutional support for BUILD II activities may include, but is not limited to, protected research time, support staff, facilities, and educational resources that will contribute to the proposed activities; plans for using institutional resources to further enhance the

training program (e.g., support for additional student positions) and/or the institution's ability to engage students and faculty, including those from [underrepresented](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html>) backgrounds, in biomedical research. Institutions should indicate their plans for recruitment of faculty and staff from diverse backgrounds, including those from [underrepresented](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html>) groups. Statements should include institutional commitment to providing faculty with mentoring, professional development, and ways to support faculty engaged in research activities. The statement should also address plans and prospects for long-term sustainability of institutional enhancements resulting from the BUILD projects, including, if applicable, how the institution will leverage the BUILD funds to build a broader base of support.

*Letters of collaboration.* Collaboration letters must be provided by authorized officials from partner institutions (if applicable) addressing their institutional commitment to the proposed project and BUILD II program goals. As applicable, key institutional leaders, faculty or senior investigators at partner organizations who will have substantial involvement in teaching, research training and mentoring, or other activities should submit letters.

**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 applicants, regardless of the amount of direct costs requested for any one year, are 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:**

Not allowed.

### **PHS Human Subjects and Clinical Trials Information (Overall)**

Use only for applications with due dates on or after January 25, 2018. 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, with the following additional instructions:

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.

#### **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.

### **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:** Describe the Specific Aims for the Administrative Core and how they relate to the Overall Specific Aims

**Research Strategy:** Describe the BUILD II project's organizational and governance structure and explain the roles and responsibilities of Administrative Core personnel including business official(s) involved in managing the grant and budget activities. Describe the processes to be used to allocate and prioritize fiscal and other resources across the various components. Describe procedures for ensuring timely and effective communication among project cores and across participating partner institutions (if applicable) and the CEC.

Describe how the evaluations and data collection across the Cores will be managed and how the program will collaborate with the CEC.

Describe the proposed composition, roles, and responsibilities of any internal and external advisory committees or boards proposed to help manage and oversee BUILD II activities, including the required Steering Committee. Describe the desired expertise of committee members, and how each committee will function in providing oversight of the development, implementation, and evaluation of proposed activities. Include frequency of meetings and other relevant information. Include current internal advisory committee members and any proposed changes. Note that proposed external advisory committee members from outside the institution should not be named in the application.

*Program Evaluation:* Describe a plan to review and determine the quality and effectiveness of the Administrative Core. This plan should include the metrics to be evaluated as well as plans to obtain feedback to help identify weaknesses and to provide suggestions for improvements.

*Progress Report.* Not applicable to this component.

**Progress Report Publication List:** Not Applicable to this component.

**Letters of Support:** Not applicable to this component.

**Resource Sharing Plan:** Not applicable to this component.

### Appendix:

Not allowed.

### PHS Human Subjects and Clinical Trials Information (Administrative Core)

Use only for applications with due dates on or after January 25, 2018. 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, with the following additional instructions:

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

## **Institutional Development Core**

When preparing your application in ASSIST, use Component Type 'Inst Dev Core'

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

### **SF424 (R&R) Cover (Institutional Development 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 (Institutional Development Core)**

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

### **Research & Related Other Project Information (Institutional Development 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) (Institutional Development 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 (Institutional Development Core)**

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Institutional Development 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 (Institutional Development Core)**

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

Funds may be used to support evaluation costs and development or enhancement of research training infrastructure and research capacity, including but not limited to purchase of equipment to enhance research training; incorporation of research experiences into science curricula; faculty training in pedagogical skills development; staff training in grants management, and faculty sabbatical or workshop training to augment the research and teaching environments at Participating, Pipeline and Graduate partner institutions. Costs for evaluation activities should not be requested under other core budgets. Support for equipment is limited to Primary, Pipeline, and Graduate partner institutions. Funds may not be used to support faculty pilot projects or student participation under this core. Funds may not be used to support construction or renovation projects to buildings, lecture halls, laboratories, or offices. In the Budget Justification attachment, describe how the budget items will be sustained after the end of BUILD II.

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 (Institutional Development Core)**

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

**Specific Aims:** Describe the specific aims for the Institutional Development Core and how they relate to the overall specific aims.

**Research Strategy:** The Institutional Development Core Research Strategy should describe the proposed approaches to enhance diversity in the biomedical research workforce at the institutional level. Applicants should delineate existing research capacity-building and infrastructure at the Primary Institution and Partner Institutions (if applicable) relating to potential advancements in research training (e.g., administrative structure, key equipment for research training purposes, curriculum development and/or faculty development). Applicants should describe how the proposed strategies reflect and support transformative approaches that will be sustained beyond the funding cycle. For BUILD II, construction or renovation projects to buildings, lecture halls, laboratories, or offices will not be supported.

Describe plans for sustainable institutional changes to enhance the research training environment. Provide specific details about how such changes will be implemented and how they will benefit faculty, research support staff, and students at participating institutions, and ultimately increase the likelihood of achieving the expected outcomes of enhanced biomedical research activity. Describe activities that will be undertaken to ensure long-term sustainability of successful approaches.

Describe institutional strategies and approaches to synergize with the Research Enrichment Core to enhance the biomedical research training environment, particularly with respect to the Faculty Pilot Program supported through the Research Enrichment Core (if applicable). Explain how the proposed activities will enhance the ability of faculty to obtain funding, engage students, and prepare trainees for biomedical research careers. Describe institutional efforts that will be undertaken to enhance faculty participation in biomedical research at the Primary Institution, Pipeline and/or Graduate Partner Institutions (if applicable).

*Program Evaluation:* Describe a plan to review and determine the quality and effectiveness of the Institutional Development Core. This plan should include the metrics to be evaluated as well as plans to obtain feedback to help identify weaknesses and to provide suggestions for improvements. Specified evaluation metrics should be tied to the goals of the program.

*Progress Report:* Describe institutional research capacity-building activities supported during BUILD I and how they advanced the aims and goals proposed in the BUILD I award. Examples of advances include, but are not limited to:

- Enhanced institutional capacity to engage students in biomedical research training and sustain their interest in research, with a particular interest in students underrepresented in the biomedical research workforce ([NOT-OD-18-129 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html)).
- Increased institutional commitment and capacity to sustain transformative student research training and mentorship activities for students and faculty beyond the grant funding period.
- Strengthened infrastructure and capacity for faculty research, improved research administration capacity, and staff training for grants management.
- Evidence of a commitment to rewarding training and mentoring of biomedical research trainees in tenure and promotion decisions.
- Increased activities to recruit and support a diverse team of biomedical science faculty (including those from groups underrepresented in the biomedical sciences, [NOT-OD-18-129 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html)) to help students have access to role models within the institution.
- Increased opportunities for faculty to engage in biomedical research; this may include opportunities for sabbatical research experiences, protected time to develop research projects, prepare grant applications, and develop manuscripts for publication, or other research-related opportunities at an institution in the United States.
- Enhanced faculty participation and competitiveness in applying for and receiving extramural funding for research and/or student training.
- Development of effective strategies to increase scholarly productivity as reflected in publications in peer-reviewed journals and presentations at scientific conferences.
- Increased opportunities for faculty to engage in professional skills development (e.g., leadership, communications, team work).

**Progress Report Publication List:** Not Applicable to this component.

**Resource Sharing Plan:** Not Applicable to this component. The Resource Sharing Plan for the entire application is included in the "Overall" component.

**Appendix:** Not Allowed.

## **PHS Human Subjects and Clinical Trials Information (Institutional Development 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, with the following additional instructions:

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

## **Research Enrichment Core**

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

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

### **SF424 (R&R) Cover (Research Enrichment Core)**

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)

- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

## **Project /Performance Site Location(s) (Research Enrichment 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 Other Project Information (Research Enrichment Core)**

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

**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.

**Facilities & Other Resources.** Describe the educational environment, including the facilities, laboratories, participating departments, computer services, and any other resources to be used in the development and implementation of the proposed program.

**Other Attachments:** The following [Training Data Tables \(https://grants.nih.gov/grants/forms/data-tables.htm\)](https://grants.nih.gov/grants/forms/data-tables.htm) are required for the Research Enrichment Core:

- Table 5C. Publications of Those in Training: Undergraduate. Name the file "RL5\_Table\_5C\_Publications.pdf"
- Table 8D. Table 8D. Program Outcomes: Undergraduate. Name the file "RL5\_Table\_8D\_Outcomes.pdf"

The filename provided for each "Other Attachment" will be the name used for the bookmark in the electronic application in eRA Commons.

## **Research & Related Senior/Key Person Profile (Research Enrichment Core)**

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Research Enrichment 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. Do not include proposed mentors and training faculty members (other than senior/key persons) in this section. Biographical Sketches for mentors and participating faculty will be included in the PHS 398 Research Training Program Plan Form, Participating Faculty Biosketches attachment.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

## **Budget (Research Enrichment Core)**

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

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

Costs for evaluation activities should be requested under the Institutional Development Core and not under any of the other Budget sections for the other Cores. Faculty support may include salary for faculty who spend substantial effort in the development and use of novel curricula or mentoring activities; equipment and supplies for key training faculty to enable or enhance mentored research experiences for participants; faculty training in pedagogical skills development; release time to conduct grant writing workshops or other activities to enhance participant awareness and competitiveness for extramural research fellowships and grant funding; and resources for highly effective mentors to train new mentors.

Participant costs may be paid if specifically required for the proposed research enrichment program and sufficiently justified. Participant costs must be itemized in the proposed Research Enrichment Core budget. Allowable participant costs depend on the educational level/career status of the individuals to be selected to participate. The salary and fringe benefits for an undergraduate participant should be consistent with the institutional salary policies for employees in similar positions.

Participant travel costs are limited to attendance at domestic scientific meetings and workshops that the awardee institution determines to be necessary for the participant's development and training experience. Foreign travel for faculty and participants is prohibited. Per diem and travel costs are allowed for BUILD II participants in the summer research experience, in accordance with institutional policies. Note: All summer research experiences for the BUILD program are expected to be eight consecutive weeks in duration. Per diem expenses under the TL4 will be limited to TL4 trainees, and per diem expenses under the RL5 will be limited to RL5 participants.

Individuals supported by NIH training and career development mechanisms (K, T, or F awards) may receive educational experiences supported by a BUILD II award, as participants, but may not receive salary or stipend supplementation from BUILD II Research Enrichment Core funds.

Participants receiving financial/monetary support must be enrolled as full-time undergraduate students at the applicant institution or Pipeline Partner or Graduate Partner institutions AND they must be U.S. citizens or U.S. non-citizen nationals or permanent residents. Student participants should be majoring or planning to major in a STEM field relevant to biomedical science.



Because the BUILD Research Enrichment component is not intended as a substitute for an NRSA institutional training program, costs to support full-time participants (supported for 40 hours/week for a continuous, 12-month period) are not allowable under the Research Enrichment Core.

Applications must propose a plan indicating cost decreases in year 2 through year 4 (decreases by 25% in year 2, by 50% in year 3, by 75% in year 4) to ramp down participant support and activities. Total costs for the project should be adjusted downward to reflect decreased numbers of participants.

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.

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

## PHS 398 Cover Page Supplement

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

## PHS 398 Research Plan (Research Enrichment Core)

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

**Specific Aims:** Describe the specific aims for the Research Enrichment Core and how they relate to the overall specific aims.

**Research Strategy:** Applications should describe the approaches to continue to engage participants in research-related activities to sustain their interests, and to prepare them for biomedical research careers. The Research Strategy must include the following subsections:

*Overview.* Provide an overview of the research enrichment activities to be continued and/or enhanced, including the objectives, types of research activities to be employed, and resources. Describe approaches that will be implemented and sustained to identify and engage participants, including those who would otherwise be unlikely to pursue biomedical research careers. Provide the rationale for these approaches and the impact that each is intended to have.

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

*Program Administration.* Describe arrangements for core administration and provide evidence that the Research Enrichment Core Leader is actively engaged in research and/or teaching in an area related to the missions of the NIH institutes and centers, and can organize, administer, monitor, and evaluate the proposed research enrichment activities. Also provide evidence of institutional and community commitment to, and support for, the proposed activities.

*Program Faculty.* Describe the characteristics and responsibilities of the participating faculty. Provide evidence that the participating faculty and preceptors have experience conducting research or other scholarly activities related to the missions of the NIH institutes and centers. Provide evidence that faculty at participating institutions are committed to the development and use of the effective training and mentoring practices. Describe faculty training in pedagogical skills and modern teaching modalities that confer improved learning outcomes and that enhance the academic learning environment at the institution. Describe plans for faculty and staff to attend workshops, seminars, and other professional development activities to acquire the knowledge and skills necessary for implementing, sustaining, and disseminating effective research training environments.

All participating training faculty from the Research Enrichment Core should be included in "Data Table 2: Participating Faculty Members" to be uploaded in the Training Core component. Indicate that the "Training Role" is in the Research Enrichment Core (RE).

*Participants.* Given the eligibility requirements detailed in the "Additional Information on Eligibility" [Section III.3](#), describe in general terms the pool of potential participants. Student participants should be majoring or planning to major in a STEM field relevant to biomedical science. Describe strategies and plans for recruiting, selecting, and assigning participants to research activities. Describe the anticipated duration of research experiences, the months in which they will occur, and the allocation of each participant's time to be spent in various activities. All BUILD II awards must include a mentored summer research experience at a minimum of 8 weeks. Provide details about the pool of expected participants. Do not name prospective participants in the application.

Applications may propose outreach activities to raise awareness of the BUILD II program and to stimulate interest in the biomedical sciences among high school students in surrounding communities. Further, a limited range of enrichment activities, including mentored research experiences, may be offered to high school seniors who are concurrently enrolled in college bridge programs in relevant sciences at participating institutions (note: BUILD II awardees will be expected to provide documentation certifying enrollment in a college bridge program). If such activities are proposed, describe the student population, the specific activities to be conducted, key personnel, and anticipated benefits to participants and to the BUILD II project as a whole.

If applicable, describe postbaccalaureate research experiences that may be provided. Explain how such experiences will enhance and/or sustain interest in biomedical research careers, and how they will prepare participants to successfully compete for admission to graduate-level biomedical research training programs. Describe how participants will be selected and the research and mentoring options that will be available to them. Describe specific goals for the postbaccalaureate training period and how progress toward these goals will be assessed and sustained. Describe how the proposed activities will be sustained after the end of BUILD II.

*Pilot Project Program.* Though not required, applicants may propose a biomedical research pilot project program to be funded from the Research Enrichment Core. A pilot project program may be used to fund faculty to support mentored research projects if the intent is to develop projects that are especially well-suited for undergraduate research, or for gathering preliminary data to support biomedical research grant applications to NIH or other extramural funding agencies.

If a biomedical research pilot project program is proposed, describe the rationale for its inclusion. Applicants should describe the scope, the types of biomedical projects to be supported, and the expected impact on student outcomes and institutional research training capacity. Applicants should describe the qualifications of individuals identified to manage the program, the expected number of projects and students to be supported each year, the eligibility requirements, and the process for solicitation, submission, review, and selection. Applicants should include plans for providing appropriate mentorship, and procedures for program oversight and evaluation.

Faculty pilot projects must be for biomedical and biomedical-related research supported by the missions of the NIH institutes and centers. Pilot projects may include human subject research, but may not propose to perform clinical trials (please see [NOT-OD-015 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-015.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-015.html) for the definition of clinical trial and [NIH Clinical Trials website \(https://grants.nih.gov/policy/clinical-trials.htm\)](https://grants.nih.gov/policy/clinical-trials.htm) for more information"). Do not include detailed descriptions of specific pilot projects in the application. The Principal Investigators for the pilot projects are intended for Program Faculty (Early Stage Investigator to Senior Faculty), not participants or trainees.

*Mentor Training.* Describe the mentoring strategy for students receiving BUILD RL5 support. The plan should include how faculty will be selected to serve as mentors and any training activities designed to enhance the mentoring skills of the faculty, with an emphasis on mentoring trainees from [underrepresented \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) groups and backgrounds. In addition, the plan should describe how sustainable mentor training will be implemented, faculty participation will be incentivized, and how mentor training will be tailored for undergraduate mentees.

Describe a mentoring plan for faculty who will receive pilot project funding with specific goals and intended outcomes. The plan should include how faculty will be mentored for preparing applications for extramural support and what resources will be available to allow them sufficient time to prepare applications, as well as what support will be available to faculty who are successful in receiving extramural grant support.

*Recruitment Plan to Enhance Diversity:* Applicants are required to comply with the instructions for a Recruitment Plan to Enhance Diversity as provided in the SF424 (R&R) Application Guide. Applications must include a description of plans to recruit a diverse trainee pool and should include data in support of past accomplishments. Information should be included on both successful and unsuccessful recruitment strategies. Do not duplicate information provided in the Training Core portion of the application regarding the "Recruitment Plan to Enhance Diversity". If the plans are the same, refer the reader to the attachment in the Training Core portion of the application described below.

*Plan for Instruction in the Responsible Conduct of Research:* All applications must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Do not duplicate information provided in the Training Core portion of the application regarding the Responsible Conduct of Research. If the plans are the same, refer the reader to the attachment in the Training Core portion of the application described below

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

*Sustainability:* Describe the Research Enrichment activities to be sustained beyond the granting period and the participants that they are intended to reach.

*Progress Report:* The progress report should also describe the research and academic enrichment programs developed for students that were implemented in BUILD I and the advances that were achieved. If there were strategies that did not lead to further student engagement in research or prevent their departure from STEM majors, describe these strategies as well. Indicate if any RL5 supported students applied to graduate, medical or other professional schools. For BUILD programs that have NIGMS R25 or T34 awards (RISE, MARC, IMSD, or PREP), indicate if RL5 students moved to these programs.

As indicated in the instructions for the Research & Related Other Project Information form, Other Attachments section, outcomes must be detailed using the NIH [Training Data Tables \(https://grants.nih.gov/grants/forms/data-tables.htm\)](https://grants.nih.gov/grants/forms/data-tables.htm) 5C and 8D.

If pilot projects were supported during BUILD I, list the projects that were funded. Discuss the number of pilot projects that resulted in submissions of grant applications to the NIH, NARCH, NSF, other federal agencies, or private foundations and indicate if any applications resulted in new awards to faculty. Describe how pilot projects enhanced faculty development with new collaborations with researchers at research intensive institutions, supported presentations at scientific meetings, and new peer-reviewed research publications.

Other indicators of progress include, but are not limited to:

- Increased opportunities for faculty to incorporate more research-related activities into existing undergraduate courses, or develop new course offerings that emphasize original research.
- Increased opportunities for faculty to engage in mentor training activities to enhance efficacy as mentors. This may include structured activities which engage experienced mentors to train the next generation of biomedical research mentors.
- Enhanced student pursuit of biomedical research-related undergraduate fields of study.
- Enhanced matriculation of undergraduate and post-baccalaureate students to accredited doctoral training programs in biomedical research fields.

- Enhanced student perceptions and attitudes toward biomedical research careers and improved understanding of the requirements for success in those careers.
- Improved readiness for biomedical research careers as determined by the [hallmarks of success](https://www.nigms.nih.gov/training/dpc/Pages/success.aspx) (<https://www.nigms.nih.gov/training/dpc/Pages/success.aspx>) developed by the DPC.
- Enhanced student engagement in research as reflected by authorship on peer-reviewed papers and presentations at scientific conferences.
- Enhanced student participation and competitiveness in applying for and receiving research fellowships, scholarships, or other awards.

**Progress Report Publication List:** Not Applicable to this component.

**Resource Sharing Plans:** Not Applicable to this component. The Resource Sharing Plan for the entire application is included in the "Overall" component.

**Appendix:** Not Allowed.

## PHS Human Subjects and Clinical Trials Information (Research Enrichment 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.

## Training Core

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

Follow all instructions provided in the SF424 (R&R) Application Guide for Preparing Institutional Ruth L. Kirschstein National Research Service Award (NRSA) except where indicated below:

### SF424 (R&R) Cover (Training Core)

Complete only the following fields:

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

### Project/Performance Site Location(s) (Training Core)

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

### Research & Related Other Project Information (Training 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 Summary/Abstract:** Summarize the objectives of the Training Core. Provide information regarding the research areas and scientific disciplines encompassed by the Core. Include a brief description of the level(s) (i.e., undergraduate) and duration of the proposed training, the projected number of participating trainees and their anticipated levels of experience.

**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.

### Research & Related Senior/Key Person Profile (Training Core)

The Training Core Leader and any other individuals whose contributions are critical to the development, management and execution of the Training Core in a substantive, measurable way (whether or not salaries are reimbursed) should be identified as senior/key persons. These would include co-Leader(s), if applicable, and other Training Core staff.

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Training 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 core.
- 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.

Do not include proposed mentors and training faculty members (other than senior/key persons) in this section. Biographical Sketches for mentors and participating faculty will be included in the PHS 398 Research Training Program Plan Form, Participating Faculty Biosketches attachment.

### **PHS 398 Cover Page Supplement (Training Core)**

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

### **PHS 398 Training Budget (Training Core)**

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

Costs for evaluation activities should be requested under the Institutional Development Core and not under any of the other Budget sections for the other Cores. BUILD Training Core linked awards (TL4) may be used to support stipends, tuition and fees for undergraduate student trainees, trainee domestic travel, and training-related expenses at the primary institution. Financial support for postbaccalaureate, predoctoral, or postdoctoral NRSA trainees is not allowed under this component. Annual stipend levels for undergraduate students are the same for all NRSA awards (see [NOT-OD-17-084 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-084.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-084.html)).

**Part A:** The application should request stipends for trainees. Enter the number of trainees, total stipend amount and total tuition/fees for each trainee category as appropriate. If a category contains different stipend levels, e.g., for varying appointment periods, itemize in the appropriate blocks. Enter the total stipends for all categories. See [NOT-OD-17-084 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-084.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-084.html) and [NOT-OD-17-086 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-086.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-086.html) for current NIH policy regarding payment of tuition and fees. Tuition and fees may be requested only to the extent that the same resident or nonresident tuition and fees are charged to regular non-Federally supported students. Grantees should request full needs. The formula currently in effect will be applied by the NIH awarding component at the time an award is calculated. Note that health insurance is not included as part of this budget category (see Training Related Expenses below).

**Part B:** Enter the total costs for Trainee Travel, Training Related Expenses, and Consortium Training Costs (if applicable). Trainee travel costs are limited to attendance at domestic scientific meetings and workshops that the awardee institution determines to be necessary for the trainee's development and training experience. Foreign travel is prohibited. Per diem and travel costs for BUILD II trainees participating in the summer research experience, in accordance with institutional policies, are allowed. Note: All summer research experiences for the BUILD II program are expected to be eight consecutive weeks in duration. Per diem expenses under the TL4 will be limited to TL4 trainees, and per diem expenses under the RL5 will be limited to RL5 participants. Enter "0" in the line for "Total Direct Costs from R&R Budget Form (if applicable)"; the SF424 R&R Budget Form is not applicable for the BUILD Training Core budget.

Training Related Expenses (TRE): Applications may request up to \$12,600 per trainee annually. Enter the total TRE cost based on the number of trainees proposed. TRE may be used to defray training costs such as personnel costs (see below); equipment and research supplies for training experiences; trainee mentoring activities; faculty/staff domestic travel directly related to the training program; student academic skills development activities (e.g., workshops in problem-solving, critical thinking, effective communication and time management); health insurance for trainees (self-only or family) to the extent that the same health insurance fees are charged to non-Federally-supported students at the applicant institution; and other program-related expenses. TRE expenses must be justified as specifically required by the proposed BUILD II training program and must not duplicate items generally available at the applicant institution. Faculty salary support for the training program director(s) is limited to 3.0 person months per year total. Support for administrative personnel (e.g., program administrator, program coordinator, program assistant) is limited to 6.0 person months per year.

Consortium Training Costs (if applicable): If training will occur at more than one institution, and any transfer of funds between institutions occurs, applications must include PHS 398 Training Budget forms for each consortium training site; add the direct costs from all consortium training sites and insert the total amount on the appropriate line for each budget period. The applicant institution is responsible and accountable for any arrangements, expenditures, and submission of all required forms when more than one institution is involved in the research training program.

**Part C:** Total Direct Costs Requested. The sum of Sections A + B will be calculated automatically in the PHS 398 Training Budget forms.

**Part D:** Indirect Costs. Facilities and Administrative (F&A) costs will be awarded at 8%, excluding tuition/fees, equipment, and consortium costs in excess of \$25,000.

Indirect Cost Type: Enter "F&A"

Indirect Cost Rate (%): Enter "8"

Indirect Cost Base (\$): Enter the sum of Stipends and Total Other Direct Costs requested.

Indirect costs are not paid on Tuition/Fees, equipment, and consortium costs in excess of \$25,000.

Funds Requested (\$): Enter the product of Indirect Cost Rate multiplied by Indirect Cost Base.

**Part E:** Total Direct and Indirect Costs Requested (C+D)

The sum of Total Direct Costs Requested and Total Indirect Costs Requested will be calculated automatically in the PHS 398 Training Budget forms.

**Part F:** Budget Justification. Attach a detailed justification to the first budget period form, reflecting the entire project period. Explain in detail the composition of requested cost items as necessary. Itemize tuition and individual fees. If tuition varies (e.g., in-state, out-of-state, student status),

identify these separately. State the purpose of any travel, giving the number of trips involved, the likely destinations, and the number of individuals for whom funds are requested. Note that PHS policy requires coach class air travel be used.

Awardees are expected to transition into a sustainable model of trainee support. Applications must propose a ramp down plan indicating a decrease in grant support in of TL4 trainees in years 2 through year 4 (e.g., decrease by 25% in year 2, by 50% in year 3, by 75% in year 4) and a description of institutional support to sustain student trainees beyond the funding cycle. Accordingly, no new students should be appointed to the grant in the final year of the award. Total costs for the project should be adjusted downward to reflect decreased numbers of trainees.

## PHS 398 Research Training Program Plan (Training Core)

The PHS 398 Research Training Program Plan Form is comprised of the following sections:

### Training Program

- Faculty, Trainees, and Training Record
- Other Training Program Sections
- Appendix

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

Particular attention must be given to the required [Training Data Tables \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=61169\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=61169). Applicants should summarize, in the body of the application, key data from the tables that highlight the characteristics of the applicant pool, faculty mentors, the educational and career outcomes of participants, and other factors that contribute to the overall environment of the program.

**Background:** Provide the rationale for the Training Core and the need for the training proposed. Indicate how the Training Core will relate to current training activities at the applicant institution.

Describe how the training development activities will continue to enhance undergraduate biomedical research training and expand the pool, including trainees from [underrepresented \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) groups and backgrounds.

### Program Plan:

*Program Administration:* Describe the acknowledged strengths, leadership and administrative skills, and training experience of the Training Core Leader. Relate these strengths to the proposed management of the training core. Describe the planned strategy and administrative structure to be used to oversee and monitor the core.

*Program Faculty:* The application must include information about the faculty who will be available to serve as faculty mentors and provide guidance and expertise appropriate to the level, either during the academic year or summer months. The mentors should have active records as researchers and experience mentoring undergraduates, including trainees from [underrepresented \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html) backgrounds in the biomedical research workforce. Describe the complementary expertise and experiences of the proposed faculty, including active research and other scholarly activities in which the faculty are engaged, as well as experience mentoring and training undergraduates. For any proposed faculty lacking research training experience, describe a plan to ensure successful trainee guidance by these individuals. Describe the criteria used to appoint and remove faculty and to evaluate their participation.

*Proposed Training:* Provide an overview of the proposed program. Outline the objectives of the program and the program activities that will be used to meet these objectives. Describe for whom the training program is intended, the academic and research background needed to pursue the proposed training, and, plans to accommodate differences in preparation among trainees. Describe how trainees will be educated in the human health- and disease-related aspects of their research training.

Describe the rationale for each activity and how, either individually or collectively, they represent an additive, transformative, or new approach to attract individuals into biomedical research careers who would otherwise be unlikely to pursue this career path. Describe how the proposed activities will be sustained after the end of BUILD II.

Include information about planned courses, mentored research experiences, and any activities designed to develop specific technical skills or other skills essential for the proposed research training. Specifically, describe plans to develop essential research skills, such as critical thinking, the ability to formulate and design ways to test hypotheses, the capacity to identify potential research problems, the ability to propose solutions or alternative approaches, and the facility to communicate research findings orally and in writing. Applicants should include information about planned courses, curricula, seminars, workshops, and/or tutorials that will be incorporated into the training program and mentored research experiences. Describe how trainees will be made aware of NIH and other extramural funding opportunities.

Applications that propose classroom-centered research training activities should describe the learning objective(s), innovative attributes, participating faculty, training frequency, expected impact on trainee outcomes, and other relevant information.

Applications that propose research experiences at partner institutions with active NIH institutional training grant (T32) programs should describe how the BUILD II PD(s)/PI(s) will interact with the T32 PD(s)/PI(s) to promote awareness of graduate research training programs in the biomedical sciences and encourage BUILD trainees to apply for admission to research-oriented graduate degree programs. Most NIH Institutes and Centers support T32 predoctoral training programs in various research areas; to identify such programs, visit the [NIH Research Portfolio Online Reporting Tools \(RePORT\) \(http://projectreporter.nih.gov/reporter.cfm\)](http://projectreporter.nih.gov/reporter.cfm) website.

*Training Program Evaluation:* Describe a plan to review and determine the quality and effectiveness of the training program. This plan should include the metrics to be evaluated as well as plans to obtain feedback from current and former trainees to help identify weaknesses and to

provide suggestions for program improvements. Metrics may include, but are not limited to, the DPC Hallmarks of Success. Specified BUILD site-specific evaluation metrics should be tied to the goals of the program.

**Trainee Participants:** Given the eligibility detailed above in the "Additional Information on Eligibility" [Section III.3](#), describe in general terms the pool of potential candidates, including those who are from underrepresented groups or from disadvantaged backgrounds ([NOT-OD-18-129 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-129.html\)](#)). Trainees should be majoring or planning to major in a STEM field relevant to biomedical science. Do not name prospective trainees in the application. Describe plans to further recruit candidates from current student populations to meet all targets and explain how these plans will foster the engagement of students in biomedical research, including those who would otherwise be likely to choose other career paths. Describe how these approaches will be implemented. Identify and provide a rationale for any novel selection factors or approaches designed to stimulate interest in scientific research careers among student populations that are not typically targeted by existing undergraduate research training programs (e.g., non-honors students, transfer students). Describe the evaluation criteria to be used in the selection of trainees, and how training plans will be tailored to the needs of prospective candidates.

**Institutional Environment and Commitment to the Program:** The sponsoring institution must assure support for the proposed Training Core including assurance that sufficient time will be allowed for the Training Core Leader and other Faculty to contribute to the proposed training. Institutions with ongoing research training, student development, or career development programs that receive external funding should explain what distinguishes the proposed Training Core from existing training programs at the same trainee level, how the programs will synergize, if applicable, whether trainees are expected to transition from one support program to another, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed training in addition to existing ones.

**Recruitment Plan to Enhance Diversity:** Individuals are required to comply with the instructions for the Recruitment Plan to Enhance Diversity as provided in the SF424 (R&R) Application Guide.

**Plan for Instruction in the Responsible Conduct of Research:** Individuals are required to comply with the instructions for Plan for Instruction in the Responsible Conduct of Research as provided in the SF424 (R&R) Application Guide.

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

**Progress Report:** Renewal applications must provide a Progress Report on training activities according to the instructions in the SF424 (R&R) Application Guide with the following additional instructions:

State the original goals and specific aims, milestones, and outcomes, as well as a summary of the specific accomplishments of the NRSA TL4 component of the BUILD program in the context of the previous application's baseline. Applicants must provide information on current and past students supported on their TL4 award listing the student names and tracking their progression and outcomes for students whose support on the TL4 award has ended using [Table 8D \(https://grants.nih.gov/grants/funding/424/datatables.htm\)](#).

As was done previously, the BUILD II Training Core will be funded as an institutional program award (TL4) and as such applicants must provide details about the institution and its setting. Such details should be described in the Progress Report and the data should be provided using the required Training Data Tables 2, 3, 4, 5C, and 8D ([http://grants.nih.gov/grants/forms/datatables.htm \(https://grants.nih.gov/grants/forms/datatables.htm\)](#)). These tables must not be modified and should be uploaded in the Data Tables section of the application.

Additional areas of progress for trainees, may include, but are not limited to the following:

- Enhanced pursuit of biomedical research-related undergraduate fields of study.
- Enhanced matriculation of undergraduate and post baccalaureate students to accredited doctoral training programs in biomedical research fields.
- Enhanced student perceptions and attitudes toward biomedical research careers and improved understanding of the requirements for success in those careers.
- Improved readiness for biomedical research careers as determined by the [hallmarks of success \(https://www.nigms.nih.gov/training/dpc/Pages/success.aspx\)](#) developed by the DPC.
- Enhanced student engagement in research as reflected by authorship on peer-reviewed papers and presentations at scientific conferences.
- Enhanced student participation and competitiveness in applying for and receiving research fellowships, scholarships, or other awards.

In addition to outcomes, describe what has been learned through the program evaluation and describe changes made in the program because of the evaluation.

**Participating Faculty Biosketches:** Faculty Biosketches for participating faculty (excluding Senior/Key Personnel) should follow the instructions in the SF424 (R&R) Application Guide for a Biographical Sketch, except that a personal statement describing training and mentoring activities must be included. All participating training faculty from Primary, Partnering Institutions for the Training Core and the Research Enrichment Core (described above) should be included. These Biosketches should be attached as a single pdf document.

**Data Tables:** Applicants should upload the Data Tables to the PHS 398 Research Training Program Plan form. The following [Data Tables \(https://grants.nih.gov/grants/forms/data-tables.htm\)](#) are required:

- Table 2. Participating Faculty Members, Undergraduate Training. Include the faculty relevant to all Core activities. In the "Training Role" column, indicate whether the faculty are relevant to the Institutional Development (ID), Research Enrichment (RE) and/or Training (T) Cores.
- Table 3. Federal Institutional Research Training Grants and Related Support Available to Participating Faculty Members.
- Table 4. Research Support of Participating Faculty Members and Undergraduate Training. Include the faculty relevant to the Training Core activities.
- Table 5C. Publications of Those in Training: Undergraduate. Include TL4 past and present trainees.

- Table 8D. Part 1. Program Outcomes: Undergraduate. Include TL4 past and present trainees.

**Appendix:** Not Allowed.

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

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

### 4. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or [Federal holiday \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82380\)](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 [Grants.gov \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11128\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

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

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

### 5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review. \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11142\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

### 6. Funding Restrictions

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

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11143\)](https://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](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](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11144\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11144). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Guidelines for Applicants Experiencing System Issues \(//grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines\)](https://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines). For assistance with application submission, contact the Application Submission Contacts in [Section VII](#).

#### **Important reminders:**

All PD(s)/PI(s) 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11146\)](https://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 [components of participating organizations](#), NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be

reviewed.

## Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82299](https://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](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11149](https://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 BUILD project 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 BUILD project 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 project that by its nature is not innovative may be essential to advance a field.

### Significance

Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project 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?

*Specific to this FOA:* Are the training, mentoring, and research capacity building interventions likely to substantially enhance the engagement of undergraduate students, including those from underrepresented groups and backgrounds, in biomedical research training, sustain their interest, and prepare them to successfully pursue biomedical research careers? Will individuals be reached who would otherwise be unlikely to pursue biomedical research as a career choice? Will the awardee institution be positioned to sustain its success beyond the granting period?

### Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate research and mentorship experience and training? If established, have they demonstrated an ongoing record of research and training 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, organizational, and communication structure appropriate for the project?

*Specific to this FOA:* Do the investigators show evidence of the ability to lead institutional transformation, develop, and direct a program focused on biomedical research, research training and mentorship for students and faculty from diverse backgrounds? Do the investigators provide a record of engaging with leadership to bring about institutional changes? Are the key personnel committed to research training, including trainees from underrepresented groups and backgrounds, and is there evidence of past success in motivating such students to pursue research careers and preparing them to be successful? Is there evidence of actively engaging faculty from partner institutions?

### 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 proposed?

*Specific to this FOA:* Are the approaches to be further developed and disseminated innovative to the field in the ways in which students from diverse backgrounds are engaged and trained for biomedical research? Are factors that contribute to student exit from biomedical research training considered and are strategies to address these factors included? Are creative approaches to research training and/or mentoring of both student and faculty clearly described and likely to substantially increase student and faculty participation in research? Does the application describe innovative ways to engage faculty in research, mentoring and teaching within the participating institution and across partnering institutions?

### Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? 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? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, 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?

*Specific to this FOA:* Does the application articulate a compelling vision for the program? Is each of the approaches to be utilized well justified and will each contribute substantially to the overarching vision established by the PD(s)/PI(s) and collaborators?

Are the activities well integrated and likely to create an environment that fosters achievement of the proposed milestones, leading to overall gains in student, faculty, and institutional outcomes above baseline indicators? Do the approaches provide a comprehensive strategy to address factors that lead students to exit the biomedical research career pathway? Are the approaches likely to encourage experiences that may lead students to select and enter biomedical research careers? Are potential problems, alternative strategies, and benchmarks for success presented?

If applicable, is an appropriate rationale for the selection and inclusion of existing and new partner organizations provided? Has each of the partner organizations made and will continue to make substantial and meaningful contributions to the goals of the project? Will the approaches enrich the biomedical research training environment at participating and partnering institutions?

Do the letters of support from authorized institutional officials and key personnel at the Primary and Partner Institutions (if applicable) demonstrate strong support for the proposed activities and include tangible examples of institutional commitment that engender confidence in the likelihood of success? Do the details of the letter of support align with and expand the efforts stated for BUILD phase I?

Have existing resources at the participating and partner institutions been appropriately leveraged to help achieve the stated aims? If previous specific aims have not been met, is there evidence that appropriate analyses have been conducted to identify the challenges and opportunities and appropriate strategies have been proposed to address the issue(s)?

Does the proposed program have a rigorous evaluation plan to assess the quality and effectiveness of the program? Is the infrastructure to support data collection to evaluate the impact and effectiveness of the proposed program described, and are proposed plans for evaluation likely to enable meaningful comparisons with institutional baseline data and outcomes from other training programs locally or at the national level?

Is the plan for transitioning into a sustainable program to enhance diversity in the biomedical research workforce feasible? Is there evidence that the proposed strategies and approaches can be integrated into current educational programs and institutional environment?

Are the plans for disseminating tested interventions via outreach, publications, presentations, and collaborations with institutions not currently part of the DPC likely to have a national impact? Does the application describe an effective training, mentoring, or research capacity intervention that might be readily implemented and evaluated by institutions across the nation?

## **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?

*Specific to this FOA:* Does the applicant provide evidence of the likelihood that best practices of enhancing the diversity of the NIH biomedical research workforce can be sustained and integrated within the current academic fabric? Are the institutional support, equipment and other physical resources available to the investigators adequate for the building research capacity at the participating institution? Is there tangible evidence of institutional commitment? Is there evidence that the faculty have sufficient institutional support to create a sound research training and mentorship environment for the participants? Where appropriate, is there evidence of collaboration and commitment among participating programs, departments, and institutions?

Are the combined environments of all partner institutions likely to foster effective collaborations for teaching and mentoring diverse students in coursework and in research? Are partnerships envisioned that will provide robust research and educational experiences for undergraduate students? Will the partnerships provide a robust mentoring pool for students to integrate with and form long-lasting mentor/mentee relationships to help shape their future careers?

## **Additional Review Criteria**

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

### **Administrative Core**

- Is the organizational and governance structure likely to support timely execution of the project and attainment of proposed priorities and objectives?
- Are the roles and responsibilities of Administrative Core personnel clearly delineated?
- Are proposed processes to allocate and prioritize fiscal and other resources clearly described and well justified?
- Is a plan provided to ensure timely and effective communication across project cores and the Diversity Program Consortium as a whole?
- Is there a comprehensive plan to ensure the evaluation and data collection activities are well integrated across the program and the CEC?
- Does the proposed management plan clearly describe the composition and roles of any proposed advisory committees or boards?
- Are effective mechanisms in place for obtaining feedback from the members of the Advisory Committee?

### **Institutional Development Core**

- Is it clear how the proposed institutional development activities will benefit the faculty and students participating in BUILD?

- Are the activities likely to result in institutional changes that will enhance the biomedical research capacity at the Primary and Partner Institutions (if applicable)?
- Are the institutional changes likely to be continued beyond the funding cycle?
- Are the strategies to synergize with the Research Enrichment Core likely to result in enhancements to the research training environment?
- Are the proposed activities likely to enhance the ability of faculty to obtain research funding, engage students, and prepare trainees for biomedical research careers?
- Are proposed plans for evaluating the Institutional Development Core activities well thought out and likely to inform strategies for enhancing the institutional research training environments?
- Are the plans for sustainability of identified components of the Institutional Development Core feasible and likely to result in lasting changes at the institution?

## **Research Enrichment Core**

- Does the Research Enrichment Core clearly state its goals and objectives, the content to be conveyed, and the intended outcomes? Is there evidence that the program is based on a sound rationale, as well as sound educational concepts and principles?
- Are specific metrics included that document the success of the first phase, including, but not limited to the numbers of participants entering biomedical research careers from the applicant institution and its partners?
- Is there evidence that previous trainee and research participant targets have been met? If not, do the recruitment plans and strategies to sustain the interest of trainees address challenges and opportunities for improvement?
- Are plans clearly described to improve above the stated baseline of participants entering graduate level biomedical research programs?
- Is there convincing evidence in the application that the proposed program will significantly advance the stated goal of the Research Enrichment Core?
- Taking into consideration the nature of the proposed research education program, does the applicant make a strong case for this program effectively reaching an audience in need of the program's offerings? Where appropriate, is the proposed program developing or utilizing innovative approaches and latest best practices to improve the knowledge and skills of the intended audience?
- Are the Core Lead(s) capable of providing both administrative and scientific leadership to the development and implementation of the proposed program? Is there evidence that an appropriate level of effort will be devoted by the program leadership to ensure the program's intended goal is accomplished? Is there evidence that the participating faculty have experience in mentoring students and teaching science? Are the faculty good role models for the participants by nature of their scientific accomplishments? If the project is collaborative, do the investigators have complementary and integrated expertise; are the leadership approach, governance and organizational structure appropriate for the project?
- Are the planned recruitment activities, and activities to sustain the interest of trainees adequate to ensure the intended population of trainees will participate?
- Given the described opportunities available to the participants, is it likely that they will engage in research projects with a biomedical focus?
- Is it likely that the proposed enrichment activities will influence the decisions by participants to enter graduate level training, and enable these individuals to be successful in future biomedical research career phases?
- Is the selection process for identifying faculty mentors clearly stated? Are faculty development activities tailored to the needs and interests of the faculty at the Primary and Participating Institutions? Will the approaches be likely to enrich and strengthen faculty credentials as biomedical research mentors? Are plans to promote faculty interactions between partnering institutions robust, and will they contribute to stronger research training environments?
- Is it clear how identified mentorship standards will guide the development of the BUILD participants?
- If outreach activities are proposed, are specific populations, key personnel, and activities appropriate for the proposed activities?
- If a pilot project program is proposed, will the program support mentored research projects to develop projects that are especially well-suited for undergraduate research, or for gathering preliminary data to support biomedical research grant applications to NIH or other extramural funding agencies?
- If the participating or partner institutions have current research education or training awards, does the application clearly distinguish between the proposed research education program and the activities supported by other programs?
- Is the plan for evaluation sound and likely to provide information on the effectiveness of the program?
- Are the plans for sustainability of identified components of the Research Enrichment Core feasible and likely to result in lasting changes at the institution?

## **Training Core**

### **Training Program and Environment**

- Does the Training Core clearly state its goals and objectives, the content to be conveyed, and the intended outcomes? Is there evidence that the program is based on a sound rationale, educational concepts, and principles?
- Is the training program likely to enhance the ability of the institution and its partners to engage a diverse group of trainees in biomedical research training pathways?
- Are training opportunities appropriately tailored for undergraduate trainees?
- Do the courses, where relevant, and research experiences provide opportunities for trainees to acquire state-of-the-art scientific knowledge, methods, and tools that are relevant to the goals of the training program?
- Does the program provide appropriate inter- or multidisciplinary research training opportunities?
- Are the proposed educational and training programs likely to ensure trainees will be well prepared for research-intensive and research-related biomedical careers?

- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to ensure continued success of the program?
- Are the proposed trainee activities transformative, feasible, and measurable?
- Are proposed strategies to improve student academic learning communities and curriculum development well-reasoned and justified?
- Are the proposed training activities likely to enable trainees to thrive as they move through each step of the biomedical research career pathway?
- Are the plans for sustainability of identified components of the Training Core feasible and likely to result in lasting changes at the institution?

#### **Program Director**

- Does the training program director have the scientific background, expertise, and experience to provide strong leadership, direction, management, and administration of the proposed academic and research training program?
- Does the program director plan to commit sufficient time to the program to ensure its success?
- If there are multiple program directors, is a strong and compelling leadership approach evident, including the designated roles and responsibilities, governance, organizational, and communication structure consistent with and justified by the aims of the training program and with the complementary expertise of each program director?

#### **Preceptors/Mentors**

- Are sufficient numbers of experienced preceptors/mentors from the participating and/or partnering institution with appropriate expertise and active funding available to support the number and level of trainees proposed in the application?
- Do the preceptors/mentors have strong records as researchers in areas directly related to the proposed research training program? Do the preceptors/mentors have strong records of training undergraduates?
- Are effective mechanisms in place for obtaining feedback from mentors and monitoring their engagement with BUILD mentees?

#### **Trainees**

- Are the selection processes and criteria for BUILD trainees clearly stated, and likely to engage a broad range of individuals at participating institutions?
- Is the description of the issues facing trainees as they consider biomedical research careers through their undergraduate and postbaccalaureate years well-developed, and are the approaches to be undertaken likely to address these factors?
- Is the potential applicant pool of sufficient size to warrant the proposed size of the training program?
- Will the trainees engage in biomedical research projects aligned with the NIH mission?

#### **Training Record**

- Does the proposed training program have a rigorous evaluation plan to assess the quality and effectiveness of the training?
- Are specific metrics included that document the success of the first phase, including, but not limited to the numbers of NRSA supported BUILD trainees entering biomedical research careers from the applicant institution and its partners?
- Is there evidence that previous trainee targets have been met? If not, do the recruitment plans and activities to sustain the interest of trainees address challenges and opportunities for improvement?
- Are plans clearly described to improve above the stated baseline of trainees entering graduate level biomedical research programs?
- Are effective mechanisms in place for obtaining feedback from trainees and monitoring their subsequent career development?

#### **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 [Guidelines for the Review of Human Subjects \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

#### **Inclusion of Women, Minorities, and Children**

When the proposed BUILD project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of 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 [Guidelines for the Review of Inclusion in Clinical Research \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11174\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

#### **Vertebrate Animals**

Not Applicable

#### **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

As applicable for the BUILD project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

### Recruitment Plan to Enhance Diversity

Peer reviewers will separately evaluate the recruitment plan to enhance diversity after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment of individuals from underrepresented groups. The plan will be rated as **ACCEPTABLE** or **UNACCEPTABLE**, and the consensus of the review committee will be included in an administrative note in the summary statement.

### Training in the Responsible Conduct of Research

All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) **Format** - Does the plan satisfactorily address the format of instruction, e.g. lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (A plan involving only on-line instruction is not acceptable.); 2) **Subject Matter** – Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics? 3) **Faculty Participation** - Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) **Duration of Instruction** - Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) **Frequency of Instruction** – Does the plan meet the minimum requirements for RCR, i.e., at least once during each career stage (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels) and at a frequency of no less than once every four years?

For renewal applications, does the progress report document acceptable RCR instruction in the five components described above? Does the plan describe how participation in RCR instruction is being monitored? Are appropriate changes in the plan for RCR instruction proposed in response to feedback and in response to evolving issues related to responsible conduct of research?

Plans and past record will be rated as **ACCEPTABLE** or **UNACCEPTABLE**, and the summary statement will provide the consensus of the review committee.

### 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) [Data Sharing Plan \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11151\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); 2) [Sharing Model Organisms \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11152\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); 3) [Genomic Data Sharing Plan \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11154\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated [review criteria](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- Will receive a written critique.

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

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the NIGMS national 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 [eRA Commons \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11156\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157\)](https://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 [Section IV.5. Funding Restrictions](#). Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

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

#### Prior Approval of Faculty Pilot Projects

All awardee-selected projects require prior approval by NIH prior to initiation (refer to the NIH Grants Policy Statement for more information, [8.1.3 Requests for Prior Approval \(https://grants.nih.gov/grants/policy/nihgps/html5/section\\_8/8.1\\_changes\\_in\\_project\\_and\\_budget.htm?TocPath=8%20Administrative%20Requirements|8.1%20Changes%20in%20Project%20and%20Budget|3#8.1.3\\_Requests\\_for\\_Prior\\_Approval\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.1_changes_in_project_and_budget.htm?TocPath=8%20Administrative%20Requirements|8.1%20Changes%20in%20Project%20and%20Budget|3#8.1.3_Requests_for_Prior_Approval)). Clinical trials are not allowed.

Prior to the commencement of any pilot or research project, the following documentation must be submitted to NIGMS staff for administrative review:

Using PHS398 forms and instructions, only the following sections need to be submitted:

- Face page (signed by institutional signing official)
- Project Summary (page 2)
- Research Strategy section
  - Research proposal
  - Rigor and transparency: As appropriate, a description of the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of project, and a description of the experimental design and methods proposed and how the investigator will achieve robust and unbiased results. If applicable, a brief description of the methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed project (see Notice [NOT-OD-16-011 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html) for details).
- External Advisory Committee approval – communication from the EAC chair (at a minimum) indicating that the EAC concurs with supporting the pilot project.
- If proposed study involves human subjects, following documents must be submitted to NIH:
  - Written protocol addressing the risks and protections for human subjects, in accordance with NIH's Instructions for Preparing the Human Subjects Section of the Research Plan.
  - Institutional Review Board (IRB) approval.
  - Human Subjects education certification.
  - Create Inclusion Data Record (IDR) and enter inclusion data in Inclusion Management System (IMS).

If the proposal involves Vertebrate Animal, IACUC approval and Vertebrate Animal Section as described above must be submitted.

## 2. Administrative and National Policy Requirements

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

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.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 [data sharing agreement \(https://www.nigms.nih.gov/training/dpc/Pages/datasharing.aspx\)](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 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 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 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) 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 DPC 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 BUILD and NRMN activities.
- Refine hallmarks of success 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 [Research Performance Progress Report \(RPPR\)](https://grants.nih.gov/grants/rppr/index.htm) ([//grants.nih.gov/grants/rppr/index.htm](https://grants.nih.gov/grants/rppr/index.htm)) annually and financial statements as required in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161). ([//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11161](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161))

#### **Other Reporting Requirements**

The institution must submit a completed Statement of Appointment ([PHS Form 2271](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=61189) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=61189](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=61189))) for each student trainee (TL4) and research participant (RL5) appointed full time for eight weeks or more or the equivalent. Grantees must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at [xTrain \(eRA Commons\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=41183) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=41183](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=41183)). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.

For non-citizens only, a notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment ([PHS Form 2271](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=61189) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=61189](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=61189))). Individuals with a Conditional Permanent Resident status must first meet full (non-conditional) Permanent Residency requirements before receiving support.

Participant Termination Notice: Within 30 days of the end of the total support period for each participant, the institution must submit a Termination Notice ([PHS Form 416-7](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=41179) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=41179](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=41179))) via [xTrain](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=41183) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=41183](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=41183)) for each participant appointed full time for eight weeks or more, or the equivalent.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161) ([//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11161](https://grants.nih.gov/grants/guide/uri_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](https://www.fsrs.gov) ([//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11170](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11170)) on all subawards over \$25,000. See the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11171) ([//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11171](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11171)) for additional information on this reporting requirement.

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

### 4. Evaluation

Evaluation of the BUILD initiative will be carried out continuously over the final years of the project.

The Diversity Program Consortium through its inclusive governance structure has established the data elements required to effectively evaluate BUILD, including data intended to measure hallmarks of success at each career stage and the impact that BUILD activities are having on student achievement of these hallmarks.

The NIH will periodically evaluate the BUILD awards to assess impact toward the overarching goal of engaging a diverse talent pool, sustaining research interests of emerging scientists, and preparing them for successful careers in biomedical research. In assessing the effectiveness of the DPC, NIH may request information from CEC and other databases, PD(s)/PI(s), and BUILD trainees and participants themselves. The BUILD



program will be evaluated on the impact of BUILD in contributing to a diverse NIH-funded workforce. At a minimum it is expected that the BUILD will be evaluated on the following key outcomes related to trainees and participants:

- Completion of undergraduate or graduate degree, completion of postdoctoral research training, and entrance into graduate programs, postdoctoral research training or faculty position.
- Involvement in 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.

Where necessary, PD(s)/PI(s), scholars, and other students participating in BUILD activities may be contacted after the completion of the BUILD program for periodic updates on subsequent educational or employment history and professional activities. Upon the completion of a program evaluation, NIH will determine whether lessons learned from BUILD should inform other NIH-funded training efforts.

## 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/](http://grants.nih.gov/support/)) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

**Grants.gov Customer Support** ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=82301](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82301)) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)

Contact Center Telephone: 800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov) (<mailto:support@grants.gov>)

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

Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov) (<mailto:GrantsInfo@nih.gov>) (preferred method of contact)

Telephone: 301-945-7573

### Scientific/Research Contact(s)

Anissa Brown, Ph.D.

National Institute of General Medical Sciences (NIGMS)

Telephone: 301-594-3900

Email: [anissa.brown@nih.gov](mailto:anissa.brown@nih.gov) (<mailto:anissa.brown@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) (<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

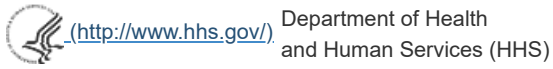
Email: [kaneisha.akinpelumi@nih.gov](mailto:kaneisha.akinpelumi@nih.gov) (<mailto:kaneisha.akinpelumi@nih.gov>)

## Section VIII. Other Information

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

### 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.



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