

# 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**

National Institute on Minority Health and Health Disparities ([NIMHD \(https://www.nimhd.nih.gov/\)](https://www.nimhd.nih.gov/))

National Institute on Aging ([NIA \(https://www.nia.nih.gov/\)](https://www.nia.nih.gov/))

National Institute on Drug Abuse ([NIDA \(https://www.drugabuse.gov/\)](https://www.drugabuse.gov/))

National Cancer Institute ([NCI \(https://www.cancer.gov/\)](https://www.cancer.gov/))

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**Funding Opportunity Title**

Long-Term Effects of Disasters on Health Care Systems Serving Health Disparity Populations (R01- Clinical Trial Optional)

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**Activity Code**

[R01 \(//grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=r01&Search.x=0&Search.y=0&Search\\_Type=Activity\)](https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project Grant

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**Announcement Type**

New

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**Related Notices**

July 26, 2019- Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research. See Notice [NOT-OD-19-128 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html)

August 23, 2019- Clarifying Competing Application Instructions and Notice of Publication of Frequently Asked Questions (FAQs) Regarding Proposed Human Fetal Tissue Research. See Notice [NOT-OD-19-137 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-137.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-137.html)

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**Funding Opportunity Announcement (FOA) Number**

PA-20-172

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**Companion Funding Opportunity**

None

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**Number of Applications**

See [Section III. 3. Additional Information on Eligibility](#).

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

93.307, 93.399, 93.866, 93.279

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**Funding Opportunity Purpose**

The purpose of this Funding Opportunity Announcement (FOA) is to support investigative and collaborative research focused on understanding the long-term effects of natural and/or human-made disasters on health care systems serving health disparity populations in communities in the U.S., including the U.S. territories. NIH-designated health disparity populations include racial and ethnic minorities (Blacks/African Americans, Hispanics/Latinos, American Indians/Alaska Natives, Asians, Native Hawaiians and other Pacific Islanders), sexual and gender minorities, socioeconomically disadvantaged populations, and underserved rural populations.

## Key Dates

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### Posted Date

April 20, 2020

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### Open Date (Earliest Submission Date)

September 04, 2020

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### Letter of Intent Due Date(s)

September 4, 2020

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### Application Due Date(s)

[Standard dates \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11111\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11111) apply.

The first standard due date for this FOA is October 5, 2020.

All applications are due by 5:00 PM local time of applicant organization. All [types of non-AIDS applications](#) allowed for this funding opportunity announcement are due on the listed date(s).

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)

[Standard AIDS dates \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11112\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11112) apply.

The first AIDS application due date for this FOA is January 7, 2021.

All applications are due by 5:00 PM local time of applicant organization. All [types of AIDS and AIDS-related applications](#) allowed for this funding opportunity announcement are due on the listed date(s).

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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### Scientific Merit Review

[Standard dates \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11113\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply

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### Advisory Council Review

[Standard dates \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11113\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply

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### Earliest Start Date

[Standard dates \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11113\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply

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### Expiration Date

September 08, 2023

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### Due Dates for E.O. 12372

Not Applicable

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## Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the [SF424 \(R&R\) Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000) ([//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 [NIH Guide for Grants and Contracts](https://grants.nih.gov/grants/guide/) ([//grants.nih.gov/grants/guide/](https://grants.nih.gov/grants/guide/))).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

### Applications that do not comply with these instructions may be delayed or not accepted for review.

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

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

[Apply Online Using ASSIST](#)

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons](https://public.era.nih.gov/commons/) (<http://public.era.nih.gov/commons/>) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov](https://www.grants.nih.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PA-20-172) (<https://www.grants.nih.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PA-20-172>) Workspace to prepare and submit your application and [eRA Commons](https://public.era.nih.gov/commons/) (<http://public.era.nih.gov/commons/>) to track your application.

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## Part 2. Full Text of Announcement

### Section I. Funding Opportunity Description

#### Background

Natural and human-made disasters are common phenomena across the U.S. and its territories, and vary by geographic location and seasonal weather changes, among other factors. In addition to the physical characteristics of the events, the magnitude of the damages caused by disasters in the U.S. depends on characteristics of the affected communities, including (but not limited to) socioeconomic status, number of persons aged = 17 or = 65 years, number of persons with disabilities and single-parent households, number of people from racial/ethnic minorities or other health disparity populations and their English proficiency, housing/dwelling characteristics and general infrastructure (e.g., roads, transportation, water, energy, emergency services, food supply/security). Federal, local, and tribal government- and non-profit organization-led response and recovery activities mostly focus on providing or facilitating emergency health services, individual assistance, basic community needs (e.g., water, food, evacuation, emotional/mental health support), and assessing the infrastructure and functionality of public and private non-profit health care facilities and their preparedness and response capacity for a future disaster.

The immediate impact of natural and human-made disasters in the U.S. on health and health care delivery has been considerably documented in the scientific literature, including very valuable lessons about health disparities and health policy. However, the long-term effects of disasters on health care systems impacted by these events and serving populations affected by health disparities- have not been adequately studied. For instance, newly developed or exacerbated chronic diseases and loss of medical infrastructure following disasters may trigger a prolonged level of increased need for medical services and health care professionals, in addition to worse clinical outcomes. Federal and local policies (e.g., Medicaid funding, federal laws or policies on territories, disaster-related individual and public assistance, emergency preparedness) may influence the promptness of the response as well as the impact of the disaster on health care systems' ability to meet the populations' health care needs, including quality of care, both in the aftermath and in the long-term. Communities with health disparities, including less than optimal health care coverage, are at risk of facing a greater threat than other communities or populations with better health profiles and access to less fragile health care systems.

Lessons learned through this initiative could lead to more effective implementation of clinical care guidelines and strategies of more effective health care delivery prior to, during and after disasters, and potentially preventing an increase in health care disparities in the most vulnerable communities in the long-term. In addition, this initiative offers an opportunity to compare long-term effects of disasters, best practices, strategies and outcomes among communities across the U.S. and its territories.

### **Research Objectives**

The overarching goal of this FOA is to invite robust investigative and collaborative research focused on understanding the long-term effects of disasters on health disparity populations and the health care systems that serve them, including the influence of risk factors or vulnerabilities of both the systems and the communities preceding the event(s). This initiative focuses on (i) describing the direct effects of disasters on health care systems, and specifically on the delivery, coordination, safety and quality of health care services, physical and organizational infrastructure, health care workforce and changes in health care needs and disparities of the communities they serve, and (ii) identifying strategies or best practices that health care systems or communities have implemented that promote appropriate system function and delivery of services during and after the disaster, maintenance of optimal continuity of care, and resilience of health care systems and populations for future events. Projects should include a focus on one or more NIH-designated U.S. health disparity populations, which include Blacks/African Americans, Hispanics/Latinos, American Indians/Alaska Natives, Asian Americans, Native Hawaiians and other Pacific Islanders, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities living in the 50 States, tribal lands, and the U.S. territories.

For the purpose of this initiative, disasters are defined as presidentially declared emergencies or major disasters under the Stafford Act, a public health emergency declared by the Secretary of the HHS, or other local, regional or national disaster(s), and include extreme weather-related disasters (e.g., hurricanes, typhoons, tsunamis, floods, mudslides, tornadoes, volcano eruptions, earthquakes, snowstorms, wildfires and others), human-made disasters (e.g., oil and chemical spills and contamination, nuclear testing and contamination, and water contamination), and their long-term consequences in the infrastructure (e.g., extended power outages, extended disruptions in the water systems, food supply, communications, transportation and housing). Public health emergencies may include the COVID-19 pandemic, influenza, zika, chikungunya or dengue outbreaks, and other epidemics. Disasters could be current, recent or past. Long-term is defined as 1 year or longer after the sentinel event(s).

Health care systems of interest include those directly impacted and/or disrupted by the disaster(s) and serving communities affected by health/health care disparities and who were also affected by the disaster(s). For the purpose of this FOA, health care systems could be networks of outpatient clinics (e.g., federally-qualified health centers or community clinics), systems that combine both outpatient and inpatient services units, or networks of clinical settings offering specific services (e.g., pharmacies, mental/behavioral health or drug use services, radiology, radiotherapy, occupational or physical rehabilitation, dialysis centers, long-term care, palliative and hospice care). Studies could also address the long-term effects on a single clinic or hospital serving rural or remote underserved communities.

The scope of health care services to be studied includes pediatric, adult, and geriatric primary and preventive care as well as specialty care (including mental health and drug use disorders), obstetrical/gynecological care, general and subspecialty surgery, critical care, emergency care (including trauma, psychiatric), dental care, interventional radiology, radiotherapy, hemodialysis, chemotherapy, occupational/physical therapy, rehabilitation, services offered by licensed clinical professionals in non-clinical settings (e.g., home, nursing home) and outpatient pharmacy services.

Research projects may address services offered by any of the settings mentioned above and collaborations with non-profit organizations (including volunteer groups), federal or local government agencies, local departments of health, academic institutions, schools and community-based organizations. Projects may focus on health care systems within a single geographic location affected by a disaster (e.g., territory, state, tribe) or collaborations among different locations affected by the same event, type of event or different events. Collaborations between investigators and institutions in areas affected by disasters and those outside of the affected areas, especially when local investigators and institutions fulfill a primary role in the research team, are encouraged. Prospective observational population studies focused on population or individual health outcomes are outside of the scope of this FOA.

### **Research Methodology**

The initiative will support retrospective quantitative research, mixed-methods analyses, simulation and modeling analyses, and evaluations of existing interventions and practices in communities with health care disparities whose health care systems have been disrupted by one or more natural or human-made disasters.

Examples of research methods could include, but are not limited to:

- Use of large-scale longitudinal data sets (e.g., public health surveillance, hospitals and outpatient health records, health insurance claims and other administrative datasets, registries), data mining techniques and integration of quantitative and qualitative frameworks and techniques to assess trends and projections on health care needs, access, delivery and utilization of health care services, patient population health profile and disparities or health care workforce
- Decision science modeling and analyses of post-disaster recovery population demographics, social determinants of health, health care needs, access and utilization of health care services and workforce trends
- Retrospective and prospective analyses (including multi-level analyses) of health care needs, health care disparities and/or health outcomes related to strategies implemented by public health entities, healthcare facilities, schools, community-based or academic institutions during and after the disaster(s)
- Retrospective analyses (including multi-level analyses) of the impact of policies on healthcare access and utilization and continuity of care before, during and after the event(s)
- Participatory engagement of stakeholders (health care facilities, patients and caregivers, clinicians, community groups, administrators, academic institutions, health care professional groups, schools, social services agencies, policymakers) in the formulation of the research and to the extent necessary, in the implementation of the research
- The ability to conduct subpopulation analyses to assess differences or similarities in the impact of these events on health care needs or to determine which interventions work best for specific population groups (e.g., based on age, sex/gender, health/clinical profile, geographic location)
- Multi-level interventions based on data already collected or strategies implemented during and/or after the disaster(s)

Multi-level analyses and interventions are encouraged.??

### Specific Areas of Interest

Examples of potential topic areas include but are not limited to:

- Change in demographics -including migration, return migration, and fatalities- following the disaster(s) and/or public health emergencies and subsequent change in actual or projected population health profile, health care needs (e.g., age-specific health services including prevention and treatment, subspecialty care, home-based care, long-term and hospice care) and health/health care disparities across the lifespan
- Strategies (including best practices) to ensure access to services and continuity of care and enhance prevention and treatment of acute exacerbations of chronic diseases -especially among patients with multiple medical conditions, disabilities and/or complex medical needs- for example, mitigation strategies to ensure storage, availability and delivery of medications and protection of electronic health records and health care system functionality
- Post-disaster and/or public health emergency health care systems re-design strategies
- Systems analyses to identify needs for or best practices of coordination among health care systems and health care workforce, public health units, local and federal agencies, community organizations, addiction treatment providers, community resources and affected communities in relation to preparedness, response to or recovery from disasters and/or public health emergencies in communities affected by health and health care disparities
- Analyses that identify needs for or best practices of coordination of health care delivery among health care systems and other sectors (e.g., water, energy, food supply, transportation, communication, housing) or the intersection of these sectors and health care services for health disparity populations during a major disaster and/or public health emergency (e.g. the COVID-19 pandemic, influenza, zika, chikungunya or dengue outbreaks, and other epidemics)
- Analyses on the short-term shifting burden of health care (e.g. the intersection of social services, law enforcement, national security with health care during and after disasters)
- Strategies to ensure access to services and continuity of care involving community-, schools- or non-profit organization-led initiatives linked or not linked to health care systems
- Pre-, during and post-disaster and/or public health emergency effectiveness or impact of state/territory and/or federal policies on access to or delivery of health care services for the general population, and for specific segments of the population [e.g. older adults, children in foster care homes, institutionalized or home-bound individuals, individuals with disabilities, patients with complex medical needs (including mental disorders and addiction)]
- Economic studies on the impact of job loss, migration, economic policies and other socioeconomic factors on projected health care needs, access to and utilization of health care services, health care delivery and health outcomes, especially of most vulnerable populations (e.g., children, older adults, persons with complex medical needs, persons receiving substance use and/or mental health services), and potential economic models for organizing and financing health care services for them during and after disasters and/or public health emergencies

- Pre- and post-disaster and/or public health emergency health care workforce migration and return; effect or projections on health care access, delivery and quality; workforce issues associated with increased demand for services; workforce retention strategies
- Comparisons of long-term effects among communities with health disparities whose health care systems were affected by disasters and/or public health emergencies across different geographic locations
- Effects of public health emergencies (e.g. the COVID-19 pandemic, influenza, zika, chikungunya or dengue outbreaks, and other epidemics), and/or serial disasters or natural events on health care systems recovering from major disasters and the health of the communities and individuals they serve (e.g. implementation of appropriate guidelines of prevention, diagnosis and care of individuals affected by the epidemic, availability of diagnostic tests, best practices at identifying individuals or communities at high-risk, multi-level health care preparedness, response and coordination during the subsequent emergency or disaster, management of health care systems and health care providers burden)

#### **National Institute on Minority Health and Health Disparities (NIMHD)**

- NIMHD is interested in any of the previously mentioned topics, and especially projects involving the U.S. territories in the Caribbean, the U.S. Affiliated Pacific Islands, Hawaii, and underserved rural communities across the U.S., including American Indian/Alaska Native tribal Nations and communities. In addition, studies that compare self-contained regions (e.g., islands territories, remote rural areas) with urban locations in the mainland or that assess the impact of federal territorial policies on health care systems are of interest.

#### **National Institute on Drug Abuse (NIDA)**

NIDA is particularly interested in the following questions relevant to responses to disasters and the effects of disasters on health disparity populations:

- Strategies to ensure access to services and continuity of care involving linking individuals with substance use disorder to addiction, mental health, and health service systems
- Understanding how changes in service availability across multiple sectors (housing, healthcare, public services, addiction treatment) affects the recovery and long-term outcomes of people with substance-use disorders
- Understanding how to minimize disruptions in treatment and how best to remediate any immediate short-term negative impacts to ensure continuity of treatment, particularly for people receiving medications for opioid use disorder
- Understanding coordination and collaboration across multiple sectors during the response to disasters to the needs of vulnerable populations, including people with substance use treatment needs

#### **National Institute on Aging (NIA)**

NIA is broadly interested in research focusing on the long-term impacts of disasters on health care systems serving older health disparity populations, including research relevant to Alzheimer's disease and related dementia (AD/ADRD) care. Within this broad umbrella, examples of specific NIA-relevant research topics include, but are not limited to:

- Intersectional approaches which consider multiple health disparity population categories simultaneously (e.g., race/ethnicity and rurality, race/ethnicity and education, etc.)
- Dynamics between formal caregiving institutions and informal caregivers
- Alternative health delivery systems to improve access to care (e.g., telemedicine, mobile health clinics, etc.)
- Health care systems serving Medicare/Medicaid dual eligible populations
- Re-establishment of medical home following displacement (either voluntary or involuntary)
- Differentiation between direct (e.g., infrastructure destruction) and indirect (governmental response) effects of disasters on health care systems
- Provision of mental health care services to address long-term disaster-related psychological trauma
- Integration of social services addressing long-term needs (e.g., food security) into health care systems
- Health care systems responses to infectious disease

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

## **Section II. Award Information**

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### **Funding Instrument**

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

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### **Application Types Allowed**

New  
Resubmission

#### Revision

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

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#### Clinical Trial?

Optional: Accepting applications that either propose or do not propose clinical trial(s)

[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)

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#### Funds Available and Anticipated Number of Awards

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

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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 scope of the proposed project should determine the project period. The maximum period is 5 years.

NIH grants policies as 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) will apply to the applications submitted and awards made from this FOA.

## Section III. Eligibility Information

### 1. Eligible Applicants

#### Eligible Organizations

##### Higher Education Institutions

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

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

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

##### Nonprofits Other Than Institutions of Higher Education

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

##### For-Profit Organizations

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

##### Governments

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

**Other**

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

**Foreign Institutions**

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

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

Foreign components, as [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/) - 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 to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov - Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

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

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

**Eligible Individuals (Program Director/Principal Investigator)**

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

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

**2. Cost Sharing**

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

**3. Additional Information on Eligibility**

## Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct. 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 \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html))

## Section IV. Application and Submission Information

### 1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in [Part 1](#) of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

### 2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=12000\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=12000) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

#### 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:

Larissa Avilés-Santa, MD, MPH  
National Institute on Minority Health and Health Disparities (NIMHD)  
Telephone: 301-827-6924  
Email: [avilessantal@nih.gov](mailto:avilessantal@nih.gov) (<mailto:avilessantal@nih.gov>)

#### Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits \(//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11133\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11133) must be followed

#### Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

##### **SF424(R&R) Cover**

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

##### **SF424(R&R) Project/Performance Site Locations**

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

##### **SF424(R&R) Other Project Information**

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

##### **SF424(R&R) Senior/Key Person Profile**

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

## R&R or Modular Budget

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

## R&R Subaward Budget

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

## PHS 398 Cover Page Supplement

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

## PHS 398 Research Plan

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

Describe the conceptual framework for the proposed multilevel analysis or intervention.

For collaborations and/or consortia of the investigators/ institutions outside of affected areas with investigators/institutions in areas affected by disasters, describe the involvement of the disaster-local investigators and/or institutions as contributors to leadership or key personnel.

**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.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

## Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

## PHS Human Subjects and Clinical Trials Information

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

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

### Study Record: PHS Human Subjects and Clinical Trials Information

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

### Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the SF424 (R&R) Application Guide must be followed.

## PHS Assignment Request Form

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

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

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

## 4. Submission Dates and Times

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

Organizations must submit applications to [Grants.gov \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11128\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). 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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142). ([//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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) ([//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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11143) ([//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.

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 [How to Apply – Application Guide](https://grants.nih.gov/grants/how-to-apply-application-guide.html) (<https://grants.nih.gov/grants/how-to-apply-application-guide.html>). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Dealing with System Issues](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) (<https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm>) guidance. For assistance with application submission, contact the Application Submission Contacts in [Section VII](#).

### Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See [Section III](#) of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See [more tips](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) ([//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, NIH. Applications that are incomplete or non-compliant will not be reviewed.

## Requests of \$500,000 or more for direct costs in any year

Applicants requesting \$500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request \$500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide.

## 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) ([//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. Applications submitted to the NIH in support of the [NIH mission](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11149](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149)) are evaluated for scientific and technical merit through the NIH peer review system.

In addition, for applications involving clinical trials: A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the

clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

## Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the 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 project proposed).

## Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. 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 the prior research that serves as the key support for the proposed project rigorous? 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?

#### In addition, for applications involving clinical trials

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy?

### 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 experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

#### Specific to this funding opportunity

Where investigators/institutions outside of affected areas are engaged in collaboration or consortium with investigators/institutions in areas affected by disaster, are disaster-local investigators fulfilling appropriate roles (e.g. key personnel and/or leadership for this project)?

#### In addition, for applications involving clinical trials

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

### 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?

#### In addition, for applications involving clinical trials

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

### Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed 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?

### **Specific to this funding opportunity**

How appropriate is the proposed multi-level analysis or intervention? Are the levels defined and is an appropriate conceptual framework included?

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 individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

### **In addition, for applications involving clinical trials**

Does the application adequately address the following, if applicable

#### *Study Design*

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

#### *Data Management and Statistical Analysis*

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

### **Environment**

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

### **In addition, for applications involving clinical trials**

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

Data collection and analyses from different sites, coordination of collection and analyses and collaboration among investigators to reach the goals.?

### **Additional Review Criteria**

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

## Study Timeline

### Specific to applications involving clinical trials

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

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

### Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Guidelines for the Review of Human Subjects \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11175).

### Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11174\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11174).

### Vertebrate Animals

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

### Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

### Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

### Renewals

Not Applicable.

### Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for

approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

### **Additional Review Considerations**

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

#### **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 \(//grants.nih.gov/grants/guide/redirect.htm?id=11151\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11151); (2) [Sharing Model Organisms \(//grants.nih.gov/grants/guide/redirect.htm?id=11152\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11152); and (3) [Genomic Data Sharing Plan \(GDS\) \(//grants.nih.gov/grants/guide/redirect.htm?id=11153\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11153).

#### **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 the Center for Scientific Review, in accordance with [NIH peer review policy and procedures \(//grants.nih.gov/grants/guide/redirect.htm?id=11154\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11154), using the stated [review criteria \(file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#\\_1\\_1.Criteria\)](file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1_1.Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

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

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

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

## **3. Anticipated Announcement and Award Dates**

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons \(//grants.nih.gov/grants/guide/redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/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 \(//grants.nih.gov/grants/guide/redirect.htm?id=11156\)](https://grants.nih.gov/grants/guide/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.

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

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

Institutional Review Board or Independent Ethics Committee Approval: Grantee institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the awardee must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

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

## 2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11159\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at [Award Conditions and Information for NIH Grants \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11158\)](https://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 laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> (<https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html>) and <http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html>).

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

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html>) and <https://www.lep.gov> (<https://www.lep.gov>). For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53> (<https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>).

- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>).
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>); <https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html>; and <https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf> (<https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf>). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see <https://grants.nih.gov/grants/policy/harassment.htm> (<https://grants.nih.gov/grants/policy/harassment.htm>).
- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see <https://www.hhs.gov/conscience/conscience-protections/index.html> (<https://www.hhs.gov/conscience/conscience-protections/index.html>) and <https://www.hhs.gov/conscience/religious-freedom/index.html> (<https://www.hhs.gov/conscience/religious-freedom/index.html>).

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

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIS) requirements. FAPIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIS, 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

Not Applicable

### 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) (<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). ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11161](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161)).

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) ([https://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.fsr.gov](http://www.fsr.gov) ([https://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) ([https://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 FAPIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

## Section VII. Agency Contacts

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

### Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threatens submission by the due date, and 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)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)

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

Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)

Contact Center Telephone: 800-518-4726

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

### Scientific/Research Contact(s)

Larissa Avilés-Santa, MD, MPH

National Institute on Minority Health and Health Disparities (NIMHD)

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

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National Cancer Institute (NCI)

Telephone: 240-276-6254

Email: [sallie.weaver@nih.gov](mailto:sallie.weaver@nih.gov) (<mailto:sallie.weaver@nih.gov>)

Amelia Karraker, PhD

National Institute on Aging (NIA)

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Email: [Amelia.Karraker@nih.gov](mailto:Amelia.Karraker@nih.gov) (<mailto:Amelia.Karraker@nih.gov>)

Julia Zur, PhD

National Institute on Drug Addiction (NIDA)

Telephone: 301-443-2261

Email: [julia.zur@nih.gov](mailto:julia.zur@nih.gov) (<mailto:julia.zur@nih.gov>)

### Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

### Financial/Grants Management Contact(s)

Priscilla Grant, JD

National Institute on Minority Health and Health Disparities (NIMHD)

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Email: [pg38h@nih.gov](mailto:pg38h@nih.gov) (<mailto:pg38h@nih.gov>)

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Mitchell Whitfield

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Pam Fleming

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## Section VIII. Other Information

Recently issued trans-NIH [policy notices](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11163](https://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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11164) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11164](https://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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)).

### Authority and Regulations

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

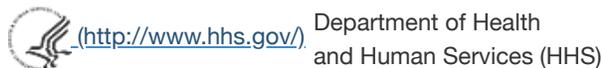
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[Weekly TOC for this Announcement](https://grants/guide/WeeklyIndex.cfm?04-24-20) ([/grants/guide/WeeklyIndex.cfm?04-24-20](https://grants/guide/WeeklyIndex.cfm?04-24-20))

[NIH Funding Opportunities and Notices](https://grants/guide/index.html) ([/grants/guide/index.html](https://grants/guide/index.html))

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