

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

Division of Program Coordination, Planning and Strategic Initiatives, Office of Disease Prevention ([ODP \(http://prevention.nih.gov/default.aspx\)](http://prevention.nih.gov/default.aspx))

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The NIH Office above may co-fund applications assigned to those Institutes/Centers.

National Cancer Institute ([NCI \(http://www.nci.nih.gov/\)](http://www.nci.nih.gov/))

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

National Institute on Alcohol Abuse and Alcoholism ([NIAAA \(http://www.niaaa.nih.gov/\)](http://www.niaaa.nih.gov/))

National Institute of Dental and Craniofacial Research ([NIDCR \(http://www.nidcr.nih.gov/\)](http://www.nidcr.nih.gov/))

National Institute on Drug Abuse ([NIDA \(http://www.nida.nih.gov/\)](http://www.nida.nih.gov/))

National Institute of Mental Health ([NIMH \(http://www.nimh.nih.gov/\)](http://www.nimh.nih.gov/))

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

Funding Opportunity Title

Increasing Uptake of Evidence-Based Screening in Diverse Adult Populations (R01 Clinical Trial Optional)

Activity Code

[R01 \(//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity)
Research Project Grant

Announcement Type

New

Related Notices	None
Funding Opportunity Announcement (FOA) Number	PA-18-932
Companion Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.121; 93.242; 93.273; 93.279; 93.307; 93.399; 93.866
Funding Opportunity Purpose	This Funding Opportunity Announcement (FOA) invites applications that seek to understand strategies to reduce disparities in the uptake of evidence-based screening (e.g. screening recommendations proven to be effective based on rigorous systematic review of scientific evidence by authoritative committees) across the adult lifespan. In this program announcement, screening is defined as a preventive service focused on detection of an undiagnosed disease in asymptomatic populations. Research supported by this initiative should enhance the screening process related to use: (1) in diverse populations, (2) in diverse clinical and community settings, and/or (3) with traditional, non-traditional and/or allied health care providers.

Key Dates

Posted Date	September 21, 2018
Open Date (Earliest Submission Date)	January 05, 2019
Letter of Intent Due Date(s)	Not Applicable
Application Due Date(s)	<p>Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11111) apply, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates.</p> <p>The first standard application due date for this FOA is February 5, 2019.</p> <p>Applicants are encouraged to apply early to allow adequate time to</p>

make any corrections to errors found in the application during the submission process by the due date.

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, 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 these dates.

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.

The first AIDS application due date for this FOA is May 7, 2019.

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

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

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

Expiration Date

January 08, 2022

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(//grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)](#), except where instructed to do otherwise (in this FOA or in a Notice from [NIH Guide for Grants and Contracts \(//grants.nih.gov/grants/guide/\)](#)).

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 \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PA-18-932\)](http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PA-18-932) Workspace to prepare and submit your application and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application.

Table of Contents

[Part 1. Overview Information](#)

[Key Dates](#)

[Part 2. Full Text of Announcement](#)

[Section I. Funding Opportunity Description](#)

[Section II. Award Information](#)

[Section III. Eligibility Information](#)

[Section IV. Application and Submission Information](#)

[Section V. Application Review Information](#)

[Section VI. Award Administration Information](#)

[Section VII. Agency Contacts](#)

[Section VIII. Other Information](#)

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Introduction

Scientific evidence suggests that health screenings (e.g., mammograms, diabetes tests, oral exams, substance abuse tests), as clinical preventive services, improve the health of populations. Evidence is further supported by expert committees performing systematic reviews to scientifically-test the effectiveness of research studies focused on the benefits of screening. Accordingly, these expert committees develop screening recommendations, now considered evidence-based, as a process of care.

Estimates from the early part of this millennium reveal that U.S. adults receive approximately half of the health care services recommended by committees such as the U.S. Preventive Services Task Force, the Community Preventive Services Task Force, and the Advisory Committee on Immunization Practices. The Affordable Care Act was enacted to help close the gap between the number of health care services recommended and the number of screening and other preventive services received routinely in the

population. More specifically, Title IV of this law is focused on 'Prevention of Chronic Diseases and Improving Public Health' by providing improved access to clinical preventive services. In December 2017, the U.S. Preventive Services Task Force published a report on clinical preventive services that highlights key evidence gaps for evidence-based screening modalities and for specific populations undergoing screening. Based on an evaluation of current gaps from research and reports, the National Institutes of Health (NIH) have identified research focused on increasing the uptake of evidence-based screenings for diverse adult populations as the primary focus of this funding opportunity.

Background

Although the focus of this funding opportunity is on increasing uptake of evidence-based screening for diverse populations, it is important to understand the past decade's trajectory of use of clinical preventive services, of which, screening services are a major component. Almost a decade after the enactment of policy designed to improve preventive care, several hurdles remain. While some improvements in utilization of screening and preventive services have been observed, those improvements are generally seen among insured compared to uninsured populations. Utilization also varies by age. Fewer evidence-based screening services are recommended for young adults (ages 18-26) than for younger and older populations. This group has been relatively overlooked in relation to guidelines for preventive services, and they are the adult age group most likely to be uninsured. Issues unique to young adults have not been addressed explicitly within most guidelines because guidelines that include adolescents and adults seldom provide specific suggestions for young adults. State level evidence suggests that young adults have low rates of preventive services generally (16.7%-50.6%).

A national study that examined differences in Medicaid expansion vs. non-expansion states provides insights into factors influencing those disparities. The study found that, among adults up to age 64, those living below the poverty level (household income < 100% of FPL) and living in a Medicaid expansion state were more likely to have health insurance coverage, a usual source of care, routine check-ups, higher levels of breast, cervical, and influenza screenings and less likely to experience unmet health care needs because of cost. Similar results were observed for persons living above the federal poverty level in Medicaid expansion states versus non-expansion states. As a result, there appears to be a prevention services gap for adults living in non-expansion states. This evidence suggests that context serves as an important determinant of service utilization.

Among older adults (age 65 and older), the Medicare annual wellness visit was designed and implemented to promote evidence-based preventive care and address health risks in aging patients. These wellness visits incorporate screening for depression and fall risk that may exceed the scope of other preventive visits. Despite Medicare coverage for preventive services, increased use of preventive screening services has been modest to none within the past decade.

In addition, service delivery settings and allied health or non-traditional healthcare providers may be important determinants of uptake of recommended adult preventive screening services. In recent years, investigators have begun to explore the effects of providing preventive screenings outside of the usual clinical setting and by diverse allied health or non-traditional health care providers as one approach to increasing uptake. These settings include: pharmacies, colleges/universities, churches, beauty shops, barber shops, and other community settings. Furthermore, persistent gaps in rates of screening in rural

compared to urban populations reflect the well documented challenges of providing clinical services, including screening, in rural settings. Studies have explored the use of a wide range of allied health and other providers in those settings including: lay health advisors/promotoras, traditional Native American healers, nurses, social workers, and pharmacists. Research has highlighted the need to consider the broader community context, both in terms of diverse settings and alternative providers, to ensure broader reach for evidence-based services (including screening) across the care continuum. The complex and multi-level environment in which patients receive care contributes to the likelihood that patients may get lost in the transitions of care and not complete the full process of screening.

U.S. populations are experiencing sex, racial and ethnic disparities in preventive screening across the adult lifespan. There is evidence that black and Hispanic young adults, as well as adults in other age categories fare better than whites in the receipt of a number of recommended preventive services. However, there are still high priority evidence gaps related to screening for chronic diseases among diverse populations such as African Americans (e.g., breast and prostate cancer screening). There are sex differences in preventive screening service utilization among young adults such that males are less likely than females to receive services. While existing research has documented a range of factors influencing disparities in receipt of screening across the continuum of the adult lifespan, recent research gaps have identified the need for studies designed to better understand mechanisms of disparities (e.g., demographic, social, cultural, place-based, or economic) in screening services across diverse populations and barriers to refine interventions designed to reduce disparities.

Scope of Research

Institutes within the NIH have separately advanced FOAs related to either the increased use of recommended preventive screenings or overuse of specific screenings in target adult populations. These initiatives are very specific to each Institute and Center (IC) mission area. However, as common risk factors are being identified for many common diseases and as more evidence-based screening interventions are identified, trans-NIH efforts to advance this research may advance more rapid exchange of insights on effective approaches across different disease areas. Therefore, the topics being addressed under this FOA are most appropriate for a trans-NIH FOA effort that addresses the interests of multiple NIH ICs. In addition, because these topics are relevant to prevention across NIH, the development of this FOA is being coordinated by the NIH Office of Disease Prevention.

Priority Areas

National Cancer Institute (NCI)

NCI addresses uptake of cancer screening among all populations and encourages research in screening that fills gaps in the science base regarding disparities among diverse populations. Studies are needed that understand screening as a process, rather than a single encounter. As a process, screening focuses on linking different healthcare entities that emphasize monitoring the context of care delivery for patients, from screening through treatment. Research is needed that focuses on multiple levels of the healthcare system that includes two or more levels of patients, providers, teams, clinic facilities, healthcare organizations. Areas of interest include, but are not limited to:

- Develop and/or test multilevel interventions to promote evidence-based screening – identifying

characteristics of the healthcare delivery context (e.g., at the patient, provider, teams, clinic facility or healthcare organization level) that might enhance or inhibit improvements to care by studying: a) promotion of HPV screening, teamwork processes, shared decision making, situational awareness, follow-up to abnormal cancer screening tests, and partnership with patients; and b) mechanisms by which multilevel characteristics operate to enhance or inhibit provision of evidence-based screening.

- Develop and/or test healthcare delivery intervention approaches to modify social determinants of health to improve delivery of evidence-based cancer screening.
- Develop and/or test implementation strategies to increase uptake of evidence-based cancer screening and follow-up practices, targeting at least two levels: patient, provider, teams, clinic facility and/or healthcare organization-level.
- Develop and/or test multilevel strategies to implement evidence-based screening practices in low-resource or underserved areas, with an emphasis on follow-up and treatment.
- Develop and/or test multilevel strategies to adapt, implement, and/or sustain evidence-based screening and follow-up practices in clinical settings.

National Institute on Aging (NIA)

The National Institute on Aging encourages experimental, observational, or interventional studies focused on adults in midlife and at older ages. Where this FOA addresses screening, other FOAs may be used to address over-screening (for example [PA-18-005 \(https://grants.nih.gov/grants/guide/pa-files/PA-18-005.html\)](https://grants.nih.gov/grants/guide/pa-files/PA-18-005.html)).

Areas of interest include, but are not limited to:

- Evaluate the impact of a personalized preventive care program on screening, health care utilization and expenditure trends
- Evaluate the impact of programs to encourage the use of annual wellness visits, overall and through mechanisms adapted to underserved populations and the practices that serve them
- Evaluate low-cost interventions designed to improve physician adherence to recommended screening guidelines to increase use of preventive services and improve health outcomes
- Evaluate approaches that would enable screening interventions to be focused on those at particular life stages or on the entire life course
- Determine how linkages and more coordinated screening activities across various healthcare and community settings could result in more efficiencies and improved health outcomes

New data collection, novel interventions, or secondary analysis of existing datasets, such as the Health and Retirement Study or the Midlife in the U.S. (MIDUS) Study, that contain rich data on adults targeted by this FOA are encouraged. For a list of datasets sponsored by the NIA, see:

<http://www.nia.nih.gov/research/dbsr/publicly-available-databases-aging-related-secondary-analyses-behavioral-and-social> (<http://www.nia.nih.gov/research/dbsr/publicly-available-databases-aging-related-secondary-analyses-behavioral-and-social>).

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

The United States Preventive Services Task Force (USPSTF) recommends that primary care providers

screen all adults and conduct brief counseling for those who misuse alcohol, as it found evidence in support of screening and brief intervention (SBI) delivered in primary care to adults. However, disparities in such screening have been found to exist, as Black non-Hispanics report significantly lower prevalence of screening than do white non-Hispanics and college graduates report significantly higher prevalence of screening than do those with a high school degree or less. Moreover, while many validated instruments already exist for alcohol screening, research indicates that many providers who do report screening for alcohol misuse do not use screening tools that are capable of detecting the full spectrum of alcohol misuse —i.e., they may be asking about drinking but are not screening—or they do not engage in follow-up questions, or they are unfamiliar with typical “standard drink” equivalents in discussing drinking with patients. Furthermore, screening for alcohol use is performed inconsistently by emergency department (ED) physicians. Other populations that likely would benefit from enhanced screening strategies are pregnant women and those in elderly care. Beyond the screening process itself, provision of brief advice about drinking and subsequent referral to specialty treatment have been found to be inconsistently provided by primary care and ED providers.

Areas of interest include, but are not limited to:

- Establish the feasibility and efficacy of providing alcohol misuse screening opportunities among: nonwhite populations, those with lower educational levels, and pregnant women
- Establish the feasibility and efficacy of providing alcohol misuse screening opportunities to those in: elderly care settings, primary care settings, emergency departments, and community settings.
- Increase the consistent use—by primary care practitioners, ED physicians, and others—of appropriate screening tools with established capability of detecting the full spectrum of alcohol misuse.
- Increase primary care and ED and community-based providers’ consistent provision of brief advice about drinking and referral to specialty treatment for those patients screening positive for alcohol misuse.

National Institute of Dental and Craniofacial Research (NIDCR)

The dental office is a primary care setting that provides an opportunity for oral health practitioners to conduct preventive general health services, such as evidence-based screenings. Many adults in the U.S. may have a dental visit in a given year, but not a routine medical visit. Therefore, evidence-based health screenings in dental offices provide opportunities to identify individuals with undiagnosed or progressing chronic conditions, beyond those conditions specific to the head and neck region. Several studies have demonstrated the feasibility of conducting evidence-based screenings in the dental setting for chronic conditions, such as diabetes. Additionally, previous research indicates acceptability of screening for chronic conditions in a dental setting to both dental professionals and patients. NIDCR encourages observational studies focused on implementing screening and referral for diabetes, hypertension, and/or Human Immunodeficiency Virus (HIV) infection (screenings that have received an evidence-based grade by the U.S. Preventive Services Task Force) by oral health professionals in a dental setting. These studies could examine aspects of screening across the care continuum from: risk assessment, to detection, through initial referral, and seeking care with medical providers. Research that explores improving uptake of screening, referral, and follow-up with medical providers would be encouraged.

Areas of interest include, but are not limited to:

- Improve the provision and uptake of screening in diverse dental settings, including those settings that target underserved populations,
- Explore the willingness/acceptability of screening for medical conditions by dental professionals,
- Improve rates of referral following screening,
- Determine the degree to which patients follow-up with and visit a physician/medical provider after being screened and referred, and
- Enhance screening and referral using technology (such as, integrated Electronic Health Records and clinical decision support systems).

National Institute on Drug Abuse (NIDA)

The United States Preventive Services Task Force (USPSTF) has concluded that the current evidence for screening adults for illicit drug use is insufficient, and does not recommend screening in primary care for adults (including pregnant women). There is a need for research to contribute to the evidence base on screening for illicit drug use and substance use disorder, prescription drug and opioid misuse, and opioid use disorder in adults, including pregnant women in primary and other healthcare settings. In addition, there is a need for research on screening in adults in settings beyond primary care, in settings where young adults work, access community services, engage in social and recreational activities, and particularly in settings that are utilized by vulnerable and at-risk populations. Of particular interest is research that focuses on screening for opioid misuse and opioid use disorder and linkage to prevention and treatment services.

Areas of interest include, but are not limited to:

- Test models for healthcare and other settings for screening and brief prevention and treatment interventions for illicit drug use and substance use disorder, prescription drug and opioid misuse, and opioid use disorder as well as linkage to prevention and treatment services.
- Test models or strategies for screening and linkage to prevention and treatment services for diverse and vulnerable populations in healthcare settings and systems (primary care, emergency departments, urgent care, school and college health centers) and other systems (workplace, community, recreational, social services, criminal justice).
- Test models and strategies for integrating screening and referral or linkage to prevention and treatment services into healthcare systems/practices (e.g., including algorithms, decision tools, reminders), and also test strategies for sustainability.
- Validate existing or new instruments for screening for illicit drug use and substance use disorder, prescription drug and opioid misuse, and opioid use disorder in healthcare and non-healthcare settings.
- Test innovative and new technologies to enhance screening and linkage to prevention and treatment services in healthcare and other settings.

National Institute on Mental Health (NIMH)

NIMH is interested in studies of the effectiveness and implementation of mental health screening delivered in approaches that include detection of symptoms, referral for diagnosis and follow-up for subsequent engagement in treatment when indicated. Populations of interest include but are not limited to those

experiencing inadequate detection of symptoms, limited access to or engagement in mental health treatment. These populations may also include but are not limited to people from underserved racial, ethnic, and language-minority groups; those living in rural areas or impoverished communities; refugees and immigrants; individuals from sexual/gender minority groups; or other underserved groups. Relevant screening sites may include non-specialty and community-based settings, or novel settings or providers when justified. New uses of technology and sustainable approaches designed for integration into existing organizational practices or systems are encouraged. Investigators must first demonstrate existing evidence-based approaches to screening, referral, and follow-up are ineffective, not available, and/or not delivered in the target population or that there are clear differences in outcomes (in the wrong direction) associated with implementing existing evidence-based approaches in the target population.

Applications that test or compare provider- or system-level interventions designed to promote uptake of screening or interventions to promote engagement/continuity of service use should detail plans to explicitly address whether the intervention engages the target(s)/mechanism(s) presumed to underlie the intervention effects (the mechanism(s) that account for changes provider- or patient- behavior), consistent with the NIMH experimental therapeutics approach (<http://www.nimh.nih.gov/about/director/2012/experimental-medicine.shtml> (<http://www.nimh.nih.gov/about/director/2012/experimental-medicine.shtml>)). Applications should address: (1) the empirical basis for the intervention target(s)/mechanism(s), i.e., the empirical evidence linking the target(s)/mechanism(s) to the patient-, provider- or system-level behaviors/processes that the intervention seeks to ultimately improve; (2) plans for assessing engagement of the target(s)/mechanism(s); and (3) analyses that will be used to examine whether the intervention engages the target(s)/mechanism(s) and whether intervention-induced changes in the target(s)/mechanism(s) are associated with clinical benefit.

Effective services that support prevention and treatment of mental illness have the potential to reduce morbidity and mortality associated with intentional injury (i.e., suicide attempts and deaths, see: www.suicide-research-agenda.org (<http://www.suicide-research-agenda.org>)). Lack of attention to the assessment of these outcomes has limited our understanding regarding the degree to which effective mental health interventions might offer prophylaxis. Accordingly, where feasible and appropriate, NIMH encourages effectiveness research that, includes assessment of suicidal behavior in order to advance understanding of how effective prevention and treatment of mental disorders might impact suicide relevant outcomes.

National Institute on Minority Health and Health Disparities (NIMHD)

NIMHD is interested in projects that address screening for conditions that are more prevalent in health disparity populations and/or for which health disparity populations have disproportionately low rates of screening. Health disparity populations include African Americans/Blacks, Hispanics/Latinos, American Indians/Alaska Natives, Asians, Native Hawaiians and Other Pacific Islanders, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities. Projects are encouraged that encompass multiple domains (e.g., biological, behavioral, socio-cultural, environmental, physical environment, healthcare system) and multiple levels (e.g., individual, interpersonal, community, societal) to understand screening behavior and effectiveness (see the NIMHD Research Framework, <https://www.nimhd.nih.gov/about/overview/research-framework.html> (<https://www.nimhd.nih.gov/about/overview/research-framework.html>)).

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

- Multilevel intervention to increase screening rates among health disparity populations
- Clinical and pragmatic trials of efficacy and effectiveness of existing screening methods, particularly those recommended by the US Preventive Services Task Force (USPSTF, <https://www.uspreventiveservicestaskforce.org/> (<https://www.uspreventiveservicestaskforce.org/>)), that have not been adequately tested or implemented in health disparity populations.
- Novel mechanisms or technology to address screening gaps in underserved health disparity populations.
- Development and testing of new screening methods or guidelines that better capture disease risk for health disparity populations.
- Comparative effectiveness of different interventions to increase screening rates among health disparity populations

Office of Disease Prevention (ODP)

The Office of Disease Prevention encourages applications that have promise for increasing uptake of adult screening interventions targeting diverse populations. These interventions should have strong implications for disease prevention and make use of innovative design, measurement, and analytic methods relevant to the overall objectives of this funding opportunity announcement. Applications must also be relevant to the objectives of at least one of the participating NIH Institutes and Centers (IC) listed above. ODP does not award grants. Please contact one of the IC program contacts listed for questions related to funding.

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

Section II. Award Information

Funding Instrument

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

Application Types Allowed

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

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

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.

Award Budget

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

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 5 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) 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)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

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

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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11118) ([//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](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) ([//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 – 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11126\)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

Buttons to access the online ASSIST system or to download application forms 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/url_redirect.htm?id=12000](https://grants.nih.gov/grants/guide/url_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.

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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=41137)).

Page Limitations

All page limitations 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 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:

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 NIH-defined human subjects research, clinical research, and/or 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

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 \(https://grants.nih.gov/grants/guide/url_redirect.html?id=82380\)](#), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(/grants.nih.gov/grants/guide/url_redirect.htm?id=11128\)](#) (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](#)

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 https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142) intergovernmental review. (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 \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](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 \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=11143\)](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 [Applying Electronically \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=11144\)](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 \(https://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines\)](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) 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11146\)](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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=82299\)](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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11149\)](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.

For this particular announcement, note the following:

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 their 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? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

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?

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?

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

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 international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

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?

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., CTSA's, 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/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Children

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/url_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/url_redirect.htm?id=11150).

Biohazards

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

Resubmissions

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

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

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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151) ([//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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11152](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152)); and (3) [Genomic Data Sharing Plan \(GDS\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11153) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11153](https://grants.nih.gov/grants/guide/url_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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11154) ([//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:

- 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. 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](http://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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11156\)](http://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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11157\)](http://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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11158\)](http://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 of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

http://grants.nih.gov/ClinicalTrials_fdaaa/

Institutional Review Board or Independent Ethics Committee Approval: Grantee institutions must ensure that the application as well as all 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. Data and Safety 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).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement](http://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](http://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](http://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](http://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.

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.

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>).

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 \(RPPR\)](http://grants.nih.gov/grants/rppr/index.htm) (<http://grants.nih.gov/grants/rppr/index.htm>) annually and financial statements as required in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161). (http://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](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161) (http://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://grants.nih.gov/grants/guide/uri_redirect.htm?id=11170) on all subawards over \$25,000. See the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11171) (http://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 threaten on-time submission, 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 processes and NIH grant resources)

Email: 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>)

Scientific/Research Contact(s)

Dionne C. Godette, PhD

Office of Disease Prevention (ODP)

Telephone: 301-480-1161

Email: dionne.godette@nih.gov (<mailto:dionne.godette@nih.gov>)

Erica S. Breslau, PhD, MPH

National Cancer Institute (NCI)

Telephone: 240-276-6773

Email: breslaue@mail.nih.gov (<mailto:breslaue@mail.nih.gov>)

Marcel E. Salive, MD, MPH

National Institute on Aging (NIA)

Telephone: 301-496-5278

Email: saliveme@mail.nih.gov (<mailto:saliveme@mail.nih.gov>)

Robert Freeman, PhD

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

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Email: rfreeman@mail.nih.gov (<mailto:rfreeman@mail.nih.gov>)

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National Institute of Dental and Craniofacial Research (NIDCR)

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Email: darien.weatherspoon@nih.gov (<mailto:darien.weatherspoon@nih.gov>)

Jacqueline Lloyd, PhD

National Institute on Drug Abuse (NIDA)

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Email: lloydj2@nida.nih.gov (<mailto:lloydj2@nida.nih.gov>)

Denise Juliano-Bult, MSW

National Institute of Mental Health (NIMH)

Telephone: 301-443-1638

Email: djuliano@mail.nih.gov (<mailto:djuliano@mail.nih.gov>)

Xinzhi Zhang, MD

National Institute of Minority Health and Health Disparities (NIMHD)

Telephone: 301-594-6136

Email: xinzhi.zhang@nih.gov (<mailto:xinzhi.zhang@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)

Crystal Wolfrey

National Cancer Institute (NCI)

Telephone: 240-276-6277

Email: wolfreyc@mail.nih.gov (<mailto:wolfreyc@mail.nih.gov>)

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National Institute on Alcohol Abuse and Alcoholism (NIAAA)

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Tamara Kees

National Institute of Mental Health (NIMH)

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Priscilla Grant, JD

National Institute of Minority Health and Health Disparities (NIMHD)

Telephone: 301-594-8412

Email: grantp@mail.nih.gov (<mailto:grantp@mail.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 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.

[Weekly TOC for this Announcement](http://grants/guide/WeeklyIndex.cfm?09-21-18) ([/grants/guide/WeeklyIndex.cfm?09-21-18](http://grants/guide/WeeklyIndex.cfm?09-21-18))

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

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