Department of Health and Human Services
Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

National Cancer Institute (NCI (http://www.nci.nih.gov/))
National Heart, Lung, and Blood Institute (NHLBI (http://www.nhlbi.nih.gov))
National Human Genome Research Institute (NHGRI (https://www.genome.gov/))
National Institute on Aging (NIA (http://www.nia.nih.gov))
National Institute on Alcohol Abuse and Alcoholism (NIAAA (http://www.niaaa.nih.gov))
National Institute of Allergy and Infectious Diseases (NIAID (http://www.niaid.nih.gov))
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (http://www.nichd.nih.gov))
National Institute on Deafness and Other Communication Disorders (NIDCD (http://www.nidcd.nih.gov))
National Institute of Dental and Craniofacial Research (NIDCR (http://www.nidcr.nih.gov))
National Institute on Drug Abuse (NIDA (http://www.nida.nih.gov))
National Institute of Environmental Health Sciences (NIEHS (http://www.niehs.nih.gov))
National Institute of Mental Health (NIMH (http://www.nimh.nih.gov))
National Institute of Neurological Disorders and Stroke (NINDS (http://www.ninds.nih.gov))
National Institute of Nursing Research (NINR (http://www.ninr.nih.gov))
National Institute on Minority Health and Health Disparities (NIMHD (http://www.nimhd.nih.gov/))
National Center for Complementary and Integrative Health (NCCIH (http://www.nccam.nih.gov))

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

Office of Behavioral and Social Sciences Research (OBSSR (http://obssr.od.nih.gov))

Funding Opportunity Title

Dissemination and Implementation Research in Health (R01 Clinical Trial Optional)

Activity Code

R01 (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

Announcement Type

Reissue of PAR-16-238 (https://grants.nih.gov/grants/guide/pa-files/PAR-16-238.html)

Related Notices

- **May 8, 2019** - This PAR has been reissued as PAR-19-274 (https://grants.nih.gov/grants/guide/pa-files/PAR-19-274.html).
- **April 23, 2019** - Notice of Special Interest to Highlight High Priority Research Opportunities on Suicide Prevention Crisis Services. See Notice NOT-MH-19-025 (/grants/guide/notice-files/NOT-MH-19-025.html).
- **April 3, 2019** - Notice of Availability of Administrative Supplements for NIH Grants to Promote Implementation Research for Brain and Nervous System Disorders in Low- and Middle-Income Countries. See Notice NOT-TW-19-003 (/grants/guide/notice-files/NOT-TW-19-003.html).
- **March 29, 2019** - Notice of Intent to Publish: Funding Opportunity Announcement for Dissemination and Implementation Research in Health (R01 Clinical Trial Optional). See Notice NOT-CA-19-038 (/grants/guide/notice-files/NOT-CA-19-038.html).
- **November 26, 2018** - NIH & AHRQ Announce Upcoming Updates to Application Instructions and Review Criteria for Research Grant Applications. See Notice NOT-OD-18-228 (/grants/guide/notice-files/NOT-OD-18-228.html).
- April 9, 2018 (https://grants.nih.gov/grants/guide/notice-files/NOT-HL-18-618.html) - Notice of Update to PAR-18-007. See Notice NOT-HL-18-618 (https://grants.nih.gov/grants/guide/notice-files/NOT-HL-18-618.html).
- May 10, 2017 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-062.html) - New NIH "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018. See NOT-OD-17-062 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-062.html).

Funding Opportunity Announcement (FOA) Number

PAR-18-007

Companion Funding Opportunity

PAR-18-017 (https://grants.nih.gov/grants/guide/pa-files/PAR-18-017.html), R21 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r21&Search.x=0&Search.y=0&Search_Type=Activity) Exploratory/Developmental Grant;

PAR-16-237 (https://grants.nih.gov/grants/guide/pa-files/PAR-16-237.html), R03 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r03&Search.x=0&Search.y=0&sort=ac&Search_Type=Activity&text_prev=) Small Grant Program

Number of Applications

See Section III. 3. Additional Information on Eligibility.

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

93.242, 93.399, 93.213, 93.865, 93.837, 93.172, 93.866, 93.273, 93.855, 93.856, 93.173, 93.121, 93.279, 93.853, 93.307,93.361, 93.113, 93.839, 93.838, 93.233; 93.840

Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) encourages investigators to submit research grant applications that will identify, develop, test, evaluate and/or refine strategies to disseminate and implement evidence-based practices (e.g. behavioral interventions; prevention, early detection, diagnostic, treatment and disease management interventions; quality improvement programs) into public health, clinical practice, and community settings. In addition, studies to advance dissemination and implementation research methods and measures are encouraged.

Key Dates

Posted Date

November 3, 2017

Open Date (Earliest Submission Date)

January 6, 2018

Letter of Intent Due Date(s)

30 days prior to the application due date

Application Due Date(s)

Standard dates (https://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.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

Standard AIDS dates (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.

The first AIDS application due date for this FOA is ~~January 7, 2018~~ May 7, 2018. Must use PAR-16-238 (https://grants.nih.gov/grants/guide/pa-files/PAR-16-238.html) for January 7, 2018 due date. .

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Scientific Merit Review

Standard dates (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward) apply

Advisory Council Review

Standard dates (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward) apply

Earliest Start Date

Standard dates (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply

Expiration Date

May 8, 2019

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts* (https://grants.nih.gov/grants/guide/)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

Table of Contents

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to support innovative approaches to identifying, understanding, and developing strategies for overcoming barriers to the adoption, adaptation, integration, scale-up and sustainability of evidence-based interventions, tools, policies, and guidelines. Conversely, there is a benefit in understanding circumstances that create a need to “de-implement” or reduce the use of strategies and interventions that are not evidence-based, have been prematurely widely adopted, yield sub-optimal benefits for patients, or are harmful or wasteful.

Background

Each year, billions of U.S. tax dollars are spent on research and hundreds of billions are spent on delivery of health services in clinical and community settings. However, relatively little is spent on research to understand how best to ensure that the lessons learned from research are relevant to inform and improve the quality of health, delivery of services and the utilization and sustainability of evidence-based tools and approaches. For years, we have known of the limitations of research publications in leading to widespread uptake of evidence-based practices, but too often the scientific pathway ends prematurely, before we can determine the best ways to improve adoption, implementation and sustainability. In the context of increased interest and investment in intervention trials that will help to determine the optimal interventions to be used in clinical and community healthcare practice, it is essential that health care providers, patients, families, caregivers, communities and healthcare practice settings are equipped with empirically-supported strategies to integrate scientific knowledge and effective health interventions into everyday use. The National Institutes of Health has recognized that closing the gap between biomedical discovery and health and health care delivery is both a complex challenge and an absolute necessity if we are to ensure that all populations benefit from the Nation’s investments in scientific discoveries.

For many years, health researchers may have assumed that tools and interventions deemed efficacious within clinical or community-based trials would be readily adopted and implemented; however, compelling evidence suggests that this has not been the case. Even when added information, tools and interventions have been tested within real-world effectiveness studies, the development of knowledge to support their broader dissemination and implementation (e.g. cost and financing of the intervention, provider training, availability of resources, integration into healthcare systems, delivery to vulnerable or difficult-to-reach populations, monitoring the quality of intervention delivery) has often remained outside the scope of these large-scale clinical trials. This has also been the case for the dissemination and implementation of policies and guidelines, such as from the U.S. Preventive Services Task Force, or the Community Guide to Preventive Services. Study of strategies to most effectively, equitably, and efficiently implement health policies and guidelines is encouraged, as are studies that evaluate policy and other contextual factors that influence the success of implementation or dissemination efforts.

Dissemination and implementation research intends to bridge the gap between clinical research, everyday practice, and public health by building a knowledge base about how health information, interventions, and new clinical practices, guidelines and policies are transmitted and translated for public health and health care service use in specific settings. Unfortunately, there continues to be great variation in how these terms are used.

For the purpose of this FOA, we make a distinction between "dissemination research" and "implementation research", as follows:

Dissemination research is the scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to understand how best to spread and sustain knowledge and the associated evidence-based interventions.

We are currently missing critical information about how, when, by whom, and under what circumstances evidence spreads throughout the agencies, organizations, front line workers and consumers of public health and clinical services. As a necessary prerequisite for unpacking how information can lead to intervention or service changes, we need to understand how and why information on physical and behavioral health, preventive services, disease

management, decision making, and other interventions may or may not reach many different stakeholders. We need to understand what underlies the creation, transmission, and reception of information on evidence-based pharmacological, behavioral, psychosocial, genomic, policy and systems interventions. Successful dissemination of health information may occur quite differently depending on whether the audience consists of consumers, caregivers, practitioners, policymakers, employers, administrators, or other or multiple stakeholder groups. Moving the field forward will require studies identifying mechanisms and approaches to package and convey the evidence necessary to improve public health, community and clinical care services in ways relevant to local settings.

Implementation research is the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health.

Implementation Research seeks to understand the behavior of healthcare professionals and support staff, healthcare organizations, healthcare consumers and family members, and policymakers in context as key influences on the adoption, implementation and sustainability of evidence-based interventions and guidelines such as those from the Community Guide to Preventive Services, U.S. Preventive Services Task Force, and clinical and professional societies. Implementation research studies should not assume that empirically-supported interventions can be integrated into any service setting and for patient groups and populations without attention to local context, nor that a unidirectional flow of information (e.g., publishing a recommendation, trial, or guideline) is sufficient to achieve practice change. Relevant studies should develop a knowledge base about "how" interventions are integrated within real-world practice settings and patient populations, which will likely require more than the distribution of information about the interventions. This research announcement encourages studies to test models, theories and conceptual frameworks of the implementation process that move away from an exclusively "top-down" approach to a greater emphasis on the resources of local care settings and the needs of multiple stakeholders, including approaches such as team science, community based participatory research, action research and related frameworks that engage stakeholders and end users throughout the process.

Dissemination and Implementation (D&I) Research**:** Studies typically involve both interdisciplinary cooperation and trans-disciplinary collaboration, utilizing theories, empirical findings, and methods from a variety of fields not traditionally associated with health research. Relevant fields include but are not limited to: information science, clinical decision-making, organizational and management theory, economics, individual and systems-level behavioral change, public health, business and public administration, statistics, anthropology, learning theory, engineering, and marketing. D&I research will often include significant and ongoing collaboration with stakeholders from multiple public health and/or clinical practice settings as well as consumers of services and their families/social networks. This FOA will support a variety of sound methodological approaches including (but not limited to) observational, experimental, quasi-experimental, and simulation modeling approaches that produce relevant evidence on outcomes, costs, and/or unanticipated consequences. The goal is to conduct dissemination and implementation studies utilizing research designs that are both rigorous and relevant. Wherever possible, studies of dissemination or implementation strategies should build knowledge both on the overall effectiveness of the strategies, as well as "how and why" they work. Data on mechanisms of action, moderators, and mediators of dissemination and implementation strategies will greatly aid decision-making on which strategies work for which interventions, in which settings, and for which populations.

For additional resources on dissemination and implementation research, including information on D&I training opportunities, funded studies, key references, past workshops and conferences, visit:

- http://cancercontrol.cancer.gov/is/ (http://cancercontrol.cancer.gov/is/); and
- http://obssr.od.nih.gov/scientific_areas/translation/index.aspx (http://obssr.od.nih.gov/scientific_areas/translation/index.aspx).

Specific Objectives and Scope of this FOA

This FOA invites research grant applications that will identify, develop, test, evaluate and/or refine strategies to disseminate and implement evidence-based practices (e.g. behavioral interventions; prevention, early detection, diagnostic, treatment and disease management interventions; quality improvement programs) into public health, clinical practice, and community settings. In addition, studies to advance dissemination and implementation research methods and measures are encouraged.

Examples of relevant research directions include but are not limited to:

- Studies of strategies to implement health promotion, prevention, screening, early detection, and diagnostic interventions, as well as effective treatments, clinical procedures or guidelines into existing care systems.
- Studies of the implementation of multiple evidence-based practices within community or clinical settings to meet the needs of complex patients and diverse systems of care.
- Studies of the local adaptation of evidence-based practices in the context of implementation that systematically identify intervention components that surpass or fall short of expected intervention effects.
- Longitudinal and follow-up studies on the factors that contribute to the sustainability of evidence-based interventions in public health and clinical practice.
- Studies testing the effectiveness and cost-effectiveness of dissemination or implementation strategies to reduce health disparities and improve quality of care among rural, minority, low literacy and numeracy, and other underserved populations.
- Studies of the de-implementation of clinical and community practices that are not evidence-based, have been prematurely widely adopted, yield sub-optimal benefits for patients, or are harmful or wasteful.
- Studies of the relationship of context and local capacity of clinical and community settings to adoption, implementation and sustainability of evidence-based practices.
- Prospective or retrospective studies of the adoption, implementation and sustainability of health policies and their interaction with programs and contextual factors.
- Studies of influences on the creation, packaging, transmission and reception of valid health research knowledge.
- Studies of systems interventions to impact organizational structure, climate, culture, and processes to enable dissemination and implementation of clinical/public health information and effective clinical/public health interventions.
- Studies that focus on the development and testing of theoretical and evaluation models for D&I processes.
- Development of D&I relevant outcome and process measures and suitable methodologies for dissemination and implementation approaches.
- Studies of the dissemination of varied strategies to promote effective patient and caregiver communication, leading to improved healthcare delivery and outcomes.
- Studies of the dissemination and implementation of effective and cost-effective strategies for incorporating genomic medicine, sequence-based diagnostics and therapeutics in clinical care.
- Studies testing the implementation and use of genomic information, family history risk information, and/or pharmacogenetic information for improved diagnosis and treatment.

In order to take advantage of existing resources and knowledge in the field, investigators are encouraged to consider the relationship of the following key characteristics of dissemination and implementation (D&I) research to their applications, which may include but are not limited to:

- Use and testing or refinement of conceptual models appropriate for D&I
- Understanding of the complexity of health interventions, including those with multiple components and those for low resource settings and for populations traditionally underrepresented in research, for which D&I may not be a simple process
- Understanding the incentives and/or barriers to the D&I of novel tools and practices to improve public health

- Incorporating the identification of mediators, moderators, and mechanisms of action, where applicable, that explain the impact of dissemination or implementation strategies
- Consideration and characterization of the multi-level context and environment in which the proposed research will be conducted
- Development and/or use of applicable outcomes, measures and analyses related to the models used and the project specific aims. Applicants are encouraged to review available resources where possible and use more harmonized and standard measures, rather than developing their own measures for each study.
- Attention to issues of resources expended, programs costs, cost-effectiveness or other economic outcomes
- Incorporation of stakeholder relevant outcomes of research (including relevant outcomes for patients, families, providers, administrators, policymakers).

Collaborative Research: In addition, given the range of expertise that may be needed for conducting dissemination and implementation research, applicants are encouraged to form trans-disciplinary teams of scientists and practice stakeholders to work together to develop and/or test conceptual models of dissemination and implementation that may be applicable across diverse community and practice settings and patient populations, and design studies that will accurately and transparently assess the outcomes of dissemination and implementation efforts.

Information Relevant to Specific Institutes/Centers

In addition to the above description of the scientific objectives, resources communicating scientific interests of selected Institutes and Centers (I/Cs) are summarized below. Applicants are encouraged to contact the Scientific/Research contact of the intended I/C to ensure that the aims of the proposed project are consistent with I/C mission.

National Heart, Lung, and Blood Institute (NHLBI (http://www.nhlbi.nih.gov)**)**

Applicants interested in apply to NHLBI through this announcement should review information on D&I research in heart, lung and blood diseases and sleep disorders available at:

- http://www.nhlbi.nih.gov/resources/docs/index.htm#blood (http://www.nhlbi.nih.gov/resources/docs/index.htm#blood);and
- http://www.nhlbi.nih.gov/about/org/ctris/ (http://www.nhlbi.nih.gov/about/org/ctris/); and the reports on sickle cell disease,
- http://www.nhlbi.nih.gov/meetings/scdmtg/execsum.htm (http://www.nhlbi.nih.gov/meetings/scdmtg/execsum.htm) ; and
- http://www.nhlbi.nih.gov/meetings/workshops/conscd.htm (http://www.nhlbi.nih.gov/meetings/workshops/conscd.htm) may be useful.

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

The National Institute of Mental Health (NIMH) is interested in applications relevant to dissemination and implementation (D&I) research that support the NIMH Strategic Plan for Research. All applications that propose clinical trials to test D&I strategies are encouraged to follow the NIMH's experimental therapeutics approach to intervention development and testing (see NIMH Clinical Trials FOAs).

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

NIDCR will support D&I research related to oral health when the efficacy and effectiveness of an intervention, product, or approach has already been established. Applicants planning a clinical trial to test the effect of an intervention on a health outcome should refer to the following NIDCR website: http://www.nidcr.nih.gov/research/DER/ClinicalResearch/ClinTrials.htm

(http://www.nidcr.nih.gov/research/DER/ClinicalResearch/ClinTrials.htm) In addition, it is recommended that investigators contact NIDCR Scientific/Research staff well in advance of submitting applications.

National Center for Complementary and Integrative Health (NCCIH (http://www.nccam.nih.gov)**)**

For specific information about NCCIH priorities for dissemination and implementation research refer to the NCCIH website: http://nccih.nih.gov/grants/disseminationPAR (http://nccih.nih.gov/grants/disseminationPAR).

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (http://www.nichd.nih.gov)**)**

For specific information about NICHD priorities for dissemination and implementation research refer to the NICHD website: http://www.nichd.nih.gov/about/org/der/branches/mpidb/Pages/diss-imp-FOAs.aspx (http://www.nichd.nih.gov/about/org/der/branches/mpidb/Pages/diss-imp-FOAs.aspx).

National Institute of Nursing Research (NINR (http://www.nimh.nih.gov)**)**

The National Institute of Nursing Research (NINR) is interested in applications relevant to dissemination and implementation (D&I) research that support the NINR Strategic Plan for Research. NINR's strategic priorities emphasize patient outcomes related to underlying symptoms, self-management of symptoms and disease conditions, general wellness and prevention, and end-of-life and palliative care. Please refer to the NINR website for more details on the NINR Strategic Plan: http://www.ninr.nih.gov/aboutninr/ninr-mission-and-strategic-plan#.Vl4XFGfluUk (http://www.ninr.nih.gov/aboutninr/ninr-mission-and-strategic-plan#.Vl4XFGfluUk).

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 (https://grants.nih.gov/grants/guide/url_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 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) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- 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
- Non-domestic (non-U.S.) Entities (Foreign Institutions)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.
Foreign components, as defined in the *NIH Grants Policy Statement* (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** 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) 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) - 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/) (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 (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 (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 (http://www.grants.gov/web/grants/applicants/organization-registration.html) – 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.* (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 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must obtain the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at Grants.gov (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11127).

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), including Supplemental Grant Application Instructions (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82216) 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 (https://grants.nih.gov/grants/guide/url_redirect.htm?id=41137).

Letter of Intent

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

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

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

The letter of intent should be sent to:

David Chambers, D.Phil.
National Cancer Institute (NCI)
Telephone: 240-276-5090
Email: dchamber@mail.nih.gov (mailto:dchamber@mail.nih.gov)

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (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, with the following modification:

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

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

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

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

Study Record: PHS Human Subjects and Clinical Trials Information: All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study: All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

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

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the *NIH Grants Policy Statement* (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11137), and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

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 (http://www.opm.gov/Operating_Status_Schedules/fedhol/2010.asp), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (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 (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)

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).

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).

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). 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). 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) 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 our Post Submission Application Materials (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/submission-policies.htm#psam) policy.

Section V. Application Review Information

NEW **Important Update:** See NOT-OD-18-228 (/grants/guide/notice-files/NOT-OD-18-228.html) for updated review language for due dates on or after January 25, 2019.

1. Criteria

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

Overall Impact

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).

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.

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 there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Specific to this FOA:

- What is the estimated public health benefit of the research?
- Do the existing data, public health and patient needs justify dissemination and implementation?

- If the aims of the proposed project are achieved, how will dissemination and implementation knowledge be advanced?
- Will potential adopters and organizations be able to determine the applicability of the results to their setting?

In addition, for applications proposing 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 the 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?

Specific to this FOA:

- Are the investigators part of stakeholder teams or have strong links and engagement of stakeholders necessary to accomplish the project aims?
- Is there clear evidence of dissemination and implementation research expertise as part of the team?

In addition, for applications proposing 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?

Specific to this FOA:

- Does the proposed dissemination or implementation research contribute new and innovative design approaches to the study of dissemination or implementation processes and/or outcomes?
- Do the methods proposed promise to speed the translation of research into practice and/or produce novel and robust findings?

In addition, for applications proposing 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 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 FOA:

- Does the applicant demonstrate an understanding of dissemination and implementation research principles?
- Is the dissemination or implementation approach appropriate to the problem and population using research methods that are relevant, rigorous and practical?
- Are the measures and analysis plan linked to the dissemination or implementation plan and study aims?
- How appropriate are the plans to sustain effective dissemination and implementation approaches once the research-funding period has ended?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed? If clinical, community or public health settings are involved, are stakeholders sufficiently engaged in the process, including project design?

In addition, for applications proposing 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?

Specific to this FOA:

- Are the investigators capable of taking the results of the proposed study to scale to achieve public health impact?
- Is there evidence of institutional support to sustain dissemination or implementation interventions once the research funding ends?

In addition, for applications proposing 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 proposing 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 six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (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 children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (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 (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

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

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); (2) Sharing Model Organisms (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).

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), 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 (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

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

Section VI. Award Administration Information

1. Award Notices

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

Additionally, ICs may specify any special reporting requirements for the proposed clinical trial to be included under IC-specific terms and conditions in the NoA. For example: If the proposed clinical trial has elevated risks, ICs may require closer programmatic monitoring and it may be necessary to require the awardee to provide more frequent information and data as a term of the award (e.g., to clarify issues, address and evaluate concerns, provide documentation). All additional communications and information related to programmatic monitoring must be documented and incorporated into the official project file. 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.nig.gov/ClinicalTrials_fdaaa/ (https://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 (https://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* (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 (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 (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (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 law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.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 https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html (https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/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 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. 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) (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/url_redirect.htm?id=11161)

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the *NIH Grants Policy Statement* (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the *NIH Grants Policy Statement* (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

Section VII. Agency Contacts

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

Application Submission Contacts

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

Grants.gov Customer Support (http://www.grants.gov/web/grants/support.html) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact CenterTelephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
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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) 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). 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).

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 (/grants/guide/WeeklyIndex.cfm?11-03-17)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

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