Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of Mental Health (NIMH) National Cancer Institute (NCI) National Center for Complementary and Integrative Health (NCCIH formerly NCCAM) National Heart, Lung, and Blood Institute (NHLBI) National Human Genome Research Institute (NHGRI) National Institute on Aging (NIA) National Institute on Alcohol Abuse and Alcoholism (NIAAA) National Institute of Allergy and Infectious Diseases (NIAID) (Clarification per NOT-AI-13-034) National Institute on Deafness and Other Communication Disorders (NIDCD) National Institute of Dental and Craniofacial Research (NIDCR) National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) National Institute on Drug Abuse (NIDA) National Institute of Neurological Disorders and Stroke (NINDS) National Institute on Minority Health and Health Disparities (NIMHD) National Institute of Nursing Research (NINR) Office of Behavioral and Social Sciences Research (OBSSR)
Funding Opportunity Title	**Dissemination and Implementation Research in Health (R01)**
Activity Code	R01 Research Project Grant
Announcement Type	Reissue of PAR-10-038
Related Notices	• May 8, 2015 - Notice of Participation of NIMHD in PAR-13-055. See Notice NOT-MD-15-007. • July 17, 2014 - See Notice NOT-HD-14-017. Notice of

	NICHDs Participation in PAR-13-055 "Dissemination and Implementation Research in Health (R01)" • June 3, 2014 - Notice NOT-14-074 supersedes instructions in Section III.3 regarding applications that are essentially the same. • December 5, 2013 - See Notice NOT-TW-14-005. Interest in Type 2 Diabetes Research Topics in PAR-13-055 "Dissemination and Implementation Research in Health (R01)" to support the Global Alliance for Chronic Diseases (GACD) Initiative. • May 30, 2013 (NOT-OD-13-074) - NIH to Require Use of Updated Electronic Application Forms for Due Dates on or after September 25, 2013. Forms-C applications are required for due dates on or after September 25, 2013. • March 15, 2013 - See Notice NOT-AI-13-034. Notice of Clarification of NIAID's Participation.
Funding Opportunity Announcement (FOA) Number	**PAR-13-055**
Companion Funding Opportunity	PAR-13-056, R03 Small Grant Program PAR-13-054, R21 Exploratory/Developmental Grant
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, 93.847, 93.279, 93.853, 93.307,93.361
Funding Opportunity Purpose	This Funding Opportunity Announcement (FOA) encourages investigators to submit research grant applications that will identify, develop, evaluate and refine effective and efficient methods, systems, infrastructures, and

	strategies to disseminate and implement research-tested health behavior change interventions, evidence-based prevention, early detection, diagnostic, treatment and management, and quality of life improvement services, and data monitoring and surveillance reporting tools into public health and clinical practice settings that focus on patient outcomes.

Key Dates

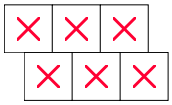
Posted Date	January 9, 2013
Open Date (Earliest Submission Date)	January 9, 2013
Letter of Intent Due Date(s)	30 days prior to the application due date
Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization.
AIDS Application Due Date(s)	Standard AIDS dates apply, by 5:00 PM local time of applicant organization.
Scientific Merit Review	Standard dates apply
Advisory Council Review	Standard dates apply
Earliest Start Date	Standard dates apply
Expiration Date	January 8, 2016

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, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). 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 to submit your application to the agency through Grants.gov. You can use the ASSIST system to prepare, submit and track your application online. You can download an application package from Grants.gov, complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons. Or, you can use other institutional system-to-system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons. Learn more.



Problems accessing or using ASSIST should be directed to the eRA Commons Help Desk.
Problems downloading forms should be directed to Grants.gov Customer Support.

Table of Contents

Part 1. Overview Information
Part 2. Full Text of the 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

Research Objectives

Each year, billions of U.S. tax dollars are spent on research and hundreds of billions are spent on service delivery and community health programs. However, relatively little is spent on, or known about, how best to ensure that the lessons learned from research are relevant to, and, inform and improve the quality of health, delivery of services and the utilization and sustainability of evidence-based tools and approaches. In the context of increased interest and investment in comparative effectiveness research 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 settings are equipped with empirically-supported strategies to integrate scientific knowledge and effective interventions into everyday use. The National Institutes of Health has recognized that closing the gap between research discovery and clinical and community practice 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.

The National Institute of Mental Health (NIMH), National Cancer Institute (NCI), National Center for Complementary and Alternative Medicine (NCCAM), National Heart, Lung, and Blood Institute (NHLBI), National Human Genome Research Institute (NHGRI), National Institute on Aging (NIA), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute of Allergy and Infectious Diseases (NIAID), National Institute on Drug Abuse (NIDA), National Institute on Deafness and Other Communication Disorders (NIDCD), National Institute of Dental and Craniofacial Research (NIDCR), National Institute of Nursing Research (NINR), and the Office of Behavioral and Social Science Research (OBSSR), invite research grant applications for research that will identify, develop, and refine effective and efficient methods, systems, infrastructures, and strategies to disseminate and implement evidence-based health behavior change interventions, prevention, early detection, diagnostic, treatment, symptom management, and quality of life improvement interventions, clinical guidelines, policies, and data monitoring and surveillance reporting tools into public health and clinical practice settings.

The purpose of this dissemination and implementation research funding opportunity announcement (FOA) is to support innovative approaches to identifying, understanding, and overcoming barriers to the adoption, adaptation, integration, scale-up and sustainability of evidence-based interventions, tools, policies, and guidelines. Conversely, there may be a benefit in understanding circumstances that create a need to "de-implement" or reduce the use of

strategies and procedures that are not evidence-based, have been prematurely widely adopted, or are harmful or wasteful.

Many researchers who propose to develop and test informational materials, diagnostic tools, and/or prevention or disease control interventions either explicitly or implicitly intend to promote evidence-based interventions to the broader population from which the study sample was drawn or the public health or clinical practice settings in which the intervention was originally tested. Thus, for many years, health researchers may have assumed that tools and interventions deemed efficacious within clinical or community-based trials would be readily transmitted to the field; 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, monitoring the quality of intervention delivery) has often remained outside the scope of these large-scale clinical trials.

This FOA also encourages research on 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.

In the past few years, both empirically-supported models (e.g., CFIR, RE-AIM, PRECEDE/PROCEED, ISF, KTA) and authoritative research syntheses have been developed to guide dissemination and implementation of evidence-based interventions both in the U.S. and abroad, but there is still limited understanding of the generalizability of these approaches to the variety of evidence-based interventions and settings that can benefit health.

Recent literature has underscored the importance of understanding the many factors that affect whether the public health or clinical practice communities will adopt, successfully implement and/or sustain a given intervention. Research on dissemination will address how information about health promotion, treatment, preventive and services interventions is packaged, transmitted, and interpreted among a variety of important stakeholder groups. Research on implementation will improve the knowledge base to guide efforts to fit health interventions within real-world public health, clinical and community service systems.

The goals of this FOA are to encourage 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.

Key characteristics of high-priority dissemination and implementation (D&I) research applications may include but are not limited to:

- Use and testing or refinement of intervention and evaluation 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
- 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
- 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).

This FOA addresses priorities laid out in a number of reports including:

NIMH Strategic Plan

NHGRI Strategic Plan

NINR Strategic Plan

National Institute on Drug Abuse Blue Ribbon Task Force Report on Services Research

NIDCR Strategic Plan

NIDCD Strategic Plan

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/ and http://obssr.od.nih.gov/scientific_areas/translation/index.aspx.

Additional information on D&I research in blood diseases is available at:

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

For D&I research in oral health, note that the NIDCR does not accept applications that include clinical trials in response to trans-NIH FOAs. Applicants proposing a clinical trial should refer to the following NIDCR websites: http://www.nidcr.nih.gov/clinicaltrials/ and http://grants.nih.gov/grants/guide/pa-files/PAR-11-338.html.

For specific information about NCCAM priorities for dissemination and implementation research refer to the NCCAM website: http://nccam.nih.gov/grants/disseminationPAR.

In addition, NIH welcomes applications from grantees with Clinical Translational Science Awards (CTSA), VA and other research and practice networks looking to conduct dissemination and implementation research studies. International investigators are also eligible to be primary or co-investigators on D&I applications.

Research Terms

Dissemination and implementation research intends to bridge the gap between public health, clinical research, and everyday practice by building a knowledge base about how health information, interventions, and new clinical practices 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. Dissemination and implementation have both been used to represent the complete process of bringing "evidence" into practice. While using these and other terms to cover such a wide area can be helpful in facilitating discussion, it does not allow for the division of this very complex process into smaller, more easily addressed research questions that can develop a robust knowledge base. We encourage applications that will continue to address the complexity of bridging research, policy and practice using both established and innovative approaches to theory, measurement, research design, and analyses.

For the purpose of this FOA, we make a distinction between "dissemination" and "implementation."

Dissemination is the targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to spread (“scale up”) and sustain knowledge and the associated evidence-based interventions.

Implementation is the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific settings.

This distinction needs to be made because interventions developed in the context of efficacy and effectiveness trials are rarely transferable without adaptations to specific settings and additional tools and guidance to support uptake and implementation. Therefore, research is needed to examine the process of transferring interventions into local settings, settings that may be similar to but also somewhat different from the ones in which the intervention was developed and tested.

Dissemination Research

We are currently missing critical information about how, when, by whom, and under what circumstances research evidence spreads throughout the agencies, organizations, and front line workers providing 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 (including information about underutilized interventions) 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-based information necessary to improve public health and clinical care services in ways relevant to local settings and that balance fidelity and adaptation.

Implementation Research

Implementation Research is the scientific study of methods to promote the integration of research findings and evidence-based interventions into healthcare practice and policy. It seeks to understand the behavior of healthcare professionals and support staff, healthcare organizations, healthcare consumers and family members, and policymakers in context as key variables in the adoption, implementation and sustainability of evidence-based interventions and guidelines such as those from the Institute of Medicine, 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 transferred into any service setting 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 transported to real-world practice settings, which will likely require more than the distribution of information about the interventions. This research announcement encourages theory-driven studies to test 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 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 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 that address the above issues including observational, experimental and simulation modeling approaches capable of producing relevant evidence on outcomes, costs, and/or unanticipated consequences. The goal is to conduct studies utilizing designs that are both rigorous and relevant.

Research Topics

Listed below are examples of topics supported by this program announcement for D&I research. The list is illustrative, not exhaustive. Additionally, it is expected that investigators responding to this FOA will identify other important research areas.

- Studies of efforts to scaffold multiple evidence-based practices within care settings, to meet the needs of complex patients, systems of care, and service integration.
- Longitudinal and follow-up studies on the factors that contribute to the sustainability of research-based improvements 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 using simulation modeling, evaluability assessments, and other estimation approaches to evaluate proposed D&I actions, policies and practices.
- Studies that address context in descriptive and innovative ways and investigate the relationship of context to adoption, implementation and maintenance.

- Comparative effectiveness research that addresses D&I issues and approaches, and that evaluate the cost, resource requirements and other economic and policy outcomes.
- Studies of the adoption, implementation and sustainability of health policies and their interaction with programs and contextual factors.
- Studies of complex health problems, co-morbid patients and complex interventions using innovative methods, models and analyses that fit these needs.
- Analysis of factors influencing the creation, packaging, transmission and reception of valid health research knowledge, ranging from psychological and socio-cultural factors affecting individual practitioners, consumers, primary caregivers and other stakeholder groups to investigations addressing large service delivery systems and funding sources.
- Studies on the fidelity/adaptation of implementation efforts, including the identification of components of implementation that will enable fidelity to be assessed meaningfully
- 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 of efforts to implement health promotion, prevention, early detection, and diagnostic interventions, as well as effective treatments, clinical procedures or guidelines into existing care systems across the lifespan to measure the extent to which such procedures are utilized, adhered to and sustained, by patients, providers and consumers.
- Studies of the capacity of specific care delivery settings (primary care, schools, worksites, community health settings, health departments, etc.) to incorporate dissemination or implementation efforts within current organizational forms.
- Studies that focus on the development and testing of theoretical and evaluation models for D&I processes, or use such models to conduct reviews of the D&I literature.
- Development of D&I relevant outcome and process measures and suitable methodologies for dissemination and implementation approaches that accurately assess the success of an approach to move evidence into practice (i.e., not just clinical outcomes). 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.
- Studies testing D&I strategies of symptom management interventions that reduce the symptom burden in patients with chronic conditions, including multiple chronic conditions.
- Studies of the dissemination of palliative care and end of life research into practice that enhances quality of life for patients and families.
- Studies of the dissemination of different strategies to promote effective patient and caregiver communication, leading to improved healthcare delivery and outcomes.
- Studies of how approaches to shared decision-making may be implemented and sustained among practitioners.

- Studies of how successful screening promotion approaches and policies are implemented in healthcare and community practice, and especially in international or low-resource settings.
- Studies of the adoption, implementation and sustainability of data and surveillance reporting tools and techniques.
- 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 incorporation and use of genomic information, family history risk information, and/or pharmacogenetic information for improved diagnosis and treatment.

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 and the SF424 (R&R) Application Guide provide details on these application types.
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 actual needs of the proposed project.
Award Project Period	The total project period for an application submitted in response to this funding opportunity may not exceed 5 years.

NIH grants policies as described in the *NIH Grants Policy Statement* 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*, **are** allowed.

Required Registrations

Applicant organizations must complete the following registrations as described in the SF424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- System for Award Management (SAM)– must maintain an active entity registration (formerly CCR registration), to be renewed at least annually. Use the Sam.gov "Manage Entity" function to manage your entity registrations. See the Grants Registration User Guide at SAM.gov for additional information.
- Grants.gov
- eRA Commons

All Program Directors/Principal Investigators (PD(s)/PI(s)) must also work with their institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

All registrations must be completed by the application due date. Applicant organizations are strongly encouraged to start the registration process at least 6 weeks prior to the application due date.

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.*

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

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

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

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must download 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.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, 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.

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 research
- 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
National Cancer Institute (NCI)
Telephone: 240-276-5090
Email: dchamber@mail.nih.gov

Required and Optional Components

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are

required for submission of applications for this FOA. Follow all instructions in the SF424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed.

PHS 398 Research Plan Component

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 (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modifications:

- 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.

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the *NIH Grants Policy Statement*, and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit applications before the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via Grants.gov, 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, NIH's electronic system for grants administration.

Applicants are responsible for viewing their application before the deadline 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.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

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

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

6. 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.

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

(R&R) Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH. Applications that are incomplete 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 NIH program staff 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 NOT-OD-10-115.

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, 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:

HIV/AIDS related applications will be assigned to a relevant Center for Scientific Review HIV-related review committee.

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? 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? 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? How broad a reach (to the population that will benefit from the knowledge/intervention) will be achieved and how equitable will reach and outcomes likely be through the knowledge/service delivery contexts selected? Has consideration been given to the resource requirements and costs of the intervention? Will potential adopters and organizations be able to determine the applicability of the results to their setting?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Are the investigators part of stakeholder teams or have strong encouragement of stakeholders necessary to accomplish the project aims? Is there clear evidence of dissemination and implementation research expertise as part of the team?

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? 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?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? 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? Does the applicant demonstrate an understanding of dissemination and implementation research principles? Has the applicant justified the research design on the basis of the current state-of-the-art and or contextual factors relevant to dissemination and/or implementation? Is the dissemination or implementation approach appropriate to the problem and population using research methods that are relevant, rigorous and practical? Are the procedures to assess and analyze the dissemination or implementation strategies appropriate? Are the measurements and analysis plan linked to the dissemination or implementation plan and study aims, and does the analysis incorporate the best available data to track dissemination or implementation process and impact, including cost-effectiveness? Where applicable, does the proposed plan for analysis take into account hierarchical relationships among multiple levels of outcomes (e.g. patient, provider, system)? How appropriate are the plans to sustain effective dissemination and implementation approaches once the research-funding period has ended?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion 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?

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? Are the applicants positioned within or to influence large or influential networks capable of taking the results of the proposed study to scale to achieve public health impact? Do the proposed

approaches take advantage of unique features of the intervention delivery environment or employ useful, collaborative arrangements? Is there evidence of institutional support to sustain dissemination or implementation interventions once the research funding ends?

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.

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 Human Subjects Protection and Inclusion Guidelines.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the Human Subjects Protection and Inclusion Guidelines.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is

unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards

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

Resubmissions

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; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).

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), in accordance with NIH peer review policy and procedures, 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.

Information regarding the disposition of applications is available in the *NIH Grants Policy Statement*.

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*.

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

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* 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 and Part II: Terms and Conditions of NIH

Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities. More information is provided at Award Conditions and Information for NIH Grants.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the annual Non-Competing Progress Report (PHS 2590 or RPPR) and financial statements as required in the *NIH Grants Policy Statement*.

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*.

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 http://grants.nih.gov/grants/guide/url_redirect.htm?id=11170 on all subawards over $25,000. See the *NIH Grants Policy Statement* 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

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Telephone 301-435-0714

TTY 301-451-5936
Email: GrantsInfo@nih.gov

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov

Scientific/Research Contact(s)

Jennifer Alvidrez, PhD
National Institute on Minority Health and Health Disparities (NIMHD)
Telephone: 301-594-9567
Email: alvidrezjl@mail.nih.gov

Joan Wasserman, DrPH
National Institute on Minority Health and Health Disparities (NIMHD)
Telephone: 301-594-1788
Email: joan.wasserman@nih.gov

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

Denise Pintello, Ph.D.
National Institute of Mental Health (NIMH)
Telephone: 301-451-1481
Email: Denise.Pintello@nih.gov

Chris Gordon, Ph.D. (for AIDS-related NIMH applications)
National Institute of Mental Health (NIMH)
Telephone: 301-443-1613
Email: cgordon1@mail.nih.gov

Cynthia Vinson, M.A.
National Cancer Institute (NCI)

Telephone: 240-276-6745

Email: cvinson@mail.nih.gov

Gila Neta, Ph.D.

National Cancer Institute (NCI)

Telephone: 240-276-6785

Email: mailto:glasgowre@mail.nih.gov

Catherine Stoney, M.D.

National Heart, Lung, and Blood Institute (NHLBI)

Telephone: 301-435-6670

Email: stoneyc@nhlbi.nih.gov

Ebony Bookman, Ph.D.

National Human Genome Research Institute (NHGRI)

Telephone: 919-541-0367

Email: ebony.bookman@nih.gov

John Haaga, Ph.D.

National Institute on Aging (NIA)

Telephone: 301-496-3131

Email: HaagaJ@mail.nih.gov

Cherry Lowman, Ph.D.

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Telephone: 301-443-0637

Email: clowman@mail.nih.gov

Melanie Bacon, R.N.

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 301-451-2747

Email: mbacon@mail.nih.gov

Amy Donahue, Ph.D.

National Institute on Deafness and Other Communication Disorders (NIDCD)

Telephone: 301-402-3458

Email: donahuea@nidcd.nih.gov

Ruth Nowjack-Kramer, M.P.H., Ph.D.
National Institute of Dental and Craniofacial Research (NIDCR)
Telephone: 301-594-5394
Email: Ruth.Nowjack-Raymer@nih.gov

Christine M. Hunter, Ph.D.
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Telephone: 301-594-4728
Email: ch514c@nih.gov

Lori J. Ducharme, Ph.D.
National Institute on Drug Abuse (NIDA)
Telephone: 301-443-2279
Email: ducharmel@nida.nih.gov

Deborah Hirtz, M.D.
National Institute of Neurological Disorders and Stroke (NINDS)
Telephone: 301-496-5821
Email: hirtzd@ninds.nih.gov

Donna Jo McCloskey, Ph.D.
National Institute of Nursing Research (NINR)
Telephone: 301-594-5971
Email: mccloskd@mail.nih.gov

Kristen Huntley, Ph.D.
National Center for Complementary and Integrative Health (NCCIH formerly NCCAM)
Telephone: 301-594-9346
Email: huntleyk@mail.nih.gov

Deborah Young-Hyman, Ph.D.
Office of Behavioral and Social Sciences Research (OBSSR)
Telephone: 301-451-0724
Email: younghyd@mail.nih.gov

Peer Review Contact(s)

Jacinta Bronte-Tinkew, Ph.D.
Center for Scientific Review (CSR)

Telephone: 301-806-0009

Email: jacinta.bronte-tinkew@nih.gov

Financial/Grants Management Contact(s)

Priscilla Grant, JD

National Institute on Minority Health and Health Disparities (NIMHD)

Telephone: 301-594-8412

Email: pg38@nih.gov

Rebecca Claycamp

National Institute of Mental Health (NIMH)

Telephone: 301-443-2811

Email: rclaycam@mail.nih.gov

Crystal Wolfrey

National Cancer Institute (NCI)

Telephone: 301-496-8634

Email: wolfreyc@mail.nih.gov

Teresa Farris Marquette

National Heart, Lung, and Blood Institute (NHLBI)

Telephone: 301-435-0172

Email: tm275a@nih.gov

Cheryl Chick

National Human Genome Research Institute (NHGRI)

Telephone: 301-435-7858

Email: chickc@mail.nih.gov

Linda Whipp

National Institute on Aging (NIA)

Telephone: 301-402-7731

Email: whippl@nia.nih.gov

Judy S. Fox

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Telephone: 301-443-4704

Email: jfox@mail.nih.gov

Ann Devine

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 301-402-5601

Email: adevine@niaid.nih.gov

Christopher Myers

National Institute on Deafness and Other Communication Disorders (NIDCD)

Telephone: 301-435-0713

Email: Myersc@mail.nih.gov

Dede Rutberg, MBA

National Institute of Dental and Craniofacial Research (NIDCR)

Telephone: 301-594-4798

Email: rutbergd@mail.nih.gov

Elizabeth Gutierrez

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Telephone: 301-594-8844

Email: gutierrezel@niddk.nih.gov

Pamela Fleming

National Institute on Drug Abuse (NIDA)

Telephone: 301-435-1369

Email: pfleming@nida.nih.gov

Lawrence Haller

National Institute of Nursing Research (NINR)

Telephone: 301-402-1878

Email: hallerl@nih.mail.gov

Shelley Carow

National Center for Complementary and Alternative Medicine (NCCAM)

Telephone: 301-594-3788

Email: CarowS@MAIL.NIH.GOV

Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts*. All awards are

subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement*.

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 Parts 74 and 92.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Department of Health and Human Services (HHS)

NIH... Turning Discovery Into Health®
