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

Funding Opportunity Title

Applied Research Toward Zero Suicide Healthcare Systems (R01)

Activity Code

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

Announcement Type

New

Related Notices

- NOT-OD-16-004 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-004.html) - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015)

Funding Opportunity Announcement (FOA) Number

RFA-MH-16-800

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-16-800.html#_3._Additional_Information).

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

93.242

Funding Opportunity Purpose

This funding opportunity announcement (FOA) is intended to support applied research that advances the National Action Alliance for Suicide Prevention's "Zero Suicide (http://zerosuicide.sprc.org/)" goal of preventing suicide events (attempts, deaths) among individuals receiving treatment within health care systems. Zero Suicide is a commitment to the prevention of suicide among individuals served by health care systems and is also a specific set of health care strategies and tools intended to eliminate suicide events. Research is needed to implement effective and comprehensive suicide prevention strategies in a variety of settings, including behavioral health and substance abuse outpatient clinics, emergency departments and crisis care programs and centers, hospitals, and integrated primary care programs. To achieve the aspirational goal of zero suicide events within healthcare settings, research is needed to improve health care approaches for the following: systematic approaches to suicide risk detection (acute or long term); appropriate risk documentation and follow-up care that is practical and effective; interventions earlier in the course of suicide risk trajectories that reduce incident suicide events in care systems; identification of effective service delivery components that work as safety nets to prevent suicidal events; and identification of service delivery policies and practices that support and maintain "Zero Suicide" goals and reduce suicide events.

Key Dates

Posted Date

December 11, 2015

Open Date (Earliest Submission Date)

February 4 , 2016

Letter of Intent Due Date(s)

February 4, 2016

Application Due Date(s)

March 4, 2016 and November 2, 2016, by 5:00 PM local time of applicant organization. All types of non-AIDS applications (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-16-800.html#Application Types Allowed) 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)

Not Applicable

Scientific Merit Review

May 2016; February 2017

Advisory Council Review

August 2016; May 2017

Earliest Start Date

September 2016; July 2017

Expiration Date

November 3, 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 (http://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* (http://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 (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-16-800.html#_Section_IV._Application_1). 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 (http://grants.nih.gov/grants/ElectronicReceipt/preparing.htm#2).

Apply Online Using ASSIST **Apply Using Downloadable Forms**

Problems accessing or using ASSIST should be directed to the eRA Service Desk (http://grants.nih.gov/grants/ElectronicReceipt/support.htm#desk).
Problems downloading forms should be directed to Grants.gov Customer Support (http://www.grants.gov/contactus/contactus.jsp).

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

This funding opportunity announcement (FOA) is intended to support applied research that advances the National Action Alliance for Suicide Prevention's "Zero Suicide (http://zerosuicide.sprc.org/)" goal of preventing suicide events (attempts, deaths) among individuals receiving treatment within health care systems. Zero Suicide is a commitment to the prevention of suicide among individuals served by health care systems and is also a specific set of health care strategies and tools intended to eliminate suicide events. Research is needed to implement effective and comprehensive suicide prevention strategies in a variety of settings, including behavioral health and substance abuse outpatient clinics, emergency departments and crisis care programs and centers, hospitals, and integrated primary care programs. To achieve the aspirational goal of zero suicide events within healthcare settings, research is needed to improve health care approaches for the following: systematic approaches to suicide risk detection (acute or long term); appropriate risk documentation and follow-up care that is practical and effective; interventions earlier in the course of suicide risk trajectories that reduce incident suicide events in care systems; identification of effective service delivery components that work as safety nets to prevent suicidal events; and identification of service delivery policies and practices that support and maintain "Zero Suicide" goals and reduce suicide events.

Research Objectives

A central approach of the National Action Alliance for Suicide Prevention's Research Prioritization Task Force (http://actionallianceforsuicideprevention.org/task-force/research-prioritization), was to estimate the number of suicidal individuals who had been seen in boundaried systems (e.g., health care, education, workplaces, incarceration, etc.), who could have been reached by improved detection and intervention, and how many suicide attempts (fatal and nonfatal) could have been prevented. A significant proportion of U.S. suicide decedents (more than 40,000 annually (http://www.cdc.gov/injury/wisqars/leadingcauses.html)) have accessed health care within the year of their death, with estimates ranging from 30% to 80%, mirroring the broader population access to health care. Approximately one-quarter of suicide decedents had treatment for psychiatric issues prior to their death. This FOA supports applied research to advance the "Zero Suicide (http://zerosuicide.sprc.org/)" goal of preventing suicide attempts and deaths among individuals under care within health systems. Zero Suicide is a commitment to prevention of suicide in health care systems and is also a specific set of health care strategies and tools intended to eliminate suicide events. It aims to reduce suicide events within facilities, as well as individuals in the community who are linked to the care system. This FOA is consistent with NIMH Strategic Research Objective 4.2, (http://www.nimh.nih.gov/about/strategic-planning-reports/strategic-objective-4.shtml) which calls for practice-based research partnerships in health care systems, and addresses the 'practice-to-science' needs identified by the National Action Alliance for Suicide Prevention (http://actionallianceforsuicideprevention.org/). This FOA also speaks to objectives in the Prioritized Research Agenda for Suicide Prevention (http://actionallianceforsuicideprevention.org/sites/actionallianceforsuicideprevention.org/files/Agenda.pdf) that focus on increasing the effectiveness of suicide risk detection and screening, and interventions and services that reduce suicide risk.

Burden of Suicidal Behavior in Health Systems. Since 1995 the Joint Commission has consistently listed suicide among the top 5 sentinel events, i.e., unexpected occurrences involving death or serious physical or psychological injury, in health care settings. Of the 1.3 million individuals in the US who reported making a suicide attempt within the past 12 months, about 6% also reported receiving treatment in an outpatient mental health clinic

(estimated 206,000 cases). Rates of individuals reporting attempts within the year have also been estimated for those receiving care in other settings that include: those receiving substance use treatment (5%, estimated 122,000 cases); and those having accessed emergency care in the same year (1%, estimated 728,000 cases). Despite the large number of suicide events among persons receiving healthcare, only 28 states require health care systems to report adverse events that include suicide deaths and attempts, that occur during or following receipt of services. Lack of information about the rate and nature of suicide events within and between care systems hinders efforts to eliminate these adverse events through quality improvement initiatives.

A Learning Healthcare System to Reduce Suicidal Behavior. A healthcare system that links suicidal behavior outcomes to care processes and service use patterns, considers what care improvements can be tested to reduce suicidal behaviors, and measures the impact of care improvements, is illustrative of a learning health care system. Several systems-level improvements have been associated with lower suicide risk in health care organizations like the Henry Ford Health System, the Veterans Health Administration (http://www.va.gov/health/aboutvha.asp), and mental health services in England and Wales. These include (1) providing 24-hour crisis teams; (2) managing patients with co-occurring disorders (e.g., mental and substance use disorders); (3) conducting multidisciplinary reviews of suicide deaths; (4) sharing information with families after a suicide and making future care improvements as a result; (5) removing ligature points from inpatient settings; (6) conducting follow-up with patients within a week of discharge; (7) conducting assertive community outreach; (8) providing regular training to frontline clinicians on the management of suicide risk; (9) responding to patients who do not comply with treatment; (10) sharing information with criminal justice agencies; and (11) reducing access to lethal means, such as firearms. The largest systems-level study found that suicide deaths decreased most in care settings that implemented the greatest number of improvements. This FOA encourages multidisciplinary collaborations between researchers and healthcare organizations that result in empirical evaluations of systems-level suicide reduction approaches such as those described in the Zero Suicide (http://zerosuicide.sprc.org/get-involved) toolkit.

In the US, a number of subgroups within health care systems have been found to have higher risk. Target subgroups have been defined by service characteristics (e.g., patients who are new to a system; individuals transitioning from one care setting to another; patients who drop out of treatment), as well as by individual patient characteristics (e.g., particular age and gender groups; those with psychotic disorders; substance abuse; chronic pain) or health history (e.g., having made multiple suicide attempts).

Examples of studies that would be considered responsive to the goals of this FOA include, but are not limited to those that:

- test strategies to enhance surveillance of suicide ideation, behaviors and deaths among individuals within health care systems over time
- develop and test strategies to promote engagement and continuity of care during known periods of heightened risk, such as care transfers between systems (e.g., handoffs between emergency departments and inpatient psychiatric or substance abuse treatment; transitions between outpatient mental health/substance abuse programs and primary care settings)
- test promising and practical risk detection, risk concentration, and efficient screening approaches in primary care, outpatient specialty care, and hospital settings
- test common but not proven suicide mitigation interventions (e.g., inpatient care practices; peer supported respite care)
- through practical trials, test the benefit of providing evidence-based care for reducing suicide risk, such as related risk screening (e.g., alcohol screening (http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/alcohol-misuse-screening-and-behavioral-counseling-interventions-in-primary-care)) safety planning, as well as implementation of psychosocial interventions known to reduce re-attempts (e.g., Caring letters, Cognitive Behavior Therapy; Dialectical Behavior Therapy, Problem Solving Therapy)
- test mobile technology enhancements intended to improve health care system interventions (e.g., cell phone apps and/ or other telephonic monitoring and therapy)

- determine the cumulative benefit of implementing multiple components of service delivery considered beneficial in suicide prevention (e.g., continuity of care; community collaboration for safe storage of lethal means; coordination with community crisis response; community outreach)
- propose and test potential solutions for policy and implementation barriers (e.g., EMR tracking of attempts, reimbursement, approaches to involuntary commitment, incentives within and outside delivery systems to reduce suicide, system and provider liability, training and staffing needs)

This FOA encourages applications that leverage existing health care networks with adequate infrastructure (e.g., electronic health records; networked health care systems) and services research expertise in quality improvement strategies, in order to improve the efficiency and relevance of research on suicide reduction approaches. The learning healthcare system (https://iom.nationalacademies.org/Activities/Quality/LearningHealthCare.aspx) envisioned by the Institute of Medicine would be an ideal platform for these 'Zero Suicide' efforts that improve patient care, and also allow for the process of scientific discovery. Analytic approaches used within learning health systems can include randomized controlled trials, quasi-experimental designs with non-randomized comparison groups, time series designs, and other designs of equivalent rigor and relevance. Considerations for selecting a research design consider practical constraints, ethical issues, and the tradeoff between maximizing internal and external validity. Practical considerations for testing these efforts may require that multiple components be combined to be safe and ethical, such as appropriate referral and follow up after screening. Other approaches could test various "bundled" quality improvement efforts, based on knowledge from system surveillance information.

Applicants are encouraged to review the Prioritized Research Agenda for Suicide Prevention (http://actionallianceforsuicideprevention.org/sites/actionallianceforsuicideprevention.org/files/Agenda.pdf) regarding the state of the science, potential research pathways, and research objectives relevant to this FOA (in particular, Key Questions 2, 3 and 4). Researchers are also encouraged to consider state collaborations in order to utilize morbidity and mortality surveillance systems (many supported by CDC, http://www.cdc.gov/injury/wisqars/ (http://www.cdc.gov/injury/wisqars/) and http://www.cdc.gov/injury/wisqars/nvdrs.html (http://www.cdc.gov/injury/wisqars/nvdrs.html)). Linking public health data with health care systems data, as well as identifying suicide registries, may offer opportunities to examine suicide morbidity and mortality among individuals enrolled in state, federal or private insurance programs. States implementing laws regarding provider training in suicide mitigation may offer opportunities to study implementation of improved provider skills and its benefits for suicide reduction in care systems. Leveraging federal investments that support behavioral health needs (SAMHSA funded services within states: http://www.samhsa.gov/grants-awards-by-state (http://www.samhsa.gov/grants-awards-by-state)), and primary care (HRSA funded services within states: http://datawarehouse.hrsa.gov/Topics/HrsaInYour.aspx (http://datawarehouse.hrsa.gov/Topics/HrsaInYour.aspx)) are also important opportunities, as a number of these investments include suicide prevention as bench mark outcomes.

Technical Assistance Teleconference

Technical Assistance teleconference will be held for potential applicants on January 20, 2016 from 1:00pm – 2:00 pm EST. The dial in number is 888-790-2043 and participant code is 3564213. NIMH staff will be available to answer questions related to this FOA.

See Section VIII. Other Information (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-16-800.html#_Section_VIII._Other) 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
Resubmissions from this FOA only

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

Funds Available and Anticipated Number of Awards

NIH intends to fund 2 to 4 awards in fiscal year 2016 and 2 to 4 awards in fiscal year 2017. Funds available for each solicitation are $4 million. Future year amounts will depend on annual appropriations.

Award Budget

Direct costs in any one year should not exceed $600,000.

Award Project Period

The maximum project period is 5 years; however, with adequate justification, the proposed project period can be as short as two years.

NIH grants policies as described in the *NIH Grants Policy Statement* (http://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

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.
Foreign components, as defined in the *NIH Grants Policy Statement* (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (http://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 (http://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 (http://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.* (http://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 (http://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 (http://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 (http://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 (http://grants.nih.gov/grants/guide/url_redirect.htm?id=41137).

Letter of Intent

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

By the date listed in Part 1. Overview Information (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-16-800.html#_Part_1._Overview), 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:
Email: NIMHreferral@mail.nih.gov (mailto:NIMHreferral@mail.nih.gov)

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (http://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.

Facilities and Other Resources: The description of the resources and environment should address how the study utilizes existing infrastructure (e.g., learning health care research networks, electronic medical records, administrative data bases, patient registries) and/or utilizes other available resources to increase the efficiency of the study (e.g., entities that could efficiently provide essential data and/or analyses of system level processes and outcomes).

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:

Research Strategy: The Research Strategy should include the following information:

Significance:

- Justify the practical effect of the intervention or service approach in terms of the estimated benefit for reducing suicide events in the system. Identify the key outcomes that are of value to the system under study, such as clinical benefit and reduction of suicide events.
- Describe whether the approach (if successful) is scalable (e.g., could it be disseminated, adopted, implemented and maintained) by other practice systems given typically available resources (e.g., electronic medical records, providers' skill levels, patient portal access), typical service structures (e.g., health care financing), and typical service use patterns.
- Justify whether the anticipated practical effect of the intervention or service approach, in terms of the estimated hypothesized effect size (in terms of key outcomes, such as clinical benefit, safety/tolerability, value and efficiency, or scalability), is better than already available approaches.
- If appropriate, describe whether the system that is a focus of the study can continue quality improvements (QI), provided the current approach is successful. Describe the potential benefits with regard to future momentum, motivation, and 'lessons learned' for additional QI efforts for further suicide event reductions.

Innovation:

Describe how the proposed design includes innovative elements (e.g., pragmatic design approaches, propensity analyses), as appropriate, that enhance its sensitivity and potential for enhancing scientific understanding of suicide prevention in health care settings.

Approach:

- Provide evidence that the denominator of care membership and possible target subgroups can be defined.
- Describe a conceptual framework that clearly identifies the system components that are the focus of change, and a rationale for how those changes will affect suicide events
- Provide evidence of stakeholder (e.g., patient, clinical, administrative, etc.) views of the value in the research question(s) posed
- Describe a rationale for the design selected (e.g., randomized controlled trials, quasi-experimental designs with non-randomized comparison groups, time series designs) that considers practical constraints, ethical issues, and the tradeoff between maximizing internal and external validity
- Provide a rationale for the selection of measures (e.g., substance use, mental disorders, suicidal behavior, insomnia, etc.) that are consistent with NIMH common data elements efforts (http://grants.nih.gov/grants/guide/notice-files/NOT-MH-15-009.html (http://grants.nih.gov/grants/guide/notice-files/NOT-MH-15-009.html)), particularly those likely to be incorporated in electronic health records and generalizable to other care systems
- Provide a plan for assessing proximal and system component changes and/or enhancements through valid and practical means (e.g., supervision observation, monitoring of health care record indicators)
- Detail the selection of the analytic strategy and corresponding power calculations for data analyses that will be used to evaluate the proposed aims.
- In the case of a multi-component strategy, specify the conceptual basis, ascertainment of implementation, and analytic strategy that allows for examination of the value of separate component changes/enhancements, as well as overall effects
- Describe the potential practicality (uptake, ease of implementation, sustainability) of the service delivery approaches/quality improvement efforts proposed.

Protection of Human Subjects: The NIMH has published updated policies and guidance for investigators regarding human research protection and clinical research data and safety monitoring (NOT-MH-15-025 (http://grants.nih.gov/grants/guide/notice-files/NOT-MH-15-025.html)). The application's Protection of Human Subjects section and data and safety monitoring plans should reflect the policies and guidance in this notice. Plans for the protection of research subjects and data and safety monitoring will be reviewed by the NIMH for consistency with NIMH and NIH policies and federal regulations.

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.
- In order to advance the goal of widespread data sharing among researchers, investigators funded under this FOA are expected to share those data via the National Database for Clinical Trials related to Mental Illness (NDCT; http://ndct.nimh.nih.gov/ (http://ndct.nimh.nih.gov/); see NOT-MH-14-015 (http://grants.nih.gov/grants/guide/notice-files/NOT-MH-14-015.html) and NOT-MH-15-012 (http://grants.nih.gov/grants/guide/notice-files/NOT-MH-15-012.html)). Applicants should explain what type of data are appropriate and available for sharing in the NDCT.

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.

Planned Enrollment Report

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in 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 (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-16-800.html#_Part_1._Overview) 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 (http://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 (http://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. (http://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* (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement* (http://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 (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-16-800.html#_Section_III._Eligibility) contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://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 (http://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines). For assistance with application submission, contact the Application Submission Contacts in Section VII (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-16-800.html#_Section_VII._Agency).

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential fieldof 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 (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-16-800.html#_Required_Registrations) 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 (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by NIMH (https://nihguide.nih.gov/FOA%20and%20Notice%20Templates/Research.doc#_Components_of_Participating), NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

In order to expedite review, applicants are requested to notify the NIMH Referral Office by email at nimhreferral@mail.nih.gov (mailto:nimhreferral@mail.nih.gov) when the application has been submitted. Please include the FOA number and title, PD/PI name, and title of the application.

Use of Common Data Elements in NIH-funded Research

NIMH encourages the use of common data elements (CDEs) in basic, clinical, and applied research, patient registries, and other human subject research to facilitate broader and more effective use of data and advance research across studies. CDEs are data elements that have been identified and defined for use in multiple data sets across different studies. Use of CDEs can facilitate data sharing and standardization to improve data quality and enable data integration from multiple studies and sources, including electronic health records. NIH ICs have identified CDEs for many clinical domains (e.g., neurological disease), types of studies (e.g., genome-wide association studies (GWAS)), types of outcomes (e.g., patient-reported outcomes), and patient registries (e.g., the Global Rare Diseases Patient Registry and Data Repository). NIH has established a "Common Data Element (CDE) Resource Portal" (http://cde.nih.gov/ (http://cde.nih.gov/)) to assist investigators in identifying NIH-supported CDEs when developing protocols, case report forms, and other instruments for data collection. The Portal provides guidance about and access to NIH-supported CDE initiatives and other tools and resources for the appropriate use of CDEs and data standards in NIH-funded research. Investigators are encouraged to consult the Portal and describe in their applications any use they will make of NIH-supported CDEs in their projects.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-030.html).

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 (http://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).

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?

How does the application justify the practical effect of the intervention or service approach in terms of the estimated benefit for reducing suicide events in the system? Are the key outcomes, such as clinical benefit and reduction of suicide events, of value to the system under study?

If the approach is successful, is it scalable (e.g., could it be disseminated, adopted, implemented and maintained) by other practice systems given typically available resources (e.g., electronic medical records,

providers' skill levels, patient portal access), typical service structures (e.g., health care financing), and typical service use patterns?

Does the application justify the anticipated practical effect of the intervention or service approach in terms of the estimated hypothesized effect size (in terms of key outcomes, such as clinical benefit, safety/tolerability, value and efficiency, or scalability), compared with already available approaches?

If appropriate, does the application describe a system that can continue quality improvements (QI), such that the current effort provides momentum, motivation, and 'lessons learned' for additional QI efforts for further suicide event reductions?

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?

As appropriate, does the application involve collaborations and/or input from relevant stakeholders, such as health care system leaders, providers, patients, and relevant policy makers in a manner that informs the research and helps to ensure the results will have utility?

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 design/research plan include innovative elements (e.g., pragmatic design approaches, propensity analyses), as appropriate, that enhance its sensitivity and potential for enhancing scientific understanding of suicide prevention in health care settings?

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?

Does the application provide (1) evidence that the denominator of care membership and possible target subgroups can be defined? Does the application include: (2) a conceptual framework that clearly identifies the system components that are the focus of change, and a rationale for how that change will affect suicide events? (3) evidence of stakeholder (e.g., patient, clinical, administrative, etc.) views of the value in the research question(s) posed? (4) a rationale for the design selected (e.g., randomized controlled trials, quasi-experimental designs with non-randomized comparison groups, time series designs) that considers practical constraints, ethical issues, and the tradeoff between maximizing internal and external validity? (5) a rationale for the selection of measures (e.g., substance use, mental disorders, suicidal behavior, insomnia, etc.) that are consistent with NIMH common data elements efforts (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-15-320.html), particularly those likely to be incorporated in electronic health records and generalizable to other care systems? (6) a plan for assessing proximal and system component changes and/or enhancements through valid and practical means (e.g., supervision observation, monitoring of health care record indicators),

and (7) an appropriate analytic strategy and corresponding power calculations for data analyses that will be used to evaluate the proposed aims?

In the case of a multi-component strategy, does the application specify the conceptual basis, ascertainment of implementation, and analytic strategy that allows for examination of the value of separate component changes/enhancements, as well as overall effects? Do the service delivery approaches/quality improvement efforts proposed to be studied have potential and practicality for being delivered in ongoing practice?

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?

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?

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 Guidelines for the Review of Human Subjects (http://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 (http://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 (http://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

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

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

Applications from Foreign Organizations

Not Applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) Sharing Model Organisms (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) Genomic Data Sharing Plan (GDS) (http://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 NIMH, in accordance with NIH peer review policy and procedures (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-16-800.html#_1._Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

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

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

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications . Following initial peer review, recommended applications will receive a second level of review by the National Advisory Mental Health Council. The following will be considered in making funding decisions:

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

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

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

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the *NIH Grants Policy Statement* (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-16-800.html#_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 (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

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

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html (http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html); and http://www.hhs.gov/ocr/civilrights/understanding/index.html (http://www.hhs.gov/ocr/civilrights/understanding/index.html). Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html (http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (http://grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (http://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* (http://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 http://grants.nih.gov/grants/guide/url_redirect.htm?id=11170 (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the *NIH Grants Policy Statement* (http://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: http://grants.nih.gov/support/ (http://grants.nih.gov/support/) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (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)
Telephone: 301-710-0267

Scientific/Research Contact(s)

Jane Pearson, Ph.D.
National Institute of Mental Health (NIMH)
Telephone: 301-443-3598
Email: jpearson@mail.nih.gov (mailto:jpearson@mail.nih.gov)

Peer Review Contact(s)

David Armstrong, Ph.D.
National Institute of Mental Health (NIMH (http://www.nimh.nih.gov/index.shtml))
Telephone: 301-443-3534
Email: armstrda@mail.nih.gov (mailto:armstrda@mail.nih.gov)

Financial/Grants Management Contact(s)

Tamara Kees
National Institute of Mental Health (NIMH)
Telephone: 301-443-8811
Email: tkees@mail.nih.gov (mailto:tkees@mail.nih.gov)

Section VIII. Other Information

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

Authority and Regulations

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

Weekly TOC for this Announcement (http://grants.nih.gov/grants/guide/WeeklyIndex.cfm?12-11-15)
NIH Funding Opportunities and Notices (http://grants.nih.gov/grants/guide/index.html)

National Institutes of Health (http://grants.nih.gov/grants/oer.htm)
Office of Extramural Research

(http://www.hhs.gov/) Department of Health and Human Services (HHS)

(http://www.usa.gov/)

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