

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	Reducing the Duration of Untreated Psychosis in the United States (R01 Clinical Trial Required)
Activity Code	R01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project Grant
Announcement Type	Reissue of PAR-18-233 (https://grants.nih.gov/grants/guide/pa-files/par-18-233.html)
Related Notices	None
Funding Opportunity Announcement (FOA) Number	PAR-19-236
Companion Funding Opportunity	PAR-19-235 (https://grants.nih.gov/grants/guide/pa-files/par-19-235.html)
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.242
Funding Opportunity Purpose	Approximately 100,000 adolescents and young adults in the United States experience a first episode of psychosis (FEP) every year. The early phase of psychotic illness is widely viewed as a critical opportunity for indicated prevention, and a chance to alter the downward trajectory and poor outcomes associated with schizophrenia and related psychotic disorders. Unfortunately, numerous studies find a substantial delay between the onset

of psychotic symptoms and the initiation of FEP care; in the U.S. treatment is typically delayed between one and three years. Early identification of FEP, rapid referral to evidence-based Coordinated Specialty Care (CSC) for early psychosis, and effective engagement in CSC services are essential to shortening the duration of untreated psychosis (DUP) and pre-empting the functional deterioration common in psychotic disorders. The World Health Organization advocates reducing DUP to 3 months or less. Accordingly, this Funding Opportunity Announcement (FOA) seeks research project grant applications that test practical, reproducible strategies for substantially reducing DUP among persons with FEP in the U.S. by eliminating bottlenecks or closing gaps in the pathway to CSC services. Alternatively, applicants whose work in this area is at a developmental stage should consider applying to the companion R34 FOA [PAR-19-235](https://grants.nih.gov/grants/guide/pa-files/par-19-235.html) (<https://grants.nih.gov/grants/guide/pa-files/par-19-235.html>).

Key Dates

Posted Date	April 2, 2019
Open Date (Earliest Submission Date)	May 05, 2019
Letter of Intent Due Date(s)	Not Applicable
Application Due Date(s)	<p>Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11111) apply, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates.</p> <p>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.</p>
AIDS Application Due Date(s)	Not applicable
Scientific Merit Review	<p>Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandawa) apply</p>
Advisory Council Review	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113)

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandawa>
apply

Earliest Start Date

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

Expiration Date

May 8, 2022

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(//grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)](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 \(//grants.nih.gov/grants/guide/\)](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](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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

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

[Apply Online Using ASSIST](#)

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-19-236\)](http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-19-236) Workspace to prepare and submit your application and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application.

Table of Contents

[Part 1. Overview Information](#)

[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

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Background and Purpose

Approximately 100,000 adolescents and young adults in the United States experience a first episode of psychosis (FEP) every year. The early phase of psychotic illness is widely viewed as a critical opportunity for indicated prevention and a chance to alter the downward trajectory and poor outcomes associated with schizophrenia and related psychotic disorders. Compared to traditional treatment approaches, programs that integrate FEP medication management, cognitive behavioral therapy, supported employment and education, family psychoeducation, case management and primary care coordination within a shared decision making framework, i.e., team-based Coordinated Specialty care (CSC), have been found to produce a range of positive clinical and functional outcomes, including reduced symptoms, lower rates of re-hospitalization, shorter hospital stays, greater involvement in work or school, improved quality of life and social functioning, increased cognitive performance and decreased substance abuse. However, the timing of this treatment is critical; short and long-term outcomes are better when individuals begin treatment close to the onset of psychosis.

International consensus statements from the World Health Organization recommend that specialty care for FEP start within 3 months of illness onset. However, more than two dozen studies conducted worldwide have observed a substantial delay (on average 2 years) between the appearance of psychotic symptoms and the initiation of treatment. Multiple meta-analyses clearly establish that the duration of untreated psychosis (DUP)—the time between the onset of psychosis and initiation of treatment to address the psychotic symptoms—is correlated with poor outcomes. In the U.S., DUP ranges between one and three years, suggesting that many people with FEP are missing a critical opportunity to benefit from early psychosis intervention.

Research indicates that DUP can be reduced by enhancing early detection, treatment referral, and CSC engagement mechanisms. Early identification of FEP, rapid referral to evidence-based CSC, and effective engagement in CSC services are essential to shortening DUP and pre-empting the functional deterioration common in psychotic disorders. Reducing DUP in the U.S. from current levels of 1-3 years to the recommended standard of no more than 3 months should be a major focus of applied research efforts. Research to improve FEP case identification and referral to and engagement in CSC in the U.S. is a logical complement to other NIMH initiatives on improving outcomes for people with FEP, such as the [Recovery After an Initial Schizophrenia Episode \(RAISE\)](#) (<https://www.nimh.nih.gov/health/topics/schizophrenia/raise/index.shtml>) initiative, which found that CSC produced superior clinical and functional improvements compared to typical care, especially among clients with shorter DUP, and the [Early Psychosis Intervention Network \(EPINET\)](#) (<https://grants.nih.gov/grants/guide/rfa-files/rfa-mh-19-150.html>), a national early psychosis learning health care endeavor in the U.S.

CSC services have expanded dramatically in the U.S., following the RAISE initiative and additional federal funding to states for evidence-based FEP treatment programs. Nearly every state now has a CSC program, with more than 265 CSC programs nationwide serving approximately 10,000 individuals with FEP annually. Systematic efforts to reduce DUP could help young people with FEP access CSC services at the earliest possible opportunity and derive the maximum benefit from this evidence-based care.

Accordingly, this Funding Opportunity Announcement (FOA) seeks research project grant applications that test practical, reproducible strategies for substantially reducing DUP among persons with FEP in the U.S. by eliminating bottlenecks or closing gaps in the pathway to CSC services.

Research Objectives

This FOA aims to support research that will test feasible and reproducible strategies for substantially reducing DUP among persons with FEP in real-world U.S. settings. The research should focus on eliminating bottlenecks or closing gaps in the pathway to specialty FEP care. For this announcement, we define "bottlenecks" and "gaps" as individual, organizational, systemic, or other impediments to rapid FEP identification, assessment, connection to and engagement in specialty FEP care. The target population is not limited to first episode schizophrenia, but includes all persons experiencing a first episode of psychosis regardless of presenting diagnosis. Applicants are encouraged to base research activities in settings that link to treatment systems with CSC programs for FEP. A variety of configurations for FEP specialty care programs are possible, but evidence-based CSC treatment involves integrated, team-based care and typically features use of single antipsychotic medications, prescribed in low doses; family psychoeducation; supported employment and education; cognitive-behavioral therapy oriented to recovery; coordination with primary care services; and continuity of care across inpatient and outpatient treatment settings.

Applications submitted to this FOA should propose projects that test practical approaches for producing one or more of the following:

- Better signal detection of psychosis onset, or symptoms suggesting high clinical risk of psychosis (CHR), within primary care settings, schools, child/youth mental health services, college counseling centers, emergency departments, criminal justice agencies, and/or other institutional or community settings;
- Methods to achieve expeditious referral of persons with FEP, or those with CHR, to an appropriate specialty care treatment program; and
- Strategies for achieving rapid initiation of and engagement in FEP treatment.

The strategies proposed to reduce DUP should aim to close gaps as well as remove significant bottlenecks in the referral pathway to CSC, including barriers that impede the following:

- Recognition of psychotic symptoms
- Referral to screening for a psychotic disorder with validated assessment instruments
- Diagnosis of a psychotic disorder
- Referral to a CSC program
- Enrollment in a CSC program and/or initiation of CSC treatment
- Engagement in CSC services

Applications submitted to this FOA should consider "supply side" approaches (e.g., targeting clinical, community, institutional or other systems), such as the development and testing of strategies for training primary care physicians and nurses, school and college counselors, emergency department staff, police, corrections officers and mental health "generalists" to recognize signs of early psychosis, and the improvement of referral networks to fast-track the initiation of FEP care. This FOA is also intended to encourage "demand side" approaches (e.g., engaging people with FEP and their family members, friends, caregivers and others

close to the affected individual) to improve recognition of early symptoms, help-seeking, access, and engagement in care for persons with FEP and/or youth with CHR, through education, decision-support systems, public awareness campaigns, and other tools, including social marketing, social media and social networking.

Research to reduce DUP requires expertise on the characteristics of service delivery systems, community settings, or other settings in which DUP reduction strategies would be embedded, as well as expertise on the needs, life circumstances, and diversity of the population of young people with FEP and/or CHR. Investigators should convey knowledge of DUP assessment strategies and factors that may contribute to treatment delays in the U.S. health care system. Multi-disciplinary research teams with complementary areas of expertise are encouraged, as are collaborations with stakeholders from the target clinical, community or institutional setting. NIMH strongly encourages the involvement of individuals with FEP and/or CHR and their family members and friends, in all aspects of developing and testing DUP reduction interventions, as relevant to the proposed strategy.

In addition, NIMH welcomes applications proposing to leverage existing practice-based research infrastructures, such as the [NIMH-sponsored Mental Health Research Network \(MHRN\)](http://www.hcsrn.org/en/Collaboration/Consortia/mhrn.html) (<http://www.hcsrn.org/en/Collaboration/Consortia/mhrn.html>), the [NCATS Trial Innovations Network](https://ncats.nih.gov/ctsa/projects/network) (<https://ncats.nih.gov/ctsa/projects/network>), the anticipated [EPINET](https://grants.nih.gov/grants/guide/rfa-files/rfa-mh-19-150.html) (<https://grants.nih.gov/grants/guide/rfa-files/rfa-mh-19-150.html>) regional scientific hubs, the [ThriveNYC Investigators' Hub](https://www.thrivehubnyc.org/) (<https://www.thrivehubnyc.org/>), and other practice networks looking to conduct studies to reduce DUP. NIMH also encourages coordination of DUP reduction research with other public and private initiatives that specifically address early identification and treatment of young people at high risk for mental illness. For example, since 2014 the Substance Abuse and Mental Health Services Administration (SAMHSA) has supported the implementation of hundreds of evidence-based treatment programs for FEP across the U.S. via a set-aside in the Community Mental Health Block Grant Program (CMHBG). These FEP treatment programs represent a tremendous opportunity for advancing DUP reduction research. Likewise, in 2018, through its [Clinical High Risk for Psychosis \(CHR-P\) initiative](https://www.samhsa.gov/grants/grant-announcements/sm-18-012) (<https://www.samhsa.gov/grants/grant-announcements/sm-18-012>) (<https://www.samhsa.gov/grants/grant-announcements/sm-18-012>), SAMHSA funded [21 service delivery programs](https://www.samhsa.gov/grants/awards/SM-18-012) (<https://www.samhsa.gov/grants/awards/SM-18-012>) to identify individuals with CHR-P and provide treatment to prevent the onset of psychosis and/or improve symptoms and functioning. These CHR-P treatment programs represent another promising setting for DUP reduction research.

This FOA, and the related FOA, [PAR-19-235](https://grants.nih.gov/grants/guide/pa-files/par-19-235.html) (<https://grants.nih.gov/grants/guide/pa-files/par-19-235.html>), support experimental and quasi-experimental studies focused on designing, refining, and testing systematic, practical and accurate case identification of persons with FEP and/or CHR within a myriad of possible clinical, community and institutional contexts, in combination with strategies that promote rapid referral to and engagement in the appropriate stage-specific specialty care.

Research Topics

Applications to this FOA should focus on practical and reproducible strategies to achieve substantial DUP reduction for persons with FEP. NIMH strongly encourages applications in which referral to evidence-based CSC programs is feasible. This FOA supports studies on the research topics listed below, which are intended to be illustrative, not exhaustive:

- Improving recognition of symptoms and increasing help-seeking behavior among people with FEP and

CHR.

- Improving recognition of symptoms and increasing help-seeking behavior among people with FEP, who often experience the highest levels of health disparities, including members of racial or ethnic minority groups or persons who identify as lesbian, gay, bisexual or transgender.
- Improving recognition of early psychosis symptoms among family members and friends of persons with FEP and facilitating their help-seeking and supportive behaviors on behalf of individuals with FEP.
- Leveraging existing mental health screening infrastructure, such as [online screening tools](https://screening.mentalhealthamerica.net/screening-tools) (<https://screening.mentalhealthamerica.net/screening-tools>), to facilitate identification of FEP and referral to specialty FEP care.
- Improving case identification and referral of patients with FEP within non-specialty clinical, community and institutional systems (e.g., pediatrics, primary care, high schools, criminal justice settings, college campuses, or workplace), as well as within child/youth and adult specialty mental health settings.
- Developing and testing decision support tools, including those embedded in electronic health records, for improving the early identification of FEP and CHR and matching of symptomatic and functional deficits with available service systems within a catchment area.
- Testing the effectiveness of strategies within emergency departments and inpatient facilities to improve identification and referral of patients with FEP to appropriate stage-specific FEP care and promote care engagement.
- Partnering with police departments, including those with Crisis Intervention Teams, to recognize possible symptoms of psychosis and divert eligible individuals to appropriate FEP screening and/or care, as indicated.
- Assessing the impact of CHR/FEP public awareness campaigns on initiation of treatment and shortening DUP.
- Social marketing, social media, and social networking approaches to identify persons with CHR or FEP and link them to treatment.
- Improving access to and engagement in care for persons with CHR, resulting in rapid FEP identification and entry into specialty CSC care for individual who convert to psychosis.

It is expected that applications submitted to this FOA will identify other important, innovative and impactful research topics. Investigators considering applying to this FOA are strongly encouraged to contact the [Scientific/Research Contact](#) for this FOA before submitting an application.

A variety of rigorous methodological approaches are possible for testing the impact of the proposed approach to reducing DUP. These approaches include randomized controlled trials, stepped-wedge trials, interrupted time series designs, quasi-experimental designs with non-randomized comparison groups, and other designs of equivalent rigor and relevance. Considerations for selecting a research design for the proposed study include the scientific question that the study is designed to answer, practical constraints, ethical issues, and the tradeoff between maximizing internal and external validity.

Investigators in this area whose work is at a developmental stage should consider applying to the companion FOA, [PAR-19-235](https://grants.nih.gov/grants/guide/pa-files/par-19-235.html) (<https://grants.nih.gov/grants/guide/pa-files/par-19-235.html>).

Note that this FOA requires a clinical trial. DUP reduction projects that don't involve a clinical trial are encouraged through other funding mechanisms, including the following (and any future re-issuances of the same):

- [PA-19-052](https://grants.nih.gov/grants/guide/pa-files/PA-19-052.html) (<https://grants.nih.gov/grants/guide/pa-files/PA-19-052.html>) (Parent R03 NIH Small Research Grant Program, Clinical Trial Not Allowed)

- [PA-19-056](https://grants.nih.gov/grants/guide/pa-files/PA-19-056.html) (<https://grants.nih.gov/grants/guide/pa-files/PA-19-056.html>) (Parent R01 NIH Research Project Grant, Clinical Trial Not Allowed)
- [PAR-17-264](https://grants.nih.gov/grants/guide/pa-files/par-17-264.html) (<https://grants.nih.gov/grants/guide/pa-files/par-17-264.html>) (R01 Innovative Mental Health Services Research Not Involving Clinical Trials)
- [PAR-18-929](https://grants.nih.gov/grants/guide/pa-files/PAR-18-929.html) (<https://grants.nih.gov/grants/guide/pa-files/PAR-18-929.html>) (R01 High-Priority Areas for Research Leveraging EHR and Large-Scale Data, Clinical Trial Not Allowed)
- [PAR-18-267](https://grants.nih.gov/grants/guide/pa-files/PAR-18-267.html) (<https://grants.nih.gov/grants/guide/pa-files/PAR-18-267.html>) (R34 Pilot Services Research Grants Not Involving Interventions, Clinical Trials Optional)
- [PA-18-566](https://grants.nih.gov/grants/guide/pa-files/PA-18-566.html) (<https://grants.nih.gov/grants/guide/pa-files/PA-18-566.html>) (R43/R44 Complex Technologies and Therapeutics Development for Mental Health Research and Practice, Clinical Trials Optional)
- [PA-18-579](https://grants.nih.gov/grants/guide/pa-files/PA-18-579.html) (<https://grants.nih.gov/grants/guide/pa-files/PA-18-579.html>) (R41/R42 Complex Technologies and Therapeutics Development for Mental Health Research and Practice, Clinical Trials Optional)

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

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New
Resubmission
Revision

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

Clinical Trial?

Required: Only accepting applications that propose clinical trial(s)

[Need help determining whether you are doing a clinical trial? \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

The NIMH intends to commit approximately \$3,000,000 in FY 2020 to fund between 4 and 6 awards submitted to this FOA and the companion FOA, [PAR-19-235 \(https://grants.nih.gov/grants/guide/pa-files/par-19-235.html\)](https://grants.nih.gov/grants/guide/pa-files/par-19-235.html).

Award Budget

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

Award Project Period

The total project period for an application submitted in response to this FOA may not exceed 5 years.

NIH grants policies as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Governments

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

Other

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

Foreign Institutions

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

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

Foreign components, as [defined in the NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11118) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11118](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11118)), **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The [NIH Policy on Late Submission of Grant Applications](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) ([//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html)) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System \(DUNS\)](http://fedgov.dnb.com/webform) (<http://fedgov.dnb.com/webform>) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\)](https://www.sam.gov/portal/public/SAM/) (<https://www.sam.gov/portal/public/SAM/>)– Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- [NATO Commercial and Government Entity \(NCAGE\) Code](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11176](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11176)) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11123](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- [Grants.gov](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=82300](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82300)) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

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

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

Eligible Individuals (Program Director/Principal Investigator)

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

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

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see [NOT-OD-11-101](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html) ([//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html))).

Section IV. Application and Submission Information

1. Requesting an Application Package

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

2. Content and Form of Application Submission

It is critical that applicants follow the Research (R) Instructions in the [SF424 \(R&R\) Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=12000](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000)), except where instructed 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.

Page Limitations

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

Instructions for Application Submission

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

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

Facilities and Other Resources: The description of the resources and environment should address how the study utilizes existing infrastructure (e.g., practice-based research networks, electronic medical records, administrative data bases, patient registries) or other available resources to increase the efficiency of participant recruitment and data collection, explicitly address how efficiencies are incorporated or provide a justification in the event that such efficiencies cannot be incorporated.

SF424(R&R) Senior/Key Person Profile

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

Biographical Sketch

Document investigators' knowledge of DUP assessment strategies and factors that may contribute to treatment delays in the U.S. health care system. The biographical sketches should also document the qualifications of the PD/PI and other senior investigators, including expertise in the identification and treatment of people with FEP and expertise in the service delivery systems or institutional or community settings in which the selected DUP reduction strategies would be embedded, and expertise in conducting research in real-world community treatment settings.

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. Applications should not duplicate information provided in the PHS Human Subjects Clinical Trial Information form but may reference it to provide context.

Significance

- Justify the 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. Address the potential impact of the intervention/service delivery approach in terms of both (1) the empirical basis for the anticipated effect size (e.g., citing data regarding the magnitude of the association between the target and the clinical endpoint of interest and/or effect sizes obtained in prior efficacy studies), and (2) the clinical meaningfulness of the anticipated increment in effects compared to existing approaches.
- Applications are expected to maximize efficiencies in effectiveness research (e.g., by utilizing existing

infrastructure such as practice-based research networks, electronic medical records, administrative data bases, patient registries, or other available resources) and should explicitly address how efficiencies are incorporated.

- Address the degree to which the proposed intervention/service delivery approach is scalable and could be disseminated into practice, given typically available resources (e.g., trained, skilled providers), typical service structures (including MH financing), and typical service use patterns.
- Explain how the scientific rationale and need for a clinical trial to test the proposed DUP reduction hypothesis or intervention are well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms. For trials focusing on clinical or public health endpoints, indicate (1) why this clinical trial is necessary for testing the safety, efficacy or effectiveness of the proposed DUP reduction intervention, and (2) how the intervention could lead to a change in clinical practice, community behaviors or health care policy. For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, justify why this trial is needed to advance scientific understanding.

Innovation

- Highlight novel strategies proposed for reducing DUP among people with FEP, as applicable.
- Highlight any innovative approaches for assessing DUP in institutional or community treatment settings via measures that are valid, reliable, and practical.
- Highlight how innovative research strategies and design/analytic elements (e.g., adaptive sequential randomization, equipoise stratification) are incorporated, as appropriate, in order to enhance the study's sensitivity or potential to advance scientific knowledge or clinical practice.

Approach

- Applications should present empirical data that support the feasibility and acceptability of the proposed strategy for reducing DUP. The empirical data presented for the selected setting should (1) quantify the overall DUP among persons with FEP at baseline using a scientifically acceptable operational definition of DUP and reliable measures of DUP, (2) map the various referral pathways that channel persons with FEP to FEP specialty care programs, and (3) identify gaps and bottlenecks in these referral pathways that prolong DUP.
- Applications should propose a DUP reduction approach that has the potential to substantially reduce DUP in the target population of people with FEP by eliminating bottlenecks or closing gaps in the pathway to CSC services. The application should describe how reduction in DUP will be included as the primary outcome.
- The application should provide justification that the DUP reduction intervention, if demonstrated effective, could be implemented and sustained in typical community or service settings using typically available personnel and resources.
- Detail the plan to explicitly address whether the intervention to reduce DUP engages the mechanism that is presumed to underlie intervention effects (i.e., the mechanism that accounts for changes in DUP). Include the following: (1) a conceptual framework that clearly identifies the target(s)/mechanism(s) and the empirical evidence linking the target(s)/mechanism(s) to DUP reduction; (2) plans for assessing engagement of the target(s)/mechanism(s) using valid measures that are as direct and objective as is feasible in the effectiveness context, including the specific measures, the assessment schedule, and the justification for the assessment strategy (e.g., evidence regarding the validity and feasibility of the proposed measures in the effectiveness context); and (3) a statistical analysis plan and corresponding power calculations for data analyses that will be used to examine whether the intervention engages the

target(s) and whether intervention-induced changes in the target(s) are associated with DUP reduction (i.e., mediation). In the case of multi-component interventions, the application should specify the conceptual basis, assessment plan, and analytic strategy, as detailed above, for the target(s)/mechanism(s) corresponding to each DUP reduction intervention component, as appropriate in the effectiveness context.

- When appropriate, for studies that involve preventive or therapeutic interventions, detail how the study takes into account RDoC or RDoC-like constructs when defining the subject eligibility (inclusion), intervention targets or mechanisms, and outcomes, as feasible in the effectiveness setting.
- Describe provisions for the assessment and monitoring of the fidelity of intervention delivery via procedures that are feasible and valid for use in community practice settings.
- Describe plans to collaborate on the research process—including project design—with community practice partners/providers, mental health service users and their family members, relevant policy makers, and other relevant stakeholders in a manner that informs the research and helps to ensure the results will have utility.
- When appropriate, incorporate secondary outcome measures that are validated and generally accepted by the field, including stakeholder-relevant outcomes (e.g., functioning or health services use).
- When appropriate, describe plans to collect data on potential moderators such as clinical and biological variables (e.g., blood for genetic analysis, other potential biomarkers) that might be used to inform or test algorithms for more prescriptive approaches in future work.
- Indicate how the trial design and research protocol are consistent with CONSORT guidelines, as appropriate.
- When appropriate, for studies proposing adaptations of existing interventions for broader use, provide a justification for the proposed adaptation based on data describing characteristics of client subgroups, settings, care providers or other relevant variables that are associated with non-response, partial response, relapse, or poor uptake (see page 19 of NAMHC Workgroup Report "[From Discovery to Cure: Accelerating the Development of New and Personalized Interventions for Mental Illnesses](http://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/fromdiscoverytocure.pdf). (<http://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/fromdiscoverytocure.pdf>)")
- As relevant, address how the trial contributes to advancing the personalization of mental health care and describe the collection of clinical and biological variables (e.g., blood for genetic analysis, other potential biomarkers) that might be used to examine moderators or inform/test algorithms for more prescriptive approaches. Address statistical power to test for moderators and/or the potential to contribute information regarding potential moderators to larger databases for future use.

For studies that involve the assessment of patient-level outcomes, plans are expected that describe the assessment of suicidal behavior and related outcomes using strategies that can facilitate integration and sharing of data (e.g., see [NOT-MH-15-009 \(https://grants.nih.gov/grants/guide/notice-files/NOT-MH-15-009.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-MH-15-009.html) and the [PhenX Toolkit \(https://www.phenxtoolkit.org/\)](https://www.phenxtoolkit.org/) for constructs and corresponding assessment strategies), as appropriate, or provide a rationale for excluding such measures if they are not included. Accordingly, the application should provide the rationale for the selection of suicide-related constructs and corresponding assessment instruments (e.g., measures of ideation, attempts), the time periods assessed (e.g., lifetime history, current), and the assessment schedule for administration (e.g., baseline, during intervention, post-intervention, follow up), taking into account the nature of the target population, participant burden, etc. The application should also address provisions for clinical management when suicidal behavior is reported. In situations where it is not appropriate or feasible to include assessment of suicide outcomes due to the nature of the intervention (e.g., services interventions that target provider behavior or systems-level factors), the target population (e.g., very young children), or unique issues related to participant burden or

safety/monitoring concerns, the application should provide an appropriate justification for excluding these assessments.

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:

In order to facilitate the goal of advancing research through 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](https://grants.nih.gov/grants/guide/notice-files/not-mh-14-015.html) (<https://grants.nih.gov/grants/guide/notice-files/not-mh-14-015.html>) and [NOT-MH-15-012](https://grants.nih.gov/grants/guide/notice-files/not-mh-15-012.html) (<https://grants.nih.gov/grants/guide/notice-files/not-mh-15-012.html>)). Established by the NIH, NDCT is a secure informatics platform for scientific collaboration and data-sharing that enables the effective communication of detailed research data, tools, and supporting documentation. NDCT links data across research projects through its Global Unique Identifier (GUID) and Data Dictionary technology. Investigators funded under this FOA are expected to use these technologies to submit data to NDCT.

To accomplish this objective, it will be important to formulate a) an enrollment strategy that will obtain the information necessary to generate a GUID for each participant, and b) a budget strategy that will cover the costs of data submission. The NDCT web site provides two tools to help investigators develop appropriate strategies: 1) the NDCT Budgeting Spreadsheet <http://ndct.nimh.nih.gov/preplanning/budget> (<http://ndct.nimh.nih.gov/preplanning/budget>) - a customizable Excel worksheet that includes tasks and hours for the Program Director/Principal Investigator and Data Manager to budget for data sharing; and 2) plain language text to be considered in your informed consent <http://ndct.nimh.nih.gov/preplanning/informed-consent> (<http://ndct.nimh.nih.gov/preplanning/#tab-3>). Investigators are expected to certify the quality of all data generated by grants funded under this FOA prior to submission to NDCT and review their data for accuracy after submission. Submission of descriptive/raw data is expected semi-annually (every January 15 and July 15); submission of all other data is expected at the time of publication, or prior to the end of the grant, whichever occurs first (see Data Sharing Expectation <http://ndct.nimh.nih.gov/preplanning/#tab-1> (<http://ndct.nimh.nih.gov/preplanning/#tab-1>) for more information); Investigators are expected to share results, positive and negative, specific to the cohorts and outcome measures studied by using the Study functionality (see <http://ndct.nimh.nih.gov/results> (<http://ndct.nimh.nih.gov/results>)). The NDCT Data Sharing Plan is available for review on the NDCT web site (http://ndct.nimh.nih.gov/wp-content/uploads/NDCT_Data_Sharing_Policy_20141002.pdf (http://ndct.nimh.nih.gov/wp-content/uploads/NDCT_Data_Sharing_Policy_20141002.pdf)). NDCT staff will work with investigators to help them submit data types not yet defined in the NDCT Data Dictionary <http://ndct.nimh.nih.gov/submit/data-dictionary> (<http://ndct.nimh.nih.gov/submit/data-dictionary>).

Appendix:

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

PHS Human Subjects and Clinical Trials Information

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

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

Subjects and Clinical Trials Information form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

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

[Section 2 - \(https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2\)](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2) **Study Population Characteristics**
(<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2>)

2.5 Recruitment and Retention Plan (<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.5>)

Applications must provide a clear description of:

1. Recruitment and Referral sources, including detailed descriptions of the census/rate of new cases and anticipated yield of eligible participants from each source;
2. Procedures that will be used to monitor enrollment and track/retain participants for follow-up assessments;
3. Strategies that will be used to ensure a diverse, representative sample;
4. Potential recruitment/enrollment challenges and strategies that can be implemented in the event of enrollment shortfalls (e.g., additional outreach procedures, alternate/back-up referral sources);
5. Evidence to support the feasibility of enrollment, including descriptions of prior experiences and yield from research efforts employing similar referral sources and/or strategies.

2.7 Study Timeline

Study Timeline: Applications must provide a timeline for reaching important study benchmarks such as: (1) finalizing the study procedures and training participating clinical site staff; (2) finalizing the intervention manual and assessment protocols, including fidelity measures/procedures, where applicable; (3) enrollment benchmarks; (4) completing all subject assessments and data collection activities, including data quality checks; (5) analyzing and interpreting results; and (6) preparing de-identified data and relevant documentation to facilitate data sharing, as appropriate.

Section 5 - Other Clinical Trial-related Attachments

5.1 Other Clinical Trial-related Attachments

Applicants must upload the attachments for Intervention Manual/Materials as separate files, as applicable. Applicants must use the "Intervention Manual/Materials" to name these other attachments files and label each attachment with a unique filename, e.g. 'Intervention Manual.1' for Study Record 1, 'Intervention Manual.2' for Study Record 2, etc. As appropriate, this may include screenshots of mobile interventions, technological specifications, training manuals or treatment algorithms.

Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).

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

PHS Assignment Request Form

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

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

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

4. Submission Dates and Times

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

Organizations must submit applications to [Grants.gov](#) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11128](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11128)) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons](#) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11123](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review](#). ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11142](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142))

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11120](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement](#) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11143](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11143)).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. [Section III.](#)

[Eligibility Information](#) contains information about registration.

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

Important reminders:

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

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

See [more tips \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=11146\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

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/>) 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.

Applicants responding to this FOA are encouraged to incorporate CDEs available in the Add PhenX Toolkit link, [PhenX Toolkit \(https://www.phenxtoolkit.org/\)](https://www.phenxtoolkit.org/) of mental health research measures, especially the [PhenX Toolkit Early Psychosis Clinical Services Specialty Collection \(https://www.phenxtoolkit.org/sub-collections/view/6\)](https://www.phenxtoolkit.org/sub-collections/view/6), as appropriate. In addition to CDEs for [demographic features \(https://www.phenxtoolkit.org/index.php?pageLink=browse.nimh.core.tier1\)](https://www.phenxtoolkit.org/index.php?pageLink=browse.nimh.core.tier1), [substance use \(https://www.phenxtoolkit.org/index.php?pageLink=browse.nimh.core.tier2\)](https://www.phenxtoolkit.org/index.php?pageLink=browse.nimh.core.tier2), and suicidal ideation and behaviors, the PhenX Toolkit contains [clinical service measures \(https://www.phenxtoolkit.org/index.php?pageLink=browse.nimh.epsc\)](https://www.phenxtoolkit.org/index.php?pageLink=browse.nimh.epsc) and translational research measures selected for use by scientists who are collecting data from human subjects in the early

stages of psychotic illness. These CDEs, along with selected measures from the [NIH Toolbox](http://www.healthmeasures.net/explore-measurement-systems/nih-toolbox) (<http://www.healthmeasures.net/explore-measurement-systems/nih-toolbox>) and the [Patient-Reported Outcomes Measurement Information System \(PROMIS\)](http://www.healthmeasures.net/explore-measurement-systems/promis) (<http://www.healthmeasures.net/explore-measurement-systems/promis>), may also be appropriate for the proposed project.

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

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

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82299) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=82299). Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

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

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Does the proposed approach have the potential to substantially reduce DUP in the target population of people with FEP?

Does the application justify the practical effect of the DUP reduction 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? Does the application adequately address both (1) the empirical basis for the anticipated effect size (e.g., citing data regarding the magnitude of the association between the target and the clinical endpoint of interest and/or effect sizes obtained in prior efficacy studies), and (2) the clinical meaningfulness of the anticipated increment in effects compared to existing approaches?

If the proposed DUP reduction approach is successful, is it scalable and could it be disseminated into practice given typically available resources (e.g., trained, skilled providers), typical service structures (including health care financing), and typical service use patterns?

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

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Do the qualifications of the PD/PI and other senior investigators include expertise in the identification and treatment of people with FEP and expertise in the service delivery systems or institutional or community settings in which the selected DUP reduction strategies would be embedded? Do research team members have complementary areas of expertise?

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

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Are novel strategies proposed for reducing DUP among people with FEP and/or measuring DUP in institutional or community treatment settings in the U.S.?

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity,

potential for information or potential to advance scientific knowledge or clinical practice?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address

- 1) the protection of human subjects from research risks, and
- 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Does the application present empirical data that support the feasibility and acceptability of the proposed strategy for reducing DUP? Does the project include a scientifically acceptable operational definition of DUP? Are methods described for obtaining reliable estimates of DUP in community or institutional programs? Does the project include DUP reduction for persons with FEP as a primary outcome?

As appropriate, will the plan for involving collaborations and/or input from community practice partners/providers, mental health service users, family members, policy makers and other relevant stakeholders inform the DUP reduction research strategy and the research plan and help to ensure the results will have utility?

Does the application adequately address the following, if applicable:

Study Design

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

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

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

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

How well does the study design address whether the intervention engages the mechanism that is presumed to underlie the DUP reduction intervention effects (the mechanism that accounts for changes in DUP)? To what extent does the application include (1) a well-supported conceptual framework that clearly identifies the target(s)/mechanism(s) and the empirical evidence linking the target(s)/mechanism(s) to DUP; (2) well justified plans for assessing engagement of the target(s)/mechanism(s), including the specific measures, the assessment schedule, and the justification for the assessment strategy (e.g., evidence regarding the validity and feasibility of the proposed measures in the effectiveness context); and (3) an appropriate analytic strategy and corresponding power calculations for data analyses that will be used to examine whether the intervention engages the target(s) and whether intervention-induced changes in the target(s) are associated with reduced DUP (i.e., mediation)? Is the study sufficiently powered to examine mediators of intervention effects? In the case of multi-component DUP reduction interventions, does the application specify the conceptual basis, assessment plan, and analytic strategy, as detailed above, for the target(s)/mechanism(s) corresponding to each intervention component, as appropriate in the effectiveness context?

When appropriate, for studies that involve preventive or therapeutic interventions, does the study take into account RDoC or RDoC-like constructs when defining the subject eligibility (inclusion), intervention targets or mechanisms, and outcomes, as feasible in the effectiveness setting?

Does the application include provisions for the assessment and monitoring of the fidelity of the DUP reduction intervention delivery via procedures that are feasible and valid for use in the intended settings?

When appropriate, are proposed secondary outcome measures validated and generally accepted by the field? Are stakeholder-relevant outcomes included, as appropriate (e.g., functioning, health services use)?

Are the trial design and description of the research protocol consistent with CONSORT guidelines, as appropriate?

For studies proposing adaptations of existing interventions for broader use, is the justification for the proposed adaptation based on data describing characteristics of subgroups of individuals, settings, care providers or other relevant variables that are associated with partial or non-response to or poor uptake of DUP reduction strategies?

As relevant, will the trial contribute to advancing the personalization of mental health care? If relevant, does it include collection of clinical and biological variables (e.g., blood for genetic analysis, other potential biomarkers), as appropriate, that might be used to inform or test algorithms for more prescriptive approaches? Will the study have either adequate statistical power to test for moderators or the potential to

contribute information to larger databases for future use?

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?

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

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

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

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

As appropriate, are the plans achievable for establishing necessary agreements with all partners (e.g., single IRB) in a timely manner?

Does the study utilize existing infrastructure (e.g., practice-based research networks, electronic medical records, administrative data bases, patient registries, or other available resources) or utilize other available resources to increase the efficiency of participant recruitment and data collection or provide justification in the event that such efficiencies cannot be incorporated?

Additional Review Criteria

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

Study Timelines

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

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

Protections for Human Subjects

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

for clinical trials.

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

Inclusion of Women, Minorities, and Individuals Across the Lifespan

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

Vertebrate Animals

Not Applicable

Biohazards

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

Resubmissions

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

Renewals

Not Applicable

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

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

Applications from Foreign Organizations

Not Applicable

Select Agent Research

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

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) [Data Sharing Plan \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11151\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) [Sharing Model Organisms \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11152\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) [Genomic Data Sharing Plan \(GDS\) \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11153\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by NIMH, in accordance with [NIH peer review policy and procedures \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11154\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated [review criteria](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

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

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

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

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11156\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

[id=11157](#)).

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

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](#). Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the [Award Conditions and Information for NIH Grants \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11158\)](#) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

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

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

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

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

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

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement](#) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11120](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)) as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](#) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11157](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157)) and [Part II: Terms and Conditions of NIH Grant](#)

[Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11159) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11159](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11159)). More information is provided at [Award Conditions and Information for NIH Grants](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11158](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158)).

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

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html>). The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html>); and <https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html> (<https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html>).

Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <https://www.hhs.gov/civil-rights/for-individuals/disability/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/disability/index.html>). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <https://www.hhs.gov/ocr/about-us/contact-us/index.html> (<https://www.hhs.gov/ocr/about-us/contact-us/index.html>) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53> (<http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>).

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative

agreements except fellowships.

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 \(RPPR\) \(//grants.nih.gov/grants/rppr/index.htm\)](https://grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the [NIH Grants Policy Statement. \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11161\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11161)

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

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

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

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

Application Submission Contacts

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

Finding Help Online: <http://grants.nih.gov/support/> (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

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

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

Telephone: 301-945-7573

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

Contact Center Telephone: 800-518-4726

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

Scientific/Research Contact(s)

Susan T. Azrin, Ph.D.

National Institute of Mental Health (NIMH)

Telephone: 301-443-3267

Email: susan.azrin@nih.gov (<mailto:susan.azrin@nih.gov>)

Peer Review Contact(s)

Nick Gaiano, Ph.D.

National Institute of Mental Health (NIMH)

Telephone: 301-827-3420

Email: nick.gaiano@nih.gov (<mailto:nick.gaiano@nih.gov>)

Financial/Grants Management Contact(s)

Tamara Kees

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

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) (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) (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) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

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

[Weekly TOC for this Announcement](http://grants/guide/WeeklyIndex.cfm?04-05-19) (<http://grants/guide/WeeklyIndex.cfm?04-05-19>)

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



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