Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH)

Components of Participating Organizations

National Institute of Mental Health (NIMH)

Funding Opportunity Title

Pilot Studies to Test the Initiation of a Mental Health Family Navigator Model to Promote Early Access, Engagement and Coordination of Needed Mental Health Services for Children and Adolescents (R34 Clinical Trial Required)

Activity Code

R34 Planning Grant

Announcement Type

Reissue of PAR-21-292

Related Notices

See Notices of Special Interest associated with this funding opportunity

NOT-OD-22-195 New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023

NOT-OD-22-189 Implementation Details for the NIH Data Management and Sharing Policy

NOT-OD-22-198 Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023

NOT-OD-23-012 Reminder: FORMS-H Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available

Funding Opportunity Announcement (FOA) Number

PAR-23-104

Companion Funding Opportunity

PAR-23-094, R01 Research Project

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.242

Funding Opportunity Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to encourage research applications to develop and pilot test the effectiveness and implementation of existing family navigator models designed to promote early access, engagement, coordination and optimization of mental health treatment and services for children and adolescents who are experiencing early symptoms of mental health problems. For the purposes of this FOA, NIMH defines a family navigator model as a health care professional or paraprofessional whose role is to deploy a set of strategies designed to rapidly engage youth and families in needed treatment and services, work closely with the family and other involved treatment and service providers to optimize care, and through the use of technology – to monitor the trajectory of mental health symptoms and outcomes over time. Applicants are required to develop and pilot test the navigator model's ability to promote early access, engagement, coordination and optimization of mental health treatment and services for children and adolescents as soon as symptoms are detected. Applicants are also required to identify and pilot test components of navigator models that drive improvements in mental health care; detect and interrogate tailoring variables that optimize the 'personalized match' between the unique mental health needs of youth to the appropriate level of intensity and frequency of mental health services; and utilize emerging novel technologies to track and monitor the trajectory of clinical, functional and behavioral progress toward achieving intended services outcomes.

This FOA is published in parallel to a companion R01 FOA, PAR-23-094 which uses the R01 funding mechanism.

Key Dates

Posted Date

January 13, 2023

Open Date (Earliest Submission Date)

January 16, 2023

Letter of Intent Due Date(s)

30 days prior to application due date

The following table includes NIH standard due dates marked with an asterisk.

Application Due Dates			Review and Award Cycles		
	Renewal / Resubmission			**Advisory**	

New	/ Revision (as allowed)	AIDS	Scientific Merit Review	Council Review	Earliest Start Date
February 16, 2023 *	March 16, 2023 *	Not Applicable	July 2023	October 2023	December 2023
June 16, 2023 *	July 16, 2023 *	Not Applicable	November 2023	January 2024	April 2024
October 16, 2023 *	November 16, 2023 *	Not Applicable	March 2024	May 2024	July 2024
February 16, 2024 *	March 16, 2024 *	Not Applicable	July 2024	October 2024	December 2024
June 16, 2024 *	July 16, 2024 *	Not Applicable	November 2024	January 2025	April 2025

All applications are due by 5:00 PM local time of applicant organization.

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.

Expiration Date

September 08, 2024

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options 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 to track your application. Check with your institutional officials regarding availability.
3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to encourage research applications to develop and pilot test the effectiveness and implementation of existing family navigator models designed to promote early access, engagement, coordination and optimization of mental health treatment and services for children and adolescents who are experiencing early symptoms of mental health problems. For the purposes of this FOA, NIMH defines a family navigator model as a health care professional or paraprofessional whose role is to deploy a set of strategies designed to rapidly engage youth and families in needed treatment and services, work closely with the family and other involved treatment and service providers to optimize care, and through the use of technology – to monitor the trajectory of mental health symptoms and outcomes over time. Applicants are required to develop and pilot test the navigator model's ability to promote early access, engagement, coordination and optimization of mental health treatment and services for children and adolescents as soon as symptoms are detected. Applicants are also required to identify and pilot test components of navigator models that drive improvements in mental health care; detect and interrogate tailoring variables that optimize the 'personalized match' between the unique mental health needs of youth to the appropriate level of intensity and frequency of mental health services; and utilize emerging novel technologies to track and monitor the trajectory of clinical, functional and behavioral progress toward achieving intended services outcomes.

Background

The onset of mental illnesses frequently occurs during childhood or adolescence. National data indicate that nearly half (45%) of youth ages 4-17 with serious emotional and behavioral difficulties do not receive mental health treatment. Among children and adolescents with emotional and behavioral difficulties that do not meet diagnostic threshold criteria, parents reported that 80% do not receive needed mental health treatment. Studies suggest that early mental illness symptoms reported in late childhood and early adolescence – if left untreated – are likely to develop into psychological disorders with long-lasting effects well into adulthood.

Traditional mental health services and coordinated care for youth have historically been provided at later time points, often after symptoms have worsened and have caused significant impairment and distress for youth and family members. Families attempting to negotiate complex health care referral processes often encounter difficulties accessing and receiving needed mental health services (e.g., youth experiencing symptoms of anxiety, depression or suicidal ideation, yet are not deemed to be at sufficient risk for psychiatric treatment or hospitalization). In addition, many youth who experience these problems represent underserved populations and thus, are less likely to access or receive needed mental health treatment and services.

Research findings suggest that early intervention programs, similar to the Coordinated Specialty Care model tested in the Recovery After an Initial Schizophrenia Episode (RAISE) research project, are effective at interrupting the developmental trajectory of mental illnesses, and improving clinical and functional outcomes for children and adolescents. In related areas such as Autism Spectrum Disorder, recent research suggests that early detection and referral to services leads to improved outcomes among young children. Several studies testing early intervention programs have reported that variations on the use and type of navigator models across a number of health care fields (e.g., cancer, substance abuse, cardiovascular care) have been found to be effective.

The mental health field has initiated the use of navigator models – primarily with adults across a variety of settings. In one model, the navigator serves as the primary mental health clinician and provides care coordination activities for adults with serious mental illness. Another model utilizes a navigator who is a health care professional with mental health expertise (e.g., care coordinator, case manager) who coordinates the needed care but does not provide the primary mental health treatment. A third navigator model consists of peer-professionals teaching health care self-management to adults, providing treatment monitoring and encouraging follow-up with needed services.

NIMH is interested in pilot testing the effectiveness and implementation of a navigator model when delivered to children and adolescents as soon as symptoms are detected. Important knowledge gaps include understanding the key components of navigator models that:

- Increase our understanding of navigator components that drive improvements in mental health care;
- Identify and pilot test tailoring variables that optimize the 'personalized match' between the level of need and available mental health services;
- Employ innovative technologies (e.g., dashboards, digital tools, real-time analytics) to enhance engagement, monitor symptoms, match youth need to available mental health resources and evaluate treatment progress;
- Identify opportunities to reduce disparities in mental health outcomes among underserved populations;
- Enhance access, engagement, coordination and optimization of needed mental health services; and
- Improve clinical, functional and behavioral outcomes for children and adolescents.

Research Objectives

The goal of this FOA is to support pilot work in preparation of larger scale projects that will develop and test navigator models that promote early access, engagement, coordination and optimization of mental health treatment and services for children and adolescents who are experiencing early symptoms of mental health problems. This initiative aims to pilot test navigator models that: (1) identify and test components of family navigator models that drive clinical improvements in mental health care; (2) detect and interrogate tailoring variables that optimize the 'personalized match' between the unique mental health needs of youth to the appropriate level of intensity and frequency of mental health services; (3) utilize emerging novel technologies to track and monitor the trajectory of clinical, functional and behavioral progress toward achieving intended services outcomes; (4) rapidly engage and work closely with youth and family members over an extended period of time to ensure that therapeutic gains (e.g., reduction in symptoms, improved family, peer and school functioning and improved behavioral outcomes) are maintained and sustained; and (5) increase our understanding about how navigator models reduce health disparities.

This FOA is intended to support applications that pilot test personalized navigation approaches that deliver the appropriate amount, intensity and frequency of needed treatment and services as symptoms wax and wane over time. NIMH requires applications to utilize innovative technology (e.g., dashboards, therapeutic milestone measurement, mobile assessment, sensory processing, digital tools, real-time analytics) to assist navigators in engaging, facilitating and optimizing personalized mental health care for each child and adolescent. When possible, applications should incorporate health information technology (HIT) and embed technologies in electronic health records (EHR) to coordinate care across delivery settings and enhance sustainability.

Navigator models to be developed and pilot tested may include but are not limited to the following: (a) mental health clinicians who provide evidence-based treatment directly to the youth and family and also serve as family navigators by monitoring coordinated care and communication with the other involved treatment and service providers; (b) health care professionals with mental health expertise (e.g., nurses, social workers, counselors) who are not responsible for providing the

primary mental health treatment, yet serve as family navigators; or (c) paraprofessionals trained in mental health education and in the application of proven engagement approaches (e.g., motivational interviewing) who serve as family navigators. Each model will develop and pilot test a set of strategies deployed by the navigator designed to promote early access, engagement, coordination and optimization of mental health treatment and services.

For the purpose of this FOA, only navigator programs that have already been established are eligible and are more likely to rapidly launch and pilot test innovative approaches within the lifetime of the project. Navigator model settings may be located in mental health clinics, public health agencies (e.g., child welfare and juvenile justice), schools, primary care or other settings. Navigators should work closely and be integrated with other treatment and service providers to facilitate and monitor routine communication to the treatment providers, youth and family members. It is anticipated that referrals to a navigator may occur through a range of referral sources (e.g., caregiver, teacher, healthcare provider), depending on the navigator model, and can occur before a formal mental health assessment or screening takes place. Navigator functions should include the following components: (a) reducing systemic barriers to care (e.g., coordination of screening, diagnosis and ongoing care from a range of treatment providers); (b) delivering mental health information, education and psychosocial support to caregivers and youth; (c) utilizing engagement strategies to increase treatment adherence; (d) utilizing novel and emerging technological approaches (e.g., mobile assessment, sensory processing, digital tools, real-time analytics) to match the unique mental health needs of youth to community resources and/or telehealth services; and (e) problem-solving challenges in accessing mental health resources (e.g., healthcare coverage, telehealth services, transportation, childcare).

A variety of rigorous methodological approaches are possible for testing the impact of the proposed navigator model. These approaches may include randomized controlled trials, quasi-experimental designs with non-randomized comparison groups, time series designs, and other designs of equivalent rigor and relevance. Considerations for selecting a research design 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.

Navigator training needs will vary among different models and applicants are required to provide a description of the training required for the proposed model. For example, when the navigator is a mental health professional, training may focus more on care coordination, availability of local resources and utilization of novel technologies, while navigators who are paraprofessionals may need supplemental training on mental health symptoms and treatment, family dynamics and the principles of engagement. All models should consider the need for ongoing supervision of or consultation with the navigator to achieve fidelity and sustainability of the model. Applicants are also encouraged to provide justification of both the likelihood of achieving the intended outcomes and the potential for broad uptake and implementation, should a tested model prove to be effective.

Responsive Areas of Research

Consistent with the NIMH experimental therapeutics approach, applications are required to provide a strong theoretical rationale for the selected targets or mechanisms of action hypothesized to lead to the intended outcomes of the proposed navigator model, measure whether those targets are engaged during the navigator intervention delivery, and design the study to test whether target engagement mediates the outcome of the navigator intervention (see Support for Clinical Trials at NIMH). Active elements of the model might occur at the navigator, treatment team (involved treatment and service providers), supervisor, interagency and/or community level, and appropriate studies should clearly describe and include such factors in the conceptualization of the intervention and in the design of the study. For more information about measurement of target engagement, see PAR-21-131, "Pilot Effectiveness Trials for Treatment, Preventive and Services Interventions (R34)".

Applicants are required to propose a navigator model that:

- Identifies factors that facilitate sustainability (e.g., utilization of existing navigator programs, shared public and private funding, enhanced economic strategies), scalability and generalizability to other settings;
- Utilizes innovative technology (e.g., dashboards, therapeutic milestone measurement, mobile assessment, sensory processing, digital tools, real-time analytics) to assist navigators in engaging, facilitating and optimizing personalized mental health care for each child and adolescent.

NIMH anticipates that studies funded by this FOA will substantially contribute to the development of the following:

- A body of generalizable knowledge regarding effective mental health navigation models;

- Identification of a set of research-informed strategies to improve care coordination;
- The use of novel technologies to tailor the 'personalized match' between the unique mental health needs of youth to the appropriate treatment and level of services;
- Enhance our understanding of the impact of navigator models on reducing mental health disparities among underserved populations.

This FOA uses the R34 activity code and runs in parallel to a companion R01 FOA, PAR-23-094, which supports empirical testing of navigator model strategies in full-scale trials in this topic area. The applicant should propose the developmental work to be performed that would enhance the probability of success in a full-scale trial. Proposed pilot studies must also meet the definition for a clinical trial. Designs need not be reduced scope versions of the anticipated larger study but should instead attempt to develop and refine the research strategies to be utilized in the subsequent large-scale study. NIMH recognizes that while the scope of interest for this FOA is consistent across both this and the companion PAR-23-094, there are specific research topics for which the field may not yet be ready for a large-scale trial. This FOA provides the opportunity for "high risk, high reward studies" that may be of high priority to the NIMH. Given the intended pilot nature of this FOA, conducting a fully powered test of outcomes is not required and obtaining an estimate of an effect size may not be possible.

Applications Not Responsive to this FOA

Applications proposing the following will be considered non-responsive to this FOA and will not be reviewed:

- Applications that propose to test the effectiveness of traditional therapeutic or preventive interventions, rather than testing navigator models that aim to identify components to improve access, engagement, coordination and optimization of services;
- Studies that propose testing task-shifting or other approaches to deliver traditional therapeutic or preventive interventions by paraprofessionals or other non-traditional therapists – without testing navigator components to improve care;
- Applications that propose to conduct studies with family navigator programs that have not yet been established nor have developed the infrastructure needed to quickly launch a pilot clinical trial;
- Studies that do not propose testing emerging technologies to assist navigators to optimize the 'personalized match' between the unique mental health needs of youth to the appropriate level of intensity and frequency of mental health services.

Potential applicants are strongly encouraged to contact Scientific/Research contacts as far in advance as possible to discuss the match between potential research applications and current NIMH priorities.

NIMH is committed to supporting research that reduces disparities and advances equity in mental health interventions, services and outcomes. Accordingly, this FOA encourages pilot phase research to identify opportunities to reduce disparities in access, engagement, coordination, and optimization of mental health treatment and services among youth from racial and ethnic minority groups, sexual and gender minority groups, or other underserved groups including individuals limited by language or cultural barriers, individuals living in rural areas, or socioeconomically disadvantaged persons.

Protections for Human Subjects: Applications with data collection plans that involve multiple respondent groups (e.g., clients/patients, therapists/providers, supervisors, administrators) should address provisions for human subject protections and consenting procedures for all participant groups, accordingly. The NIMH has published updated policies and guidance for investigators regarding human research protection and clinical research data and safety monitoring (NOT-MH-19-027). The application's Protection of Human Subjects section plans should reflect the policies and guidance in this notice. Plans for the protection of research subjects and data and safety monitoring will be reviewed by the NIMH for consistency with NIMH and NIH policies and federal regulations.

See Section VIII. Other Information for award authorities and regulations.

Investigators proposing NIH-defined clinical trials may refer to the Research Methods Resources website for information about developing statistical methods and study designs.

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

Resubmission from PAR-18-429, PAR-21-292 and PAR-23-104

Revision from PAR-17-266, PAR-18-429, PAR-21-292 and PAR-23-104

The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

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

Need help determining whether you are doing a clinical trial?

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are limited to $225,000 direct costs per year, and $450,000 in direct costs over the three year project period.

Award Project Period

The total project period for applications submitted in response to this FOA may not exceed three years

NIH grants policies as described in the NIH Grants Policy Statement 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)

Local 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)

Federal Government

- 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*, **are not** allowed.

Required Registrations

Applicant Organizations

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

- System for Award Management (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 – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
    - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; 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 – Applicants must have an active 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 diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019.

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

2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement.

3. Additional Information on Eligibility

Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per 2.3.7.4 Submission of Resubmission Application. 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 2.3.9.4 Similar, Essentially Identical, or Identical Applications)

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 instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

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

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

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

The letter of intent should be sent to:

Email: nimhpeerreview@mail.nih.gov

Page Limitations

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

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages.

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

SF424(R&R) Senior/Key Person Profile

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

R&R or Modular Budget

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

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

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

Research Strategy:

This FOA supports the development and/or pilot testing of new or adapted navigator models, pilot testing of navigator models with demonstrated efficacy in broader scale effectiveness trials, or conducting pilot innovative services research on navigator models that requires preliminary testing or development. Because this is a clinical exploratory/developmental grant application, it need not have extensive background material or preliminary information as one might normally expect in an R01 application. Accordingly, applicants will emphasize the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Applicants will place less emphasis on methodological details and certain indicators traditionally used in evaluating the scientific merit of R01 applications, including supportive preliminary data. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator generated data. Preliminary data and power analyses are not required for R34 applications, but may be included if available.

Applications should include the following:

***Significance**:*

- Describe the potential public health impact of the proposed strategy, and how the proposed pilot work will contribute to the development of a navigator model intended to promote early access engagement, coordination and optimization of needed mental health services for children and adolescents
- Describe a developmental process that is likely to produce a navigator model that could be implemented in typical service settings using typically available resources and personnel.
- Describe how the proposed pilot work will demonstrate the feasibility of conducting a subsequent test of the effectiveness of the navigator model in a future large-scale project.
- Provide evidence that the developmental process is likely to enhance the navigator model's potential for implementation and future uptake in diverse settings.
- Identify how the proposed project will pilot test navigator components that drive improvements in mental health care – and how they will facilitate sustainability, scalability and enhance the navigator model's potential for implementation and future uptake in diverse settings.
- Describe how the navigator model may reduce or eliminate racial, ethnic, gender or socio-economic disparities in the delivery of mental health interventions and services.

Innovation:

- Describe any innovations in navigator model development, feasibility testing, research strategy, design or analytic approach, if they are employed, and how these may enhance the potential value of study results.
- Describe the use of innovative technologies (e.g., use of dashboards, outcome tracking, and therapeutic milestone measurement, incorporation of health information technology) to assist navigator models in delivering personalized mental health care for each child and adolescent.
- Identify new approaches to promote early access, engagement and coordination of mental health treatment and services for children and adolescents who are exhibiting early symptoms of mental health problems.

Approach:

- This FOA is intended to explicitly inform our understanding of whether the services intervention engages the target(s)/change mechanism(s) that are presumed to underlie downstream changes in access, engagement and coordination. Accordingly, the application should address: (1) the empirical basis for the selection of the proximal targets/change mechanisms; (2) the approach used for assessing target engagement (specific measures that will be used to assess changes in the putative proximal targets/ change mechanisms); and (3) the analysis plan that will be used to determine whether the intervention leads to changes in the targets/ change mechanisms, and whether changes in these targets account for changes in the services outcomes.
- Describe the proposed method for assessing the effectiveness and implementation of a navigator model and specify the research strategies that will be used to measure the active attributes of the navigator model, clinical progress and clinical, functional and behavioral outcomes.

- Describe plans to promote long-term sustainability by incorporating stakeholder perspectives to enhance partnerships with public and private agencies, healthcare systems, and community programs. Describe the steps for navigator model development/refinement and a clear rationale for the choice of methods proposed.
- As needed for the subsequent large-scale project description(s) of: refining details of the navigator model, examine the feasibility of novel approaches and technologies; enhancing the protocol for the comparison group and randomization procedures (if appropriate); examining the feasibility of recruiting and retaining participants into the study condition(s); and developing supportive materials such as training curricula for the navigators.
- Describe how a strategy for navigator model fidelity monitoring will be established for use in the subsequent large-scale project.
- 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 how the proposed navigator model will improve care coordination strategies and optimize the 'personalized match' with appropriate treatment and services (e.g., under what conditions might navigators and their use of technology determine the needed amount, frequency and intensity of mental health services) to ensure that therapeutic gains are maintained over time.

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.

Other Plan(s):

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages.

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

- All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

To advance 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 Institute of Mental Health Data Archive (NDA; see NOT-MH-19-033). Established by the NIH, NDA is a secure informatics platform for scientific collaboration and data-sharing that enables the effective communication of detailed research data, tools, and supporting documentation. NDA 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 NDA.

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 NDA web site provides two tools to help investigators develop appropriate strategies: 1) the NDA Data Submission Cost Model which offers 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 available from the NDA's Data Contribution page. Investigators are expected to certify the quality of all data generated by grants funded under this FOA prior to submission to NDA 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 NDA Sharing Regimen for more information); Investigators are expected to share results, positive and negative, specific to the cohorts and outcome measures studied. The NDA Data Sharing Plan is available for review on the NDA website. NDA staff will work with investigators to help them submit data types not yet defined in the NDA Data Dictionary.

Appendix:

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

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the

Appendix.

PHS Human Subjects and Clinical Trials Information

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

Note: Delayed onset 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, the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration. 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.

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.

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

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. 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 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 fieldof the Senior/Key Person Profile form**.** 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 unique entity identifier provided on the application is the same identifier 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 for avoiding common errors.

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

Use of Common Data Elements in NIH-funded Research

Many NIH ICs encourage 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.

NIMH has released expectations for collecting common data elements when an application involves human research participants. Details can be found at NOT-MH-20-067 and the NIMH webpage on Data Sharing for Applicants and Awardees.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described 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 are evaluated for scientific and technical merit through the NIH peer review system.

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) will not be evaluated at time of review.

This FOA supports the development and/or pilot testing of new or adapted navigator models, pilot testing of navigator models

with demonstrated efficacy in broader scale effectiveness trials, or conducting pilot innovative services research on navigator models that requires preliminary testing or development. Because this is a clinical exploratory/developmental grant application, it need not have extensive background material or preliminary information as one might normally expect in an R01 application. Preliminary data and power analyses are not required for R34 applications, but may be included if available.

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?

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?

- Does the application adequately describe how the proposed pilot work will contribute to the development of a navigator model intended to promote early access, engagement, coordination and optimization of mental health treatment and services for children and adolescents who are experiencing early mental health symptoms?
- Does the application identify how the proposed project will pilot test navigator components that drive improvements in mental health care – and how they will facilitate sustainability, scalability and enhance the navigator model’s potential for implementation and future uptake in diverse settings?
- Does the project describe how the navigator model may reduce or eliminate racial, ethnic, gender or socio-economic disparities in the delivery of mental health interventions and services?
- Does the description of the developmental process of the navigator intervention provide strong evidence that it is likely to produce a navigator model that could be implemented in typical services settings using typically available resources and personnel? How well does the application justify that the developmental process is likely to enhance the navigator model's potential for implementation and future uptake in diverse settings across the U.S.? How well does the description of the proposed pilot work demonstrate the feasibility of conducting a subsequent test of the effectiveness of the navigator model in a future R01?

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?

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?

- For the Senior/Key Personnel proposed, is there appropriate evidence of their experience and expertise at collaborating with community practice partners/providers, consumers, and relevant entities?

Innovation

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

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

- Does the application describe any innovations in navigator model development, feasibility testing, research strategy, design or analytic approach, if they are employed, and how these may enhance the potential value of study results?
- Is there a description of innovative technologies (e.g., dashboards, digital tools, mobile assessment, real-time analytics, sensory processing, digital tools) to assist navigator models in delivering the ‘personalized match’ between the unique mental health needs of youth and the appropriate level of mental health care?
- Does the application identify new approaches to promote early access, engagement, coordination and optimization of mental health treatment and services for children and adolescents who are exhibiting early symptoms of mental health problems?

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 adequately address the following, if applicable

Study Design

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

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines

feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

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

- Does the application describe the proposed method for assessing the effectiveness and implementation of a family navigator model and specify the research strategies that will be used to monitor coordinated care strategies, clinical progress and measure clinical, functional and behavioral outcomes? Does the application describe plans to promote long-term sustainability?
- Does the application provide sufficient empirical basis for the proposed targets/mechanisms that are presumed to account for changes in access, engagement, coordination and optimization of mental health services? Is there a feasible plan for assessing target engagement? Is there an adequate description of the analysis plan to determine whether the intervention leads to changes in the targets/mechanisms?
- How well does the application provide an adequate justification for using validated measures? For any new measures that will be validated in the course of the pilot work, how scientifically sound is the process by which this will occur? How well does the described work demonstrate the feasibility of collecting data with these measures in the future large scale project?
- As needed for the subsequent large scale project, how sound and adequate are the plans for: working out the details of the assessment and navigator model protocols, and for comparison group and randomization procedures (if appropriate); determining the needed time-frame and feasibility of recruiting and retaining study participants/sites; and developing operational materials such as training manuals for the navigator model-delivery personnel? How well does the application justify the strategy for intervention fidelity monitoring and its feasibility for use in the subsequent large-scale project?
- How adequate is the description of how the intervention strategy may reduce or eliminate racial, ethnic, gender or socio-economic disparities in the delivery of services and interventions? How sound and feasible are the plans to involve collaborations and/or input from community practice partners/providers, consumers and relevant decision-makers, as appropriate?
- Does the application utilize a deployment-focused approach (e.g., the incorporation of stakeholder perspectives, consideration of financial/workforce resources and clinical/administrative routines) in order to ensure a feasible, practice-ready navigator model and ensure the results will have utility for end-users?
- Is there a description regarding how navigator models will utilize technology to improve care coordination strategies and optimize the ‘personalized match’ with appropriate treatment and services to ensure that therapeutic gains are maintained over time?

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?

- How well does the description of the sites justify their selection for involvement in the research?

Additional Review Criteria

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

Study Timeline

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.

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.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animals Section.

Biohazards

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

Resubmissions

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

Renewals

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

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) will not be evaluated at time of review.

Reviewers will comment on whether the Resource Sharing Plan(s) (i.e., Sharing Model Organisms) or the rationale for not sharing the resources, is reasonable.

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, 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 will receive a written critique.

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.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

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

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons. 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.

Section VI. Award Administration Information

1. Award Notices

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

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

Recipients 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 website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

The NIMH has published policies and guidance for investigators regarding human research protection, data and safety monitoring, Independent Safety Monitors and Data and Safety Monitoring Boards, reportable events, and participant recruitment monitoring (NOT-MH-19-027). The application's PHS Human Subjects and Clinical Trials Information should reflect the manner in which these policies will be implemented for each study record. These plans will be reviewed by the NIMH for consistency with NIMH and NIH policies and federal regulations. The NIMH will expect clinical trials to be conducted in accordance with these policies including, but not limited to: timely registration to ClinicalTrials.gov, submission of review determinations from the clinical trial's data and safety monitoring entity (at least annually), timely submission of reportable events as prescribed, and establishment of recruitment milestones and progress reporting.

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). 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

Institutional Review Board or Independent Ethics Committee Approval: Recipient 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 recipient 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 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 as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities, including of note, but not limited to:

- Federal wide Research Terms and Conditions
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment
- Acknowledgment of Federal Funding

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which the recipient agrees, as a term and condition of receiving the grant, to administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html

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.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.htmlandhttps://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see https://www.hhs.gov/civil-rights/for-individuals/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.

- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/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 or call 1-800-368-1019 or TDD 1-800-537-7697.

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 and 2 CFR Part 200.206 "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. Data Management and Sharing

Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023.

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement. Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the NIH Grants Policy Statement.

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. NIH FOAs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the NIH Grants Policy Statement 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: https://www.era.nih.gov/need-help (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 (preferred method of contact)
Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov

Scientific/Research Contact(s)

Mary Acri, Ph.D.
National Institute of Mental Health (NIMH)
Telephone: 301-910-8230
Email: mary.acri@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

Financial/Grants Management Contact(s)

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

Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75 and 2 CFR Part 200.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

National Institutes of Health
Office of Extramural Research

Department of Health
and Human Services (HHS)

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