

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

Funding Opportunity Title

Mental Health Research Awards for Investigators Early in their Career in Low and Middle-Income Countries (R01 Clinical Trial Optional)

Activity Code

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

Announcement Type

New

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-MH-21-120

Companion Funding Opportunity

None

Number of Applications

See [Section III. 3. Additional Information on Eligibility](#).

Assistance Listing Number(s)

93.242

Funding Opportunity Purpose

Mental illnesses are a global concern, presenting shared opportunities to advance science across international boundaries. The goal of this initiative is to support the scientific work and research career development of exceptionally talented scientists who are in the early, formative stages of their careers and who plan to make a long-term career commitment to mental health research. This initiative seeks to assist these researchers in launching an innovative basic, translational, clinical, or services research program that holds the potential to transform the understanding, prevention, diagnosis, or treatment of mental illnesses in low resource international settings.

Key Dates

Posted Date

February 23, 2021

Open Date (Earliest Submission Date)[October 14, 2021](#)**Letter of Intent Due Date(s)**[October 14, 2021](#)

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
November 15, 2021	Not Applicable	Not Applicable	March 2022	May 2022	July 2022

All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s).

[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.](#)

No late applications will be accepted for this Funding Opportunity Announcement

Expiration Date

November 16, 2021

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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)](#), except where instructed to do otherwise (in this FOA or in a Notice from [NIH Guide for Grants and Contracts \(//grants.nih.gov/grants/guide/\)](#)).

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 \(http://public.era.nih.gov/commons/\)](#) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-MH-21-120\)](#) Workspace to prepare and submit your application and [eRA Commons \(http://public.era.nih.gov/commons/\)](#) to track your application.

Table of Contents

[Part 1. Overview Information](#)

[Key Dates](#)

[Part 2. Full Text of Announcement](#)

[Section I. Funding Opportunity Description](#)

[Section II. Award Information](#)

[Section III. Eligibility Information](#)

[Section IV. Application and Submission Information](#)

[Section V. Application Review Information](#)

[Section VI. Award Administration Information](#)

[Section VII. Agency Contacts](#)

[Section VIII. Other Information](#)

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Research Objectives

The mission of NIMH is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for recovery, prevention, and cure. This mission includes supporting the next generation of exceptionally talented and creative scientists who are dedicated to producing the scientific knowledge that will help to prevent, treat, and ultimately cure mental illnesses across diverse populations. Investigators from low- and middle-income countries (LMICs, [World Bank designated](#) (<https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>) low- and middle-income countries (LMICs) and previously designated LMICs re-categorized as high income on or after January 1, 2021) are currently underrepresented in mental health research, curtailing **their** ability to partner and learn with other countries in conducting research on shared priorities. **This underrepresentation also inhibits our ability to incorporate the full range of genetic, cultural, social, and environmental variability found worldwide in mental health research, and thereby to better understand the mechanisms that underlie mental illnesses and identify new and better intervention targets.**

In order to identify outstanding basic, translational, clinical, and services investigators and assist them in launching innovative research programs at an early stage in their career, the NIMH established the Biobehavioral Research Awards for Innovative New Scientists (BRAINS) program in 2009 (see [RFA-MH-20-525](#) (<https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-20-525.html>)). The BRAINS program provides a unique opportunity for innovative investigators, early in their career, **to advance NIMH research with applications that demonstrate a high level of risk, ambitious research plans, and a lower emphasis on preliminary data than is generally required for research awards.** This initiative will complement the BRAINS program by supporting similarly talented investigators, early in their career, from LMICs (see specific eligibility criteria in section III), who are conducting research that aligns with [NIMH scientific priorities](#) (<https://www.nimh.nih.gov/about/strategic-planning-reports/index.shtml>). These priorities include, but are not limited to: **enhancing our fundamental understanding of mental illnesses**, transforming prevention and treatment of mental illnesses, and translating evidence into practice and policy.

Research Scope and Goals

This Funding Opportunity Announcement (FOA) seeks to support the scientific work and research career development of exceptionally talented scientists, from LMICs, who are in the early, formative stages of their careers and who plan to make a long-term career commitment to mental health research (see specific eligibility criteria in section III). This FOA seeks to assist these individuals in launching an innovative clinical, translational, basic or services research program that holds the potential to enhance our fundamental understanding of mental illnesses, transform prevention and treatment of mental illnesses, and/or to translate evidence into practice and policy in low resource international settings. **This program is designed specifically to support unusually creative investigators with highly innovative research ideas that may lack preliminary data necessary for a traditional R01. Accordingly, preliminary data are not required or expected but may be included to demonstrate feasibility.**

The program emphasizes both the potential of the PD/PI to be a future leader in the field while promoting innovative and generalizable research that addresses NIMH and LMIC relevant research priorities.

In addition, this initiative strongly encourages national and international partnerships and collaborations, within country or across countries government agencies, NGOs, health care institutions, organizations, and /or across other sectors (e.g., education,

employment, social welfare, and justice settings) in order to be responsive to local needs and to increase the likelihood of long-term sustainability. **All collaborations should directly promote the scientific goals of the project while preserving the leadership role of the LMICs investigators.** Thus, building additional resources to enhance LMIC Mental Health research cadre and capacity.

NIMH encourages applicants to consider RDoC or RDoC-like constructs when defining intervention targets and outcomes, as feasible in the setting and appropriate (see the [RDoC webpage \(https://www.nimh.nih.gov/research/research-funded-by-nimh/rdoc/index.shtml\)](https://www.nimh.nih.gov/research/research-funded-by-nimh/rdoc/index.shtml) for more details).

Potential applicants are encouraged to consult the recent [National Advisory Mental Health Council Genomics Workgroup \(https://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/report-of-the-national-advisory-mental-health-council-workgroup-on-genomics.shtml\)](https://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/report-of-the-national-advisory-mental-health-council-workgroup-on-genomics.shtml) report and [research recommendations summary \(https://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/namhc-genomics-workgroup-research-recommendations-summary.shtml\)](https://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/namhc-genomics-workgroup-research-recommendations-summary.shtml) which describe NIMH priorities for genetics research on the etiology of mental disorders.

Applicants must have a long-term commitment to a career in research on any of the following: causes, diagnosis, treatment and/or prevention of mental illnesses focusing on the research priorities and gap areas in LMICs that align with the NIMH Strategic Plan (https://www.nimh.nih.gov/about/strategic-planning-reports/index.shtml).

This initiative is distinguished from most other research initiatives/opportunities in that the projects should include a statement of career goals relevant to the research priorities and gap areas in LMICs that align with the NIMH Strategic Plan; active participation of an external advisory committee; and a commitment from the institution to actively support the proposed research and the career development of the PD/PI. **Applicants are strongly encouraged to contact NIMH Scientific/Research staff prior to submission to determine if their project meets the goals of the program.**

Project effort for mentored [K43 \(https://grants.nih.gov/grants/guide/pa-files/PA-19-098.html\)](https://grants.nih.gov/grants/guide/pa-files/PA-19-098.html)-awardees: Mentored K43 awardees are encouraged to seek R01 or equivalent funding to support their research programs. Therefore, the NIMH expects that such awardees may be particularly interested in seeking support through this program. Such PDs/PIs are encouraged to consult with their mentored K43 Program Official at NIH prior to submission to ensure that the large effort commitments of both awards are feasible for their individual circumstance. However, **since this program requires a minimum of 6 person-months per year,** K43-Awardees should not apply unless they will be in the final two years of the K43-Award at the time of this award in light of NIH policy limiting reduction in minimum required percent effort for K43 recipients (see [NOT-OD-18-156 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-156.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-156.html)).

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 \(https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html)). The application's PHS Human Subjects and Clinical Trials Information, including the Data and Safety Monitoring Plan, should reflect the policies and guidance in this notice. Plans for the protection of research participants and data and safety monitoring will be reviewed by the NIMH for consistency with NIMH and NIH policies and federal regulations.

Applications may propose new studies or secondary data analyses. Applications to conduct secondary data analyses must demonstrate the sufficiency of existing data sets in both quantity and quality to test hypothesized mediational pathways or to generate new hypotheses using computational and/or data science analytic approaches.

For Clinical Trials: applications that propose primary data collection must specify the models, variables, and measures that will be used to identify and test potential pathways and mechanisms that may account for changes in key outcomes. Proposed studies should be consistent with the NIMH [experimental therapeutics approach. \(http://www.nimh.nih.gov/about/director/2012/experimental-medicine.shtml\)](http://www.nimh.nih.gov/about/director/2012/experimental-medicine.shtml) Valid and reliable measures will provide useful information about pathways and mechanisms that may account for intervention effects. Accordingly, applicants should plan to use the most direct and objective measures possible in the study setting, including validated measures beyond self-reports and other subjective measures, where possible, and inclusion of measures that span more than one level of assessment if possible and appropriate.

Applications considered NOT responsive to this FOA are those which:

- **Propose research using animal or cell-based models.**

Technical Assistance Teleconference

A Technical Assistance teleconference will be held via Zoom (Webinar ID [160 830 1062 \(https://nih.zoomgov.com/j/1608301062\)](https://nih.zoomgov.com/j/1608301062)) for potential applicants on May 24, 2021 at 10:00am ET. Click [here \(https://nih.zoomgov.com/j/1608301062\)](https://nih.zoomgov.com/j/1608301062) to join. Please check the [NIMH Center for Global Mental Health website \(https://www.nimh.nih.gov/about/organization/cgmhr/index.shtml\)](https://www.nimh.nih.gov/about/organization/cgmhr/index.shtml) for webinar updates.

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

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. Only those application types listed here are allowed for this FOA.

Clinical Trial?

Optional: Accepting applications that either propose or do not propose clinical trial(s).

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

Funds Available and Anticipated Number of Awards

NIMH intends to commit \$2.5M in FY 2022 to fund 5 to 6 awards.

Award Budget

Application budgets are limited to \$500,000 in direct costs in any project year and need to reflect the actual needs of the proposed project.

Award Project Period

The scope of the proposed project should determine the project period. **The maximum project period is 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

Non-domestic (non-U.S.) Entities (Foreign Institutions)

Eligible organizations must be in a LMIC, as defined by The World Bank, and include research institutions in LMICs.

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

The submitting institution must be based in a Low or Middle-Income Country (LMIC). LMIC Definition: World Bank designated low- and middle-income countries (LMICs) (see [World Bank Data Helpdesk webpage \(https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups\)](https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups)).

LMIC institutions are eligible to partner either with U.S. institutions or directly with other institutions with or without a U.S. partner. **An individual from a U.S. institution can serve as a co-investigator, consultant, other key personnel, but cannot serve as a PD/PI.**

Applicants are expected to devote at least 6 person months (50%), and preferably up to 9 person months (75%) effort to the grant. However, after three full years of funding for this grant, should the PD/PI be successful in obtaining funding through another R01 or similar award, the effort on this award may be negotiated with the NIMH program staff down to no less than 3.6 person months, (30%), if adequate progress has been made on the aims of this award. In addition, the awardees' departments are encouraged to provide an additional 3-3.6 person months (25-30%) release time from clinical, teaching, and administrative duties in order to allow the awardee to devote a larger amount of time to research effort.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as [defined in the NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11118\)](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 \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html\)](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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11176\)](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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](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 – 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.

Eligible PD/PI should have a primary appointment at an LMIC accredited institution.

Eligible PD/PI should be at early stages in their career which is defined as: completed his or her terminal degree (MD or PhD or equivalent) or medical residency—whichever date is later—within the past 15 years and has not yet competed successfully for a substantial, competing NIH research grant and/or foreign equivalent at the time of application submission. See definition of R01 Equivalent Grant (https://grants.nih.gov/grants/glossary.htm#R01EquivalentGrant).

Use of the multiple PD/PI format is encouraged but not required. All PD/PI must be from the LMIC institution and must also have completed their terminal degree within 15 years without substantial grant support (R01 or equivalent as defined above). **PD/PIs are expected to prepare the application jointly.**

U.S.-based HIC investigators are not eligible as the contact PD/PIs but may be included, especially if they present special opportunities for furthering research programs for the principal PD/PI, or if they can provide resources relevant to the proposed project that either are not readily available in the eligible LMICs.

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 instructions in 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.

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 (<mailto:nimhpeerreview@mail.nih.gov>)

Page Limitations

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

Primary performance site must be at a LMIC institution.

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.

The PD/PI is encouraged to budget sufficient travel costs to present results of the research at a variety of high-caliber technical meetings, at least one of which is devoted directly to mental health research and is widely attended by other NIMH grantees. A portion of the budget could include travel for external members of the advisory committee to meet yearly. In addition, the PD/PI should budget for travel to the NIH campus in Bethesda, MD, USA each year in years 3-5 to present a seminar or participate in a research symposium.

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:

Significance:

- Describe in detail what is the hypothesis or problem that will be addressed. If you are testing an unconventional, exceptionally novel hypothesis, please describe how does it challenge the standard paradigm. If no paradigm exists, describe how your project will create one.
- The potential impact: describe how testing your hypothesis is solving an important problem to the mission of the NIMH and LMICs. Explain how a successful outcome has the potential to transform our understanding of the underlying mechanisms of mental illness, translate research to the clinic in order to develop effective interventions, prevent onset, improve diagnostic accuracy, and/or create cures.

Innovation: State clearly and concisely what makes your project unusually innovative.

Approach: Provide enough information so that reviewers can determine what you are proposing to do. If your methodology is standard, what is unconventional and exceptionally innovative about your approach? How does your approach differ from what other investigators have attempted to do? If the approaches entail a high degree of risk, what will you do if these approaches are unsuccessful and how do the potential benefits/rewards outweigh the risks? If you are including collaborators on the project for aspects of the project that are not within your expertise, please describe their roles and how they will contribute to the success of the project and the research career advancement of the PD/PI. This information should not overlap with information in the biosketches.

The appropriateness of this program: Why is the proposed research uniquely suited to the stated goals of this initiative, rather than a conventional research grant application?

This initiative will not support studies focusing on animal or cell-based models.

If the application is proposing to utilize RDoC like constructs please refer to the guidance on the NIMH [RDoC website](https://www.nimh.nih.gov/research/research-funded-by-nimh/rdoc/index.shtml) (<https://www.nimh.nih.gov/research/research-funded-by-nimh/rdoc/index.shtml>) prior to submission.

If the proposed research will conduct secondary analyses of existing data sets, describe how the existing data sets in both quantity and quality are appropriate to test the hypothesized mediational pathways or to generate new hypotheses using computational and/or data science analytic approaches.

Timeline: Provide a timeline for the proposed research that does not overlap the Study Timeline submitted on the Human Subjects-Clinical Trial Information form, if applicable.

Advisory Committee: The PD/PI is expected to include the establishment of a to-be-named external advisory committee. It is very important that potential advisory board members not be contacted or identified in advance (i.e., in the application) to minimize conflicts during the review process. If an application is selected for funding, NIMH will request the names of advisory committee members as part of the Just-in-Time process. The application should indicate the areas of scientific expertise and anticipated input, and any critical considerations in the selection of potential members. Advisory committee members cannot be collaborators or consultants on the proposed project. The Advisory Committee is expected to meet at least annually to provide ongoing assessment of the progress of the research; to discuss future research goals, aims, and ideas; and to provide research career guidance to the awardee during the five years of the grant.

NIMH suggests an Advisory Committee structure such as the following: At least three scientists, two of whom are external to the Department, (one external to the University or Institution). One member should have research expertise similar to that of the PD/PI, and one should be an individual who is expert in human or clinical studies and who can provide input into the translation of the research. A schedule for the Advisory committee meetings should be included in the timeline. During the project period, the PD/PI will be expected to describe the proceedings of the advisory committee in annual progress reports.

Letters of Support: The Chair of the Department where the PD/PI holds the primary academic appointment must provide a letter describing any tangible research support that has been committed to the PD/PI. This may include start up packages provided to the investigator, salary commitment, protected time for research, space and equipment allocations, core facilities that will be made available without charge-back, specialized training and mini-sabbatical experiences to promote career enhancement, etc. In addition, the letter should discuss the departmental commitment to protected research time for the applicant. The department is encouraged to provide release time so that the applicant will be able to devote at least 6, and preferably up to 9 person months (75%) of his/her professional effort to research. The strength of the institutional support will be considered a factor in the review of the application.

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.

The following modifications also apply:

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

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 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.

Foreign Institutions

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

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

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

4. Submission Dates and Times

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

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

If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

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

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

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142). ([//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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120). ([//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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11143). ([//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) ([//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 and responsiveness by [components of participating organizations](#), NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy](#) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=82299](https://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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11149](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149)) are evaluated for scientific and technical merit through the NIH peer review system.

In addition, for applications involving clinical trials: 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?

In addition, for applications involving clinical trials

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is 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 past achievements of the PD/PI suggest that the investigator is exceptionally innovative and likely to make paradigm-shifting, high-impact discoveries relevant to mental illness?

In addition, for applications involving clinical trials

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

Innovation

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

Is the project original and innovative? Is the hypothesis and/or the proposed methodology unconventional and exceptionally innovative?

In addition, for applications involving clinical trials

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

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators 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?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

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

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

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

Data Management and Statistical Analysis

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

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Comment on the appropriateness of the strength of the Institutional support to the career advancement of PD/PI.

In addition, for applications involving clinical trials

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

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

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

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

Additional Review Criteria

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

Study Timeline

Specific to applications involving clinical trials

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSA, 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/url_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/url_redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11150\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

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

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

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

Applications from Foreign Organizations

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

Select Agent Research

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

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) [Data Sharing Plan \(//grants.nih.gov/grants/guide/redirect.htm?id=11151\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11151); (2) [Sharing Model Organisms \(//grants.nih.gov/grants/guide/redirect.htm?id=11152\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11152); and (3) [Genomic Data Sharing Plan \(GDS\) \(//grants.nih.gov/grants/guide/redirect.htm?id=11153\)](https://grants.nih.gov/grants/guide/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 \(//grants.nih.gov/grants/guide/redirect.htm?id=11154\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11154), using the stated [review criteria \(file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#/1.Criteria\)](file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#/1.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.

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

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. 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 \(//grants.nih.gov/grants/guide/redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/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 \(//grants.nih.gov/grants/guide/redirect.htm?id=11156\)](https://grants.nih.gov/grants/guide/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 \(//grants.nih.gov/grants/guide/redirect.htm?id=11157\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient'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 \(//grants.nih.gov/grants/guide/redirect.htm?id=11158\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

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 PHS Human Subjects and Clinical Trials Information, including the Data and Safety Monitoring Plan, should reflect the policies and guidance in this notice. Plans for the protection of research participants and data and safety monitoring will be reviewed by the NIMH for consistency with NIMH and NIH policies and federal regulations.

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: 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 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 and in the application instructions (SF424 (R&R) and PHS 398).

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

2. Administrative and National Policy Requirements

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

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. 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> (<https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html>) and <http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/section1557/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. HHS provides 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/fact-sheet-guidance/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html>) and <https://www.lep.gov> (<https://www.lep.gov>). 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 <https://minorityhealth.hhs.gov/omh/browse.aspx?vl=2&vlid=53> (<https://minorityhealth.hhs.gov/omh/browse.aspx?vl=2&vlid=53>).
- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>).

- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>); <https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html>; and <https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf> (<https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf>). 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> (<https://grants.nih.gov/grants/policy/harassment.htm>).
- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see <https://www.hhs.gov/conscience/conscience-protections/index.html> (<https://www.hhs.gov/conscience/conscience-protections/index.html>) and <https://www.hhs.gov/conscience/religious-freedom/index.html> (<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> (<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 "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) (<https://grants.nih.gov/grants/rppr/index.htm>) annually and financial statements as required in the NIH Grants Policy Statement (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11161)

A final 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 \(\[https://grants.nih.gov/grants/guide/url_redirect.htm?id=11161\]\(https://grants.nih.gov/grants/guide/url_redirect.htm?id=11161\)\)](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.fsrs.gov (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over \$25,000. See the NIH Grants Policy Statement (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.**

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/> ([//grants.nih.gov/support/](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)

For dissemination and implementation research and services research:

Andrea Horvath Marques, M.D., MPH, Ph.D.

National Institute of Mental Health (NIMH)

Telephone: 301-646-7320

Email: andrea.horvathmarques@nih.gov (<mailto:andrea.horvathmarques@nih.gov>)

For basic science:

Miri Gitik, Ph.D.

National Institute of Mental Health (NIMH)

Telephone: 301-827-3523

Email: miri.gitik@nih.gov (<mailto:miri.gitik@nih.gov>)

For translational research:

Eric R. Murphy, Ph.D.

National Institute of Mental Health (NIMH)

Telephone: 301-443-9230

Email: eric.murphy@nih.gov (<mailto:eric.murphy@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)

Telephone: 301-443-811

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) ([//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)

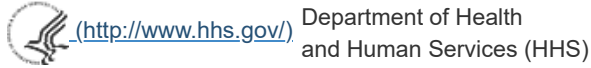
([//grants.nih.gov/grants/guide/url_redirect.htm?id=11164](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164)). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) ([//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 \(/grants/guide/WeeklyIndex.cfm?02-26-21\)](#)

[NIH Funding Opportunities and Notices \(/grants/guide/index.html\)](#)



NIH... Turning Discovery Into Health®

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