March 31, 2025

This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

Funding Opportunity Title

Innovative Mental Health Services Research Not Involving Clinical Trials (R01 Clinical Trials Not Allowed)

Activity Code

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

Announcement Type

Reissue of PAR-23-095 (https://grants.nih.gov/grants/guide/pa-files/PAR-23-095.html)

Related Notices

See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=42219) associated with this funding opportunity

- **March 31, 2025** - This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission.
- **April 4, 2024** - Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice NOT-OD-24-084 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html).
- **August 31, 2022**- Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198 (https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html).
- **August 5, 2022**- Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22-189 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html).

Funding Opportunity Number (FON)

PAR-25-283

Companion Funding Opportunity

PAR-25-284 (https://grants.nih.gov/grants/guide/pa-files/PAR-25-284.html), R34 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R34&&Search.x=0&&Search.y=0&&Search_Type=Activity) Planning Grant

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.242

Funding Opportunity Purpose

The purpose of this notice of funding opportunity (NOFO) is to encourage innovative research that will inform and support the delivery of high-quality, continuously improving mental health services to benefit the greatest number of individuals with, or at risk for developing, a mental illness. This announcement invites applications for non-clinical trial R01-level projects that address NIMH strategic priorities that strengthen the public health impact of NIMH-supported research as described in Goal 4 of the NIMH Strategic Plan (https://www.nimh.nih.gov/about/strategic-planning-reports/goal-4-strengthen-the-public-health-impact-of-nimh-supported-research).

This NOFO solicits research projects including, but not limited to the following: (a) research identifying mutable factors that impact access, continuity, utilization, quality, value, and outcomes, including disparities in outcomes, or scalability of mental health services, which may serve as targets in future service delivery intervention development, (b) research that develops and tests new research tools, technologies, measures, or methods and statistical approaches to study these issues, and/or (c) research that integrates and analyzes large data sets to understand factors affecting mental health services outcomes using advanced computational and predictive analytic approaches. Wherever possible, projects should leverage existing infrastructure and partnerships to accomplish these goals.

Funding Opportunity Goal(s)

The mission of the National Institute of Mental Health (NIMH) is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure.

Key Dates

Posted Date

December 30, 2024

Open Date (Earliest Submission Date)

January 05, 2025

The following table includes NIH standard due dates (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm) marked with an asterisk.

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
February 05, 2025 *	March 05, 2025 *	Not Applicable	July 2025	October 2025	December 2025
June 05, 2025 *	July 05, 2025 *	Not Applicable	November 2025	January 2026	April 2026
October 05, 2025 *	November 05, 2025 *	Not Applicable	March 2026	May 2026	July 2026
February 05, 2026 *	March 05, 2026 *	Not Applicable	July 2026	October 2026	December 2026
June 05, 2026 *	July 05, 2026 *	Not Applicable	November 2026	January 2027	April 2027
October 05, 2026 *	November 05, 2026 *	Not Applicable	March 2027	May 2027	July 2027
February 05, 2027 *	March 05, 2027 *	Not Applicable	July 2027	October 2027	December 2027

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
June 05, 2027 *	July 05, 2027 *	Not Applicable	November 2027	January 2028	April 2028
October 05, 2027 *	November 05, 2027 *	Not Applicable	March 2028	May 2028	July 2028

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

January 08, 2028

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 How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), except where instructed to do otherwise (in this NOFO or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.php?id=11164)).

Conformance to all requirements (both in the Application Guide and the NOFO) 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 (https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PAR-25-283) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Purpose

The healthcare landscape in the United States and globally is constantly changing, creating new challenges to the delivery of high-quality treatments and services to children, youth, adults, and older adults with unmet or under-met mental health needs. Epidemiological findings suggest that approximately one half of the United States population meets lifetime criteria for a mental illness, and approximately one fifth of people over 18-years-old meet criteria in any given year. However, only one half of people with any mental health disorder and only two thirds of adults with a serious mental health disorder received mental health services in the previous year. Among young adults with serious mental illness, approximately half received mental health services in the previous year. Of those that find their way into mental health care, many fall out of care and/or do not receive guideline-concordant treatment. Statistics for low and middle income countries (LMICs (https://pmc.ncbi.nlm.nih.gov/articles/PMC9185671/)) show even less coverage. Disparities in population status (e.g., members of racial and ethnic communities), a fragmented healthcare system, provider shortages, healthcare affordability, and other factors moderate these findings. Innovative mental health services research is needed to improve access, continuity, quality, effectiveness, efficiency, and value of mental health services, and to bring effective strategies to scale to maximize public health impact.

Research Scope and Objectives

This notice of funding opportunity (NOFO) uses the R01 mechanism and is intended to foster mental health services research in strategic but understudied areas where new knowledge has the potential for high public health impact. This announcement supports non-clinical trials research, including but not limited to natural experiments (that are not clinical trials), survey, mixed methods research, clinical epidemiology, and development and refinement of new research methods, measures, financing approaches, or statistical approaches related to mental health services research. Services research can target patients, providers, healthcare leaders, and administrators, and/or healthcare systems or other organizations that provide services to persons with mental disorders, including those with early psychosis or autism spectrum disorders across the lifespan. NIMH encourages investigators to design their applications to maximize the likelihood that findings will meaningfully inform future research and/or be translated rapidly into practice, whether at the patient, clinic, healthcare/other system, or policy level. Studies involving providers, technologies, and workflows whose findings can be readily and widely implemented in routine care settings are encouraged. Studies (using non-trial designs) that are seeking to develop, refine or evaluate services or system interventions, should employ methods that seek to understand how, why, for whom, and/or in what circumstances the intervention may be effective.That is, methodology should go beyond evaluating simply whether an intervention is effective. Studies that evaluate interventions must not employ NIH-defined clinical trial designs (https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials#:~:text=A%20research%20study%20in%20which%20one%20or%20more,outcomes.%20the%20NIH%20definition%20of%20a%20clinical%20trial.) (e.g., must not prospectively assign participants to one or more interventions).

Pilot studies consistent with NIMH priorities for mental health services research not involving interventions should be submitted via PAR-25-284 (https://grants.nih.gov/grants/guide/pa-files/PAR-25-284.html), Pilot Services Research Grants Not Involving Clinical Trials (R34 Clinical Trial Not Allowed).

NIMH encourages investigators to develop and leverage strong research-practice partnerships with public and private stakeholders, so that the research follows a deployment-focused model of services design and testing. Deployment-focused studies consider the perspective of relevant stakeholders and key characteristics of settings intended to implement optimized mental health interventions. This attention to end-user perspectives and characteristics of intended clinical and/or community practice settings is intended to ensure that resultant interventions and service delivery strategies are feasible and scalable, and to ensure that the research results will have utility for end users. Such stakeholders include, but are not limited to, federal agencies (e.g., Centers for Medicare and Medicaid Services, Substance Abuse and Mental Health Services Administration, Health Resources and Services Administration, U.S. Department of Defense, Department of Veterans Affairs); state agencies including state Medicaid leadership, commercial health insurers/funders; public and commercial disability insurers; employers and other payers; delivery systems; professional/trade associations; accrediting and licensing organizations; medical education and other training programs; clinicians; vendors of information technology and other relevant products/services; service users; family members; and community organizations or comparable institutions and stakeholders in LMICs. Such communication and collaboration will ensure findings are relevant and practical, create opportunities for research that is not otherwise feasible, and enable stakeholders to anticipate relevant research initiatives in their planning and activities.

Given the critical need for practice-relevant research in community and practice settings, collaborations between academic investigators and clinical or community practice partners or networks are encouraged. When possible, studies should capitalize on existing infrastructure (e.g., practice-based research networks such as the NIMH-sponsored Early Psychosis Intervention Network (EPINET (https://www.nimh.nih.gov/research/research-funded-by-nimh/research-initiatives/early-psychosis-intervention-network-epinet)); NIMH-sponsored ALACRITY Research Centers (https://www.nimh.nih.gov/research/research-funded-by-nimh/research-initiatives/advanced-laboratories-for-accelerating-the-reach-and-impact-of-treatments-for-youth-and-adults-with-mental-illness-alacrity); NIMH-sponsored suicide research centers, NIMH-sponsored Scale-Up Hubs, electronic medical records, administrative databases, patient registries, institutions with Clinical and Translational Science Awards) to increase the efficiency of participant recruitment, data collection and management, and securing stakeholder support.

NIMH is committed to supporting research that reduces disparities in mental health interventions, services, and outcomes. Accordingly, this NOFO encourages research on innovative service delivery models that seek to reduce disparities in service access, quality, and outcomes for underserved groups, for example, racial and ethnic minority groups, individuals limited by language or cultural barriers, and individuals living in rural areas.

Under this NOFO, NIMH seeks mental health services research applications that align with Goal 4 of the NIMH Strategic Plan (https://www.nimh.nih.gov/about/strategic-planning-reports/goal-4-strengthen-the-public-health-impact-of-nimh-supported-research.shtml) for Research. Examples of high-priority research include, but are not limited to, the following:

Research to improve the efficiency, reach, and clinical impact of existing mental health services:

1. Developing and evaluating performance feedback systems, decision support tools, and quality improvement processes, which can be utilized across a range of systems (e.g., primary care, schools, criminal justice system, child welfare agencies), or levels within a single system, to optimize the delivery of effective mental health interventions.
2. Developing pragmatic, valid, and reliable measures of intervention fidelity, quality, and treatment outcomes, including outcome-focused quality measures, that can be applied at the person, clinic, system, and/or population levels.
3. Identifying mutable patient, provider, organizational, and policy-level factors, including social determinants of health, that are likely to influence disparities in healthcare access, continuity, quality, and mental health outcomes for racial and ethnic minorities and other underserved groups. Social determinants of health include, but are not limited to housing, food security, employment, social contact, and education. Social determinants of health may be operationalized in multi-level terms. These identified factors can serve as targets for future intervention development and testing.
4. Investigating alternative financing mechanisms, policies, regulations, and healthcare system rules, to include provider- or payer-level incentives, that promote high value (e.g., clinically effective and efficient) care, including integrated medical and psychosocial treatment approaches, and discourage low-value services.
5. Evaluating existing strategies to enhance treatment engagement and adherence (e.g., shared decision making or behavioral economic approaches to behavior change).
6. Identifying potential strategies for promoting the development, expansion, and continuity of a high-quality workforce to promote efficient and effective access to mental health services.

Research to expedite the adoption, scaling, sustained implementation, and continuous quality improvement of evidence-based mental health or autism services as part of a learning healthcare system:

1. Improving the dissemination, implementation, and delivery of evidence-based prevention and treatment practices in community mental health centers and other non-specialty care settings (e.g., primary medical care, schools, online and virtual communities).
2. Examining mutable patient, provider, organizational, and policy-level factors that influence the degree to which evidence-based interventions are implemented with fidelity, and sustained over time, to include mutable factors that influence sustainment after the research project period has ended.
3. Systematic, data-guided quality improvement activities that rigorously examine mental health care processes and outcomes within healthcare systems, to inform potential strategies that could lead to rapid, durable, and generalizable improvements in access and continuity of services, quality of care, and mental health outcomes at the individual and population level.
4. Designing or validating instruments to measure dissemination, implementation, or sustainability processes; to measure changes in service user functioning or provider practice over time; or to assess organizational or systems processes related to access and continuity of services, quality of care, and mental health outcomes at the individual and population level.
5. Employing studies (with quasi-experimental or quality improvement designs and methodologies that are not clinical trials) that simultaneously evaluate the effectiveness and implementation of mental health services to enhance the delivery of evidence-based mental health practices and improve implementation of mental health services to enhance the delivery of evidence-based mental health practices and improve implementation outcomes (e.g., fidelity, acceptability, feasibility, appropriateness, penetration, and sustainability of services).

Research on innovative service delivery models to reduce or eliminate known health disparities related to race, ethnicity, geography, sex and/or socio-economic status, to dramatically improve outcomes in understudied populations in the United States and global communities, and to ensure high value mental health services are readily accessible to those in need:

1. Using innovative technologies (e.g., mobile devices, health information systems, social networking platforms) to improve early detection of mental illnesses, engaging and connecting service users to evidence-based care, and increasing the reach, clinical impact, and scalability of services for unserved populations in a variety of settings.
2. Developing and examining strategies for delivering evidence-based mental health services in non-specialty settings (e.g., criminal justice system, community-based programs providing mental health services to military or veteran populations, colleges or other academic settings, the child welfare system, or geriatric service settings), and leveraging those strategies to bolster the delivery of high quality evidence-based care in specialty care settings.
3. Investigating the role of peer support specialists to improve access, engagement, and effectiveness of services for people with mental illnesses, with or without co-occurring medical and other conditions. This research may address related issues, such as the optimal integration of peer support staff in service delivery systems and the financing of such services.
4. Studying service delivery models that fully integrate treatment for mental illnesses with primary medical care, including medical decision models for treating mental illnesses and multiple chronic medical conditions.
5. Using non-clinical trial methodology (e.g., natural experiments) to evaluate service delivery models for comorbid conditions, such as care decision models that integrate treatment for mental illness and medical conditions, including service delivery interventions to reduce modifiable health risks associated with premature mortality in people with serious mental illnesses.

Research to evaluate the public health impact of mental health services or autism services innovations using large representative data sets and novel computational approaches:

1. Using electronic health record data to examine the clinical epidemiology, service utilization, response to treatment, and health state transitions of people with mental health needs within or across large systems responsible for mental health service delivery.
2. Monitoring real-time trends in suicidal behavior, serious mental illness, and other mental illnesses in health care and other settings (e.g., school, work, or home) and promoting effective data-driven planning to improve detection and help-seeking in these populations.

3. Developing and using big data and commensurate analytic approaches (e.g., predictive analytics, machine learning, artificial intelligence, large language models, etc.) for the purposes of understanding concentrations of risk and optimizing mental health care.
4. Developing, refining, or applying new methodological and computational approaches for the analysis of complex and dynamic systems affecting mental health outcomes, with the goal of demonstrating the impact of such factors on client outcomes.
5. Developing sampling frames and leveraging/enhancing existing epidemiological datasets to understand mental health needs in treatment-seeking and general populations.

Applications Not Responsive to this NOFO

The following types of studies are not responsive to this NOFO. Applications proposing such studies will be considered non-responsive and will not be reviewed or considered for funding.

- Applications that do not include mental health services research.
- Applications whose scope of work primarily involves the provision of direct services (e.g., the creation of a clinic or center).
- Applications that have no clearly articulated relevance to people with or who are at risk for mental illness or autism spectrum disorder.
- Studies focused on stigma or health literacy that examine knowledge about or attitudes towards mental health and mental health care without also examining mental health policy, actual service access, engagement, quality and/or outcomes of care.
- Applications that propose a clinical trial.

Mental health services research questions that require a clinical trial design must be submitted via the appropriate NIMH Clinical Trials NOFO (see Support for Clinical Trials at NIMH (https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml)). Applicants considering research studies where participants are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related outcomes are encouraged to review the NIMH clinical trials website (https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas) and contact NIMH Program Officials regarding the match between a potential application and current priorities.

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

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New
Renewal
Resubmission
Revision

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the How to Apply Application Guide provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials.

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

Funds Available and Anticipated Number of Awards

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

Award Budget

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

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.php?id=11120) will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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 Governments

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

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Organizations)

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **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.php?id=11118), **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the How to Apply- 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. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference the NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423) for additional information.

- System for Award Management (SAM) – (https://grants.nih.gov/grants/guide/url_redirect.php?id=82390) 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.php?id=11176) – 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 (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; 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 (//grants.nih.gov/grants/guide/url_redirect.php?id=82300) – 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 their organization to develop an application for 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 How to Apply-Application Guide.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement Section 1.2 Definition of Terms (//grants.nih.gov/grants/guide/url_redirect.php?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, per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application (//grants.nih.gov/grants/guide/url_redirect.php?id=82415). 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 NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423)).

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 NOFO. 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 How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the How to Apply- Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html) and the Table of Page Limits (https://grants.nih.gov/grants/guide/url_redirect.php?id=61134) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the How to Apply- Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html) and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply- Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the How to Apply- Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the How to Apply- Application Guide must be followed.

R&R or Modular Budget

All instructions in the How to Apply- Application Guide must be followed.

R&R Subaward Budget

All instructions in the How to Apply-Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the How to Apply- Application Guide must be followed.

PHS 398 Research Plan

All instructions in the How to Apply- Application Guide must be followed, with the following additional instructions:

Research Strategy:

Factor 1. IMPORTANCE OF THE RESEARCH (SIGNIFICANCE AND INNOVATION)

1. Discuss how the results of the proposed work will lead to a firm conclusion about the tested hypothesis.
2. Address the potential public health impact of the proposed work in terms of a) reach and effect on the target population and/or b) meaningfulness of the anticipated outcome(s) compared to existing approaches and/or current state of science in the topic area.
3. Describe collaborations and/or input from community partners and relevant policymakers/health leaders. Discuss how information gleaned from these relationships influenced the development of the research, ensure it is deployment focused (as defined above) and/or deployed and sustained if study is successful, and/or will help ensure that the results will have utility to community practice and/or other relevant stakeholders or end users of the research.

Factor 2. RIGOR AND FEASIBILITY (APPROACH)

1. For studies that evaluate interventions (using non-clinical trial designs) or can inform future intervention development and testing (including services and system-level interventions), describe plans to inform how, why, and for whom those interventions may be effective. Examples include (but are not limited to), a) identifying sets of relevant socio-demographic variables, including social determinants of health, to help minimize unaccounted outcome variance in those future studies, b) appraising and comparing measures for target (mediator) and outcome variables, c) employing approaches such as, but not limited to, mediation analysis (e.g., mediator mapping), moderator analysis, and temporally organized dismantling designs.
2. For applications that propose to develop, refine and evaluate new research tools, measures, or methods, describe how the research will lead to validated and deployable products, services, and/or methodologies that are broadly and efficiently usable in community practice settings.
3. Applications that propose to integrate and/or analyze existing data sets should discuss how results will enhance and extend our understanding of factors affecting access, continuity, quality, delivery, efficiency, financing, value, effectiveness, or outcomes of care.
4. For studies involving services interventions (e.g., research with quasi-experimental or quality improvement designs and methodologies that are not clinical trials), address the degree to which the proposed services intervention is scalable and could be broadly implemented using typically available resources, staff, and service structures, including financing mechanisms.
5. Describe any planned collaborations or input from stakeholders, and describe how these will contribute to the utility of study results. Beyond providing letters of support, consider proposing an advisory board that includes relevant stakeholders and decision makers (e.g., local, state, or federal policymakers; health system executives) or strategically including such decision makers as part of the study team.
6. Provide evidence that common data elements will be collected, consistent with NIMH's expectation (per NOT-MH-20-067 (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-20-067.html)), or provide a reasonable justification for not collecting one or more of these elements.
7. Describe factors that are mutable and have the potential to serve as targets in future intervention development that impact access, continuity, utilization, quality, value, financing, effectiveness, outcomes, or scalability of mental health or autism services.
8. Provide evidence that outcome measures are valid and reliable, including measures of outcomes that are meaningful to the stakeholders involved.
9. For studies that involve the assessment of patient-level outcomes, describe plans for the detection of suicidal behavior/ideation and non-suicidal self-harm and for clinical management to reduce subject risk when these factors are identified.

Factor 3. EXPERTISE AND RESOURCES (INVESTIGATORS AND ENVIRONMENT)

1. Describe how the study will leverage resources and expertise from existing infrastructure (e.g., CTSAs; practice-based research networks; other NIMH investments such as ALACRITY Research Centers, and EPINET; electronic medical records; administrative databases; patient registries) or utilize other available resources to increase the efficiency of participant recruitment and data collection. Or, provide a justification in the event that such efficiencies cannot be incorporated.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the How to Apply-Application Guide.

Other Plan(s):

All instructions in the How to Apply-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 by NIMH under this NOFO are expected to share those data via the National Institute of Mental Health Data Archive (https://nda.nih.gov/) (NDA; see NOT-MH-23-100 (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-23-100.html)). 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 NOFO 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 (https://nda.nih.gov/) website provides two tools to help investigators develop appropriate strategies: 1) t (https://nda.nih.gov/contribute_cost_estimation.html)he NDA Data Submission Cost Model (https://nda.nih.gov/contribute/contribute-data.html#cost)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 (https://nda.nih.gov/contribute/contribute-data.html). Investigators are expected to certify the quality of all data generated by grants funded under this NOFO 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 (https://nda.nih.gov/contribute/sharing-regimen.html) for more information); Investigators are expected to share results, positive and negative, specific to the cohorts and outcome measures studied.For more guidance on submitting data to NDA, refer to the NDA Data Management and Sharing Plan on the NDA website (https://nda.nih.gov/). NDA staff will work with investigators to help them submit data types not yet defined in the NDA Data Dictionary (https://nda.nih.gov/data_dictionary.html).

Appendix: Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the How to Apply- 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 How to Apply- 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 How to Apply- Application Guide must be followed.

Section 2 - Study Population Characteristics

2.5 Recruitment and Retention Plan

For studies involving human subjects, applications must provide a clear description of:

1. Recruitment and Referral sources, including detailed descriptions of the census/rate of new cases and anticipated yield of eligible participants from each source;

2. Procedures that will be used to monitor enrollment and track/retain participants for follow-up assessments;

3. Strategies that will be used to ensure a robust, representative sample;

4. Potential recruitment/enrollment challenges and strategies that can be implemented in the event of enrollment shortfalls (e.g., additional outreach procedures, alternate/back-up referral sources);

5. Evidence to support the feasibility of enrollment, including descriptions of prior experiences and yield from research efforts employing similar referral sources and/or strategies.

2.7 Study Timeline

Applications must provide a timeline for reaching important study benchmarks. Benchmarks should be objective, quantifiable, and justifiable. Benchmarks may include but are not limited to the following: (1) finalizing the study procedures and training participating clinical site staff; (2) finalizing the intervention manual and assessment protocols, including fidelity measures/procedures, where applicable; (3) establishing data use agreements, accessing data sets, data cleaning, and linking data sets where applicable; (4) enrollment benchmarks; (5) completing all subject assessments and data collection activities, including data quality checks; (6) analyzing and interpreting results; and (7) preparing de-identified data and relevant documentation to facilitate data sharing, as appropriate.

Delayed Onset Study

Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the How to Apply- Application Guide must be followed.

PHS Assignment Request Form

All instructions in the How to Apply- Application Guide must be followed.

Foreign Organizations

Foreign (non-U.S.) organizations must follow policies described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11137), and procedures for foreign organizations described throughout the How to Apply- Application Guide.

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

See Part 2. 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. 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.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.php?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 Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423).

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 How to Apply-Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm)

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/ (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 expects investigators for this funding announcement to collect Common Data Elements (CDEs) for mental health human subjects research. Unless NIMH stipulates otherwise during the negotiation of the terms and conditions of a grant award, this Notice applies to all grant applications involving human research participants. The necessary funds for collecting and submitting these CDE data from all research participants to the NIMH Data Archive (NDA) (https://nda.nih.gov/) should be included in the requested budget. A cost estimator (https://nda.nih.gov/ndarpublicweb/Documents/NDA_Data_Submission_Costs.xlsx (https://nda.nih.gov/ndarpublicweb/Documents/NDA_Data_Submission_Costs.xlsx)) is available to facilitate the calculation of these costs. NIMH may seek further information regarding CDEs prior to award. Additional information about CDEs can be found at the NIMH webpage on Data Management and Sharing for Applicants and Awardees. (https://www.nimh.nih.gov/funding/managing-your-grant/nimh-data-management-and-sharing-for-applicants-and-awardees)

6. Funding Restrictions

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

Pre-award costs are allowable only as described in the NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost. (//grants.nih.gov/grants/guide/url_redirect.php?id=11143)

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the How to Apply 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/guide/url_redirect.php?id=82400). 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) 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 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 NOFO 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 How to Apply Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.php?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.

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

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

Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, 2 CFR 200.113 (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) and NIH Grants Policy Statement Section 4.1.35 (https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm).

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the HHS Office of Inspector Grant Self Disclosure Program (https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) at grantdisclosures@oig.hhs.gov (mailto:grantdisclosures@oig.hhs.gov).

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.php?id=82299)

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 (//grants.nih.gov/grants/guide/url_redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following scored review criteria and additional review criteria (as applicable for the project proposed). An application does not need to be strong in all categories to be judged likely to have a major scientific impact.

Scored Review Criteria

Reviewers will consider Factors 1, 2 and 3 in the determination of scientific merit, and in providing an overall impact score. In addition, Factors 1 and 2 will each receive a separate factor score.

Factor 1. Importance of the Research (Significance and Innovation)

Significance

- Evaluate the importance of the proposed research in the context of current scientific challenges and opportunities, either for advancing knowledge within the field, or more broadly. Assess whether the application addresses an important gap in knowledge in the field, would solve a critical problem, or create a valuable conceptual or technical advance.

- Evaluate the rationale for undertaking the study, the rigor of the scientific background for the work (e.g., prior literature and/or preliminary data) and whether the scientific background justifies the proposed study.

Innovation

- Evaluate the extent to which innovation influences the importance of undertaking the proposed research. Note that while technical or conceptual innovation can influence the importance of the proposed research, a project that is not applying novel concepts or approaches may be of critical importance for the field.
- Evaluate whether the proposed work applies novel concepts, methods or technologies or uses existing concepts, methods, technologies in novel ways, to enhance the overall impact of the project.

Specific to this NOFO:

- Evaluate the extent to which the proposed work leads to a firm conclusion about the tested hypothesis.
- Evaluate the extent to which the application adequately addresses the potential public health impact of the proposed work in terms of 1) reach and effect on the target population and/or 2) meaningfulness of the anticipated outcome(s), compared to existing approaches and/or current state of science in the topic area.
- Evaluate the extent to which research-practice collaborations and/or input from community partners and relevant policymakers/health leaders informed the development of the research and will ensure that the research is deployment-focused and/or the results will have utility to end users.

Factor 2. Rigor and Feasibility (Approach)

Approach

- Evaluate the scientific quality of the proposed work. Evaluate the likelihood that compelling, reproducible findings will result (rigor) and assess whether the proposed studies can be done well and within the timeframes proposed (feasibility).

Rigor:

- Evaluate the potential to produce unbiased, reproducible, robust data.
- Evaluate the rigor of experimental design and whether appropriate controls are in place.
- Evaluate whether the sample size is sufficient and well-justified.
- Assess the quality of the plans for analysis, interpretation, and reporting of results.
- Evaluate whether the investigators presented adequate plans to address relevant biological variables, such as sex or age, in the design, analysis, and reporting.
- For applications involving human subjects or vertebrate animals, also evaluate:
    - the rigor of the intervention or study manipulation (if applicable to the study design).
    - whether outcome variables are justified.
    - whether the results will be generalizable or, in the case of a rare disease/special group, relevant to the particular subgroup.
    - whether the sample is appropriate and sufficiently diverse to address the proposed question(s).
- For applications involving human subjects, including clinical trials, assess the adequacy of inclusion plans as appropriate for the scientific goals of the research. Considerations of appropriateness may include disease/condition/behavior incidence, prevalence, or population burden, population representation, and/or current state of the science.

Feasibility:

- Evaluate whether the proposed approach is sound and achievable, including plans to address problems or new challenges that emerge in the work. For proposed studies in which feasibility may be less certain, evaluate whether the uncertainty is balanced by the potential for major advances.
- For applications involving human subjects, including clinical trials, evaluate the adequacy and feasibility of the plan to recruit and retain a study population that appropriately models the target population. Additionally, evaluate the likelihood of successfully achieving the proposed enrollment based on age, race, ethnicity, and sex.
- For clinical trial applications, evaluate whether the study timeline and milestones are feasible.

***Specific to this NOFO*:**

- Assess the extent to which the application employs methods that seek to understand how, why, for whom, and/or in what circumstances the intervention is effective.
- For an application that proposes to develop and test new research tools, measures, or methods, assess how the research will lead to validated and deployable products, services, and/or methodologies that are broadly and efficiently usable in community practice settings.
- For applications that propose to integrate and/or analyze existing data sets, assess how likely it is that the project will produce results that enhance and extend our understanding of factors affecting access, continuity, quality, delivery, efficiency, value, effectiveness, or outcomes of care.
- For studies involving services interventions, using non-clinical trial designs (e.g., research with quasi-experimental or quality improvement designs and methodologies), evaluate the extent to which the proposed services intervention is scalable and the extent to which it could be broadly implemented using typically available resources, staff, and service structures, including financing structures.
- Evaluate how well the application describes any planned collaborations or input from community partners, end users, etc. and to what extent these collaborations will contribute to the utility of study results.
- If appropriate, evaluate the extent to which the application describes factors that are mutable and have the potential to serve as targets in future intervention development that impact access, continuity, utilization, quality, financing, outcomes, effectiveness, or scalability of mental

health services.
- If appropriate, assess if the application provides sufficient evidence that outcome measures are valid and reliable, including measures of outcomes that are meaningful to the stakeholders involved.
- For studies that involve the assessment of patient-level outcomes, evaluate how adequately the application describes plans for the detection of suicidal behavior/ideation and non-suicidal self-harm, and for clinical management to reduce subject risk when these factors are identified.

Factor 3. Expertise and Resources (Investigator(s) and Environment)

Investigator(s)

Evaluate whether the investigator(s) have demonstrated background, training, and expertise, as appropriate for their career stage, to conduct the proposed work. For Multiple Principal Investigator (MPI) applications, assess the quality of the leadership plan to facilitate coordination and collaboration.

Environment

Evaluate whether the institutional resources are appropriate to ensure the successful execution of the proposed work.

***Specific to this NOFO*:**

- Evaluate the extent to which the study will leverage resources and expertise from existing infrastructure or utilize other available resources to increase the efficiency of participant recruitment and data collection, as appropriate.

Additional Review Criteria

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

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, 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, 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 (https://grants.nih.gov/grants/guide/url_redirect.php?id=11175).

Vertebrate Animals

When the proposed research includes Vertebrate Animals, evaluate the involvement of live vertebrate animals 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. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animals Section (//grants.nih.gov/grants/guide/url_redirect.php?id=11150).

Biohazards

When the proposed research includes Biohazards, evaluate whether specific materials or procedures that will be used are significantly hazardous to research personnel and/or the environment, and whether adequate protection is proposed.

Resubmissions

As applicable, evaluate the full application as now presented.

Renewals

As applicable, evaluate the progress made in the last funding period.

Revisions

As applicable, evaluate the appropriateness of the proposed expansion of the scope of the project.

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.

Authentication of Key Biological and/or Chemical Resources

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

Budget and Period of Support

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

2. Review and Selection Process

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

As part of the scientific peer review, all applications 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. 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.

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 Section 2.5.1. Just-in-Time Procedures (//grants.nih.gov/grants/guide/url_redirect.php?id=82418). This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 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.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.php?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 Section 2.4.4 Disposition of Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82416).

Section VI. Award Administration Information

1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

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.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the NIH Grants Policy Statement Section 5. The Notice of Award (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm) and NIH Grants & Funding website, see Award Process. (https://grants.nih.gov/grants/pre-award-process.htm#award)

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that 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.

2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through NIH:

- The rules listed at 2 CFR Part 200 (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.php?id=11159).
- If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance (HHS-690 (https://www.hhs.gov/sites/default/files/form-hhs690.pdf)). To

learn more, see the Laws and Regulations Enforced by the HHS Office for Civil Rights website (https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html).

- HHS recognizes that NIH 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 NOFO.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in NIH Grants Policy Statement Section 4 Public Policy Requirements, Objectives and Other Appropriation Mandates. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandates.htm)

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. NIH may terminate awards under certain circumstances. See 2 CFR Part 200.340 Termination (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340) and NIH Grants Policy Statement Section 8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support (https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions-_suspension__termination__and_withholding_of_support.htm).

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B) to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit https://www.healthit.gov/topic/certification-ehrs/certification-health-it (https://www.healthit.gov/topic/certification-ehrs/certification-health-it) to learn more.

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
2. receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework (https://www.nist.gov/cyberframework), to protect HHS systems and data. Please refer to NIH Post-Award Monitoring and Reporting (https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm) for additional information.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

Consistent with the 2023 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 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). 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) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement Section 8.4.1 Reporting. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm) To learn more about post-award monitoring and reporting, see the NIH Grants & Funding website, see Post-Award Monitoring and Reporting (https://grants.nih.gov/grants/guide/url_redirect.php?id=82428).

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 Section 8.6 Closeout (//grants.nih.gov/grants/guide/url_redirect.php?id=82420). NIH NOFOs 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 2 CFR Part 200.301.

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 (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 (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-480-7075

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)

Jennifer Humensky, PhD
National Institute of Mental Helath (NIMH)
Telephone: 301-480-1265
Email: Jennifer.Humensky@nih.gov

For research to be conducted in low and middle income countries:

Leonardo Cubillos, M.D., M.P.H.
National Institute of Mental Health (NIMH)
Telephone: 301-827-9095
Email: leonardo.cubillos@nih.gov (mailto:leonardo.cubillos@nih.gov)

Peer Review Contact(s)

Nicholas 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)

Christine Clarkson
National Institute of Mental Health (NIMH (http://www.nimh.nih.gov/index.shtml))
Telephone: 301-402-5765
Email: christine.clarkson@.nih.gov (mailto:christine.clarkson@.nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.php?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 (//grants.nih.gov/grants/guide/url_redirect.php?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?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 2 CFR Part 200.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?01-03-25)
NIH Funding Opportunities and Notices (/grants/guide/index.html)
