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	Laboratories to Optimize Digital Health (R01 Clinical Trial Required)
Activity Code	R01 (///grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project Grant
Announcement Type	Reissue of PAR-23-096 (https://grants.nih.gov/grants/guide/pa-files/PAR-23-096.html)
Related Notices	See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=41794) associated with this funding opportunity • **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-25-136
Companion Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Assistance Listing Number(s)	93.242
Funding Opportunity Purpose	NIMH seeks applications for innovative research projects to test strategies to increase the reach, efficiency, effectiveness, and quality of digital mental health interventions which may impact mental health outcomes, including suicide behaviors and serious mental illness. This Notice of Funding Opportunity (NOFO) is intended to support the development of digital health test beds that leverage well-established digital health platforms and infrastructure to rapidly refine and optimize existing evidence-based digital health interventions and to conduct clinical research testing digital mental health interventions that are statistically powered to provide a definitive answer regarding the intervention's effectiveness particularly in populations who experience health disparities (https://www.nimhd.nih.gov/about/overview/) and vulnerable populations.
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	November 07, 2024
Open Date (Earliest Submission Date)	January 05, 2025
Letter of Intent Due Date(s)	30 days before application due date

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
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 (/grants/guide/ApplyButtonSplash.cfm?dest=https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PAR-25-136) 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

NIMH seeks applications for innovative research projects to test strategies to increase the reach, efficiency, effectiveness, and quality of digital mental health interventions which may impact mental health outcomes, including suicide behaviors and serious mental illness. This NOFO is intended to support the development of digital health test beds that leverage well-established digital health platforms and infrastructure to rapidly refine and optimize existing evidence-based digital health interventions and conduct clinical research testing digital mental health interventions that are statistically powered to provide a definitive answer regarding the intervention's effectiveness particularly in populations who experience health disparities (https://www.nimhd.nih.gov/about/overview/) and vulnerable populations.

Background

The healthcare landscape in the United States 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 disorder, and approximately one-quarter of the population meets criteria in any given year. However, only one-half of people with any mental health disorder and only two-thirds of people with a serious mental health disorder 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, including suicide risk assessment and evidence-based preventive interventions. Disparities in population status (e.g., members of racial, ethnic, sexual, and gender minority communities), a fragmented healthcare system, provider shortages, healthcare affordability, and other factors moderate these findings.

Digital health incorporates mobile health (mHealth) and health information technology (smartphones, wearable sensors, internet platforms, and electronic health records) with biological, social, and behavioral data. Digital health technology offers unprecedented opportunities to help consumers, clinicians, and researchers measure, manage, and improve health and productivity. These tools also have the potential to improve our understanding of mental illness, to track the course of illnesses and recovery, and to provide and enhance mental health care. Digital mental health interventions are treatments that aim to improve mental health and deliver the treatment as a standalone intervention or as an adjunct to face-to-face interventions via a digital health platform (including mobile phone, website, virtual reality systems, and offline computer programs). Digital health interventions offer the potential to bridge the treatment gap and provide evidence-based interventions to the many individuals who currently are unable to access treatments.

Over the last decade, NIMH has supported the development and testing of digital health technology, with a focus on establishing the efficacy of digital health assessments and digital health interventions. This research has demonstrated that digital health technology can be used as a means for reducing symptoms. However, with few exceptions, the majority of NIMH-funded research of digital health interventions has not moved into or beyond the effectiveness stage of research. In contrast to federally funded mental health research, the pace of commercial technology development has progressed rapidly. Over the last 5 years commercially available digital health platforms for mental health have gained considerable traction in the marketplace. Recent estimates suggest that focus on mental health and a significant cross-section of consumers are regularly utilizing digital health technology to access treatment for

mental health. As digital health technology for mental health is being increasingly used to provide standalone self-managed interventions and/or to supplement in-person treatment, well-designed pragmatic research is necessary to evaluate the effectiveness of existing digital health technology, optimize existing digital health interventions, and examine factors related to uptake and engagement.

Research Scope and Objectives

This NOFO uses the R01 mechanism and is intended to promote partnerships between software developers and academic researchers and leverage existing digital mental health platform infrastructure. It is expected that the proposed digital health platforms will be well established, provide evidence-based interventions and have a substantial existing user base. It is also expected that these partnerships will enable applicants to conduct research both to rapidly test ideas and conduct exploratory research as well secondary data analyses and large cost-effective pragmatic effectiveness trials. While this NOFO will support testing of evidence-based digital health intervention approaches, it is not intended to support the translation of existing face-to-face treatments into technology-based applications.

Investigators are strongly encouraged to review NOT-MH-18-031 (https://grants.nih.gov/grants/guide/notice-files/not-mh-18-031.html) for guidance concerning the NIMH high priority topics in digital mental health. For this NOFO, NIMH requires investigators to develop and leverage partnerships with digital health developers and existing well-established digital health delivery platforms, so that the research follows a deployment-focused model of services design and testing. Deployment-focused studies take into account the perspective of relevant stakeholders and key characteristics of settings intended to implement optimized digital mental health interventions. Potential 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, Department of Defense, Department of Veterans Affairs); 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. The applicant should identify key stakeholders based on the characteristics of the proposed intervention and how the intervention will be deployed within service systems. 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. Where appropriate, it is strongly encouraged that applicants seek consultation from the Food and Drug Administration (https://www.fda.gov/medical-devices/digital-health/device-software-functions-including-mobile-medical-applications) for guidance related to regulatory approval/certification of the digital mental health interventions that are being tested.

Consistent with the NIMH Experimental Therapeutics approach (https://www.nimh.nih.gov/about/director/messages/2017/an-experimental-therapeutic-approach-to-psychosocial-interventions) to intervention development and testing, this NOFO is intended to support studies that not only examine the intervention effects on outcomes of interest, but also inform understanding of the intervention's mechanisms of action. As such, the scope of work must include specification of intervention target(s)/mechanism(s) and assessment and analysis of intervention-induced changes in the presumed target(s)/mechanism(s) that are hypothesized to account for the intervention outcomes (see the NIMH Clinical Trials web page for additional information).

Proposed studies should capitalize on existing infrastructure (e.g., existing evidence based digital mental health platforms) to increase the efficiency of participant recruitment, and data collection and management. Platforms should be well established with a sufficient existing user base (i.e. at least a thousand or more active users) to support nimble intervention refinement and testing with appropriate sample size to achieve adequate statistical power.

Of note, the goal of this funding announcement is not just to conduct pragmatic trials on digital health platforms. Rather, applicants must propose additional research beyond the primary effectiveness trial that capitalize on the unique features of the proposed digital health platform. Such additional research might include but is not limited to: analyses of baseline characteristics of users to develop treatment matching algorithms, analyses of existing data to determine the optimal sequence and dose of the digital intervention and to further understand the etiology, pathophysiology, and trajectories of mental health disorders, development and testing of real time adaptive customized interventions that augment the base digital intervention.

Examples of responsive applications include, but are not limited to, studies that:

- Test strategies to rapidly identify and enroll participants, and parametrically refine intervention content, dose, and delivery parameters to optimize the digital health intervention’s therapeutic benefit and efficiency.
- Test the effectiveness of digital health platforms to optimize the benefit of in-person treatment and bridge therapy sessions and promote between-session skill practice/acquisition.
- Develop and test adaptive interventions and just-in-time interventions that can be 'pushed out' via mobile technology based on information regarding the individual's current state. For example, interventions that prompt users to complete an assessment at specific times during the day or passive ascertainment of changes in clinical status, immediately followed by provision of behavioral support, such as self-management strategies.
- Test strategies to deliver digital mental health interventions designed to overcome well-documented uptake and adherence challenges with digital health interventions (e.g., using research-informed approaches to enhance motivation and promote continued engagement).
- Test digital health technology-driven approaches to improve access to and promote engagement with and continuity of care during known periods of heightened risk, such as care transitions between systems (e.g., handoffs between emergency departments and inpatient psychiatric or substance abuse treatment; transitions between outpatient mental health/substance abuse programs and primary care settings).
- Leverage patterns of use to identify subcategories of users (i.e., brief users, social users, persistent users) and develop and test strategies to encourage continued engagement.
- Within digital health platforms that connect users with paraprofessionals and clinicians, test flexible patient matching algorithms and strategies to increase treatment fidelity to Evidence Based Practices (EBPs).
- Test whether digital interventions can mitigate racial/ethnic/gender disparities in access, service utilization, and mental health outcomes.
- Utilize electronic health record data in conjunction with digital health interventions to examine the clinical epidemiology, service utilization, response to treatment, within or across large systems responsible for mental health service delivery in order to inform timing and targets for intervening.
- Use big data and commensurate analytic approaches (e.g., predictive analytics, machine learning, etc.) for the purposes of understanding concentrations of risk and optimizing mental health care within the digital health ecosystem
- Studies that are designed to test whether digital interventions can mitigate racial/ethnic and gender disparities in access, service utilization, and health outcomes.

Areas of High Program Priority

- Digital mental health interventions being tested should be based on existing social and behavioral science theories.
- Interventions should take advantage of the unique functionality of mobile and wireless devices. Utilization of real-time data collection and feedback is encouraged where appropriate.
- Studies designed to test if the proposed digital mental health intervention yields significant reductions in symptoms in individuals who exhibit clinically significant symptoms and/or functional impairment at baseline.
- Applications that propose digital mental health interventions that focus on treating serious mental illness (SMI).
- Studies that utilize software, devices, and systems that are interoperable with existing infrastructure such that resulting data is interoperable with relevant health information systems where applicable.
- Applications that test generalizable principles or approaches to using technology to improve the accuracy and efficiency of assessment and the effectiveness and quality of intervention and service delivery.
- Studies that address known challenges with uptake and adherence/sustained use of technology-based approaches and attention to privacy and other safety/ethical considerations associated with the use of technology for research and clinical purpose.
- Applications that utilize digital health interventions that address health disparities or focus particularly on vulnerable populations.

Applications Not Responsive to this NOFO:
The following will be considered non-responsive for this announcement and will not be reviewed:

- Applications that leverage mental health interventions that are not empirically based.
- Testing of digital mental health interventions that do not focus on reducing the severity of clinically significant mental health symptoms and/or functional impairments.
- Proposed studies that do not plan to enroll participants with baseline levels of measurable clinically significant symptoms and/or functional impairment.
- Proposing the use of digital mental health platforms with an insufficient base of existing users to conduct rapid, appropriately powered studies.
- Applications that propose the translation of existing face-to-face treatments into digital health interventions.
- Applications that propose clinical trials with a non-active comparator.
- Applications that only propose research aims associated with primary effectiveness and do not capitalize on the unique features of the proposed digital health platform.
- Applications that do not include specification of intervention target(s)/mechanism(s) and assessment and analysis of intervention-induced changes in the presumed target(s)/mechanism(s) that are hypothesized to account for the intervention outcomes.

Scale and Scope of Studies Covered Under this Announcement This NOFO encourages studies that utilize well-established digital MH platforms to conduct statistically powered trials testing strategies to optimize existing evidence-based digital health interventions. Applicants pursuing other stages of research (e.g., intervention development, pilot testing, clinical trials

outside of existing well-established platforms) are encouraged to visit the Support for Clinical Trials at NIMH (https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml#part_156836) webpage for a list of alternative NOFOs for other stages of intervention development and testing. Applicants are strongly encouraged to consult with NIMH staff when developing plans for an application (see Agency Contacts, Section VII (http://nihguide.nih.gov/AppData/Local/Microsoft/AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/Content.Outlook/). This early contact will provide an opportunity to clarify NIMH policies and guidelines, and discuss whether the proposed project is consistent with NIMH program 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.

Investigators proposing NIH-defined clinical trials may refer to the Research Methods Resources (https://researchmethodsresources.nih.gov/) website for information about developing statistical methods and study designs.

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?	Required: Only accepting applications that propose clinical trial(s). Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.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 project.
Award Project Period	The scope of the proposed project should determine the project period. **The maximum project period is 4 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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized).

Federal 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.

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:

nimhpeerreview@mail.nih.gov (mailto:nimhpeerreview@mail.nih.gov?subject=LOI%20for%20RFA-MH-20-510)

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 Research

Significance

- Justify the practical effect of the digital mental health intervention in terms of the estimated hypothesized effect size (e.g., in terms of remediation of symptoms or functional impairment, sustained skill use, improved adherence), compared with already available approaches. Address the potential impact of the digital mental health intervention in terms of both (1) the empirical basis for the anticipated effect size (e.g., citing data regarding the magnitude of the association between the target and the clinical endpoint of interest and/or effect sizes obtained in prior efficacy studies), and (2) the clinical meaningfulness of the anticipated increment in effects compared to existing approaches.
- Address the degree to which the proposed digital mental health intervention is scalable and could be disseminated into practice, given typically available resources (e.g., trained, skilled providers), typical service structures (including mental health care financing), and typical service use patterns.
- Detail how the proposed research will generate data that will lead to a firm conclusion about the digital mental health intervention and provide information about the anticipated scope and goals of intended future work.

Innovation

- Highlight how innovative research strategies and design/analytic elements are incorporated, as appropriate, to enhance the study's potential for yielding practice-relevant information, and enable the research to be conducted within a rapid time frame.
- Highlight how the digital health platform capitalizes on the unique functionality of mobile and wireless devices, utilizes real-time data collection, incorporates regular software updates that are informed by the research and user feedback.
- Highlight how the research will leverage mobile health and health information technology (smartphones, wearable sensors, internet platforms, and electronic health records) with biological, social, and behavioral data.

Factor 2. Rigor and Feasibility

Approach

- Detail the rationale and empirical basis for the digital mental health intervention approach in terms of the intended target population, stage of intervention (e.g., acute care, continuation or maintenance treatment, transition to independent care management), corresponding goals and focus of the intervention (e.g., remediating symptoms or impairments; promoting sustained adherence), potential scalability, key window or timeframe over which the digital mental health intervention should be administered.
- Consistent with NIMH's experimental therapeutics approach, include a plan that explicitly addresses whether the digital mental health intervention engages the mechanism that is presumed to underlie the intervention effects (the mechanism that accounts for changes in clinical/ functional outcomes, changes in patient or provider behavior, etc.). Specifically, include a conceptual framework that clearly identifies the target mechanisms and the empirical evidence linking the mechanisms to the study outcomes, plans for assessing engagement of the target mechanisms, and analytic strategies that will examine target engagement and associations with clinical benefit. In the case of multi-component interventions, the application should specify the conceptual basis, assessment plan, and analytic strategy for the target mechanisms corresponding to each intervention component, as appropriate in the effectiveness context.
- Clearly describe the proposed digital health platform including a clear description of the digital health intervention, the number of currently active daily users, and the necessary infrastructure to remotely administer and record assessments.
- Provide an enrollment plan that documents how current users will be recruited, consented and randomized. Ensure the enrollment plan aligns with the proposed sample size and power analysis**.**
- Describe the assessment and monitoring of the fidelity of intervention delivery via procedures that are feasible and valid.
- Include outcome measures that are validated and generally accepted by the field, including stakeholder-relevant outcomes (e.g., individual functioning, health services use), as appropriate.
- Justify the proposed period of observation (i.e., timing of assessments and length of follow-up), given the intent of the intervention (e.g., acute care, continuation therapy, skill generalization, maintenance of gains, adherence promotion).
- Include the assessment of symptoms and related outcomes using strategies that can facilitate sharing of data as appropriate.

Factor 3. Expertise and Resources

Investigator(s)

- Describe plans to involve collaborations and/or input from community practice partners/providers, consumers, and relevant policy makers in a manner that informs the research (e.g., to help ensure the interventions/service delivery approaches are acceptable, feasible, and scalable) and helps to ensure the results will have utility for end-users.

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 under this FOA are expected to share those data via the National Institute of Mental Health Data Archive (https://nda.nih.gov/) (NDA; see NOT-MH-19-033 (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-033.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 FOA are expected to use these technologies to submit data to NDA.

To accomplish this objective, it will be important to formulate a) an enrollment strategy that will obtain the information necessary to generate a GUID for each participant, and b) a budget

strategy that will cover the costs of data submission. The NDA web site provides two tools to help investigators develop appropriate strategies: 1) the NDA Data Submission Cost Model (https://nda.nih.gov/contribute_cost_estimation.html) 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 FOA prior to submission to NDA and review their data for accuracy after submission. Submission of descriptive/raw data is expected semi-annually (every January 15 and July 15); submission of all other data is expected at the time of publication, or prior to the end of the grant, whichever occurs first (see NDA Sharing Regimen (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. The NDA Data Management and Sharing Plan is available for review on the NDA website (https://s3.amazonaws.com/nda.nih.gov/Documents/NDA+Data+Sharing+Terms+and+Conditions+01.01.20.pdf). 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.

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 Sharing for Applicants and Awardees (https://www.nimh.nih.gov/funding/managing-your-grant/nimh-data-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

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 NIMH, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

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.

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 an appropriately diverse population of participants. Additionally, evaluate the likelihood of successfully achieving the proposed enrollment based on age, racial, ethnic, and sex or gender categories.
- For clinical trial applications, evaluate whether the study timeline and milestones are feasible.

Specific to this NOFO:

- Evaluate the degree to which the proposed digital mental health intervention is scalable and could be disseminated into practice, given typically available resources (e.g., trained, skilled providers), typical service structures (including mental health care financing), and typical service use patterns.
- Evaluate the rationale and empirical basis for the digital mental health intervention approach in terms of the intended target population, stage of intervention (e.g., acute care, continuation or maintenance treatment, transition to independent care management), corresponding goals and focus of the intervention (e.g., remediating symptoms or impairments; promoting sustained adherence), potential scalability, key window or time frame over which the digital mental health intervention should be administered.
- Consistent with NIMH's experimental therapeutics approach, evaluate the proposed analysis plan that confirm that it explicitly addresses whether the digital mental health intervention engages the mechanism that is presumed to underlie the intervention effects (the mechanism that accounts for changes in clinical/ functional outcomes, changes in patient or provider behavior, etc.). Specifically, evaluate the conceptual framework that clearly identifies the target mechanisms and the empirical evidence linking the mechanisms to the study outcomes, plans for assessing engagement of the target mechanisms, and analytic strategies that will examine target engagement and associations with clinical benefit. In the case of multi-component interventions, evaluate the conceptual basis, assessment plan, and analytic strategy for the target mechanisms corresponding to each intervention component, as appropriate in the effectiveness context.

- Evaluate if the application includes a clear description of the digital health intervention, the number of currently active daily users, and the necessary infrastructure to remotely administer and record assessments.

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.

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 submitted in response to this NOFO. 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)

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

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

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration and Results System Information Website (https://register.clinicaltrials.gov (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 recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

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

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)

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Email: Haima@mail.nih.gov (mailto:Haima@mail.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 (http://nick.gaiano@nih.gov)

Financial/Grants Management Contact(s)

Tamara Kees
National Institute of Mental Health (NIMH)
Telephone: 301-443-8811
Email: tkees@mail.nih.gov (http://<a href=)

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.