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

Clinical High Risk for Psychosis Research Network (U01 Clinical Trial Not Allowed)

Activity Code

U01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project – Cooperative Agreements

Announcement Type

New

Related Notices

July 26, 2019 - Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-128 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html)

August 23, 2019 - Clarifying Competing Application Instructions and Notice of Publication of Frequently Asked Questions (FAQs) Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-137 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-137.html)

Funding Opportunity Announcement (FOA) Number

RFA-MH-20-340

Companion Funding Opportunity

RFA-MH-20-341 (https://grants.nih.gov/grants/guide/rfa-files/rfa-mh-20-341.html), U24 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u24) Resource-Related Research Projects--Cooperative Agreements

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.242

Funding Opportunity Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to solicit applications to establish research network(s) focused on rapidly recruiting a sufficient number of participants to dissect the heterogeneity of the clinical high risk for psychosis (CHR) syndrome so as to predict differential CHR outcomes. Results from these studies will inform future treatment development efforts.

Key Dates

Posted Date

November 27, 2019

Open Date (Earliest Submission Date)

December 31, 2019

Letter of Intent Due Date(s)

December 31, 2019

Application Due Date(s)

January 31, 2020
No late applications will be accepted for this Funding Opportunity Announcement.
All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s).
Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

Not applicable

Scientific Merit Review

May 2020

Advisory Council Review

August 2020

Earliest Start Date

September 2020

Expiration Date

February 01, 2020

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000),except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)).

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

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

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

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

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-MH-20-340) 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. Funding Opportunity Description

This FOA invites applications to establish a collaborative multi-site network(s) to rapidly recruit and characterize a sufficient number of CHR participants to dissect the heterogeneity of the CHR syndrome and predict differential outcomes. The tools and results generated from these studies are anticipated to advance intervention development and treatment for the CHR syndrome.

Background

Approximately 100,000 young persons in the United States experience a first episode of psychosis every year. During the same interval, it is estimated that over one million children and adolescents experience problems in

perception, thinking, mood, and social functioning suggestive of a pre-psychosis risk state. Given the highly disruptive and disabling nature of psychotic disorders, early intervention has been recommended as a means of preventing psychosis onset among at-risk individuals, as well as averting other adverse outcomes such as mood syndromes, substance abuse disorders, and functional decline in social, academic, and vocational domains.

Researchers have noted that clinical heterogeneity within the CHR population presents a substantial challenge for intervention development. Approaches for addressing this heterogeneity to enable future intervention trials require the development of tools to address: (a) defining a core set of clinical and functional outcomes beyond onset of psychosis to include affective, cognitive, and negative symptom domains and functional outcomes; (b) prospective stratification of CHR individuals into more homogeneous risk subtypes to predict the likelihood of clinical outcomes; and (c) testing of interventions that target hypothesized underlying mechanisms for emerging psychosis, mood syndromes, and functional disability.

The ultimate outcome of project(s) funded under this FOA and companion RFA-MH-20-341 (//grants.nih.gov/grants/guide/rfa-files/rfa-mh-20-341.html) will be a set of validated tools - biomarkers, biomarker algorithms, and outcome measures - for selection of help-seeking/CHR subjects for enrollment in future clinical trials, to serve as readouts of early treatment effects, and/or to monitor disease progression and clinical and functional outcomes.

Research Objectives

This FOA solicits applications to establish a multi-site CHR network(s) for recruitment of large numbers of CHR participants and to employ a common set of biomarker and clinical outcome measures to be determined in conjunction with NIMH and an external working group in order to predict differential outcomes.

Specifically, the FOA encourages proposed studies that will:

- Demonstrate the capability for large-scale implementation of clinical measures and biomarkers such as brain structure and function, genomics (including polygenic risk scores (PRS) derived from extant cohorts with neuropsychiatric conditions), cognition, electrophysiology (*e.g.,* EEG/ERP), blood-based markers, and speech and language analysis;
- Develop, test, and validate, in collaboration with the Data Processing, Analysis and Coordination Center (DPACC; See below) multimodal biomarker approaches for CHR risk stratification and/or predicting clinical trajectories or outcomes, including computational approaches to independently validate predictive algorithms;
- Use state-of-the-art approaches for assessing functional outcomes, including, for example, ongoing monitoring of various aspects of everyday functioning using passive data collection and/or ecological momentary assessment;
- Expand CHR risk stratification tools (*e.g.,* individualized risk calculators) to include trajectories and outcomes beyond the onset of psychosis, including non-progressive attenuated psychotic symptoms (APS), enduring mood, anxiety, or negative symptoms despite remission of APS, and full recovery from the CHR syndrome;
- Have the expertise and capability to add additional exploratory biomarker or digital technologies.

Anticipated outcomes from this program of research include:

- Rapid recruitment of large numbers of CHR individuals characterized with a common set of biomarker and clinical and functional outcome assessments;
- A multivariate biomarker approach for predicting CHR outcomes based on data from standardized clinical assessments and other measures which may include neurocognitive tests, structural and/or functional neuroimaging, genetic predictors such as PRS, blood-based assays, electrophysiological measures, ambulatory measures of physiology, cognition, day-to-day functioning and/or symptoms, or speech and language-based metrics assessing thought dysfunction;
- Testing of exploratory biomarker or digital technologies at one or more sites in the network(s);
- Individualized CHR risk calculators that include outcomes beyond onset of psychosis, including non-progressive APS, remission of APS with enduring mood, anxiety, cognitive, or negative symptoms; and full recovery from the CHR syndrome.

This FOA strongly encourages the development of new collaborations among academic CHR research centers, as well as new partnerships between academic centers and community-based treatment programs for CHR. NIMH is interested in collaborations that leverage ongoing CHR recruitment efforts such as those recently established by the Substance Abuse and Mental Health Services Administration (see SM-18-012 (https://www.samhsa.gov/grants

/grant-announcements/sm-18-012)), CHR clinical programs associated with the Early Psychosis Intervention Networks (EPINET) funded under RFA-MH-19-150 (https://grants.nih.gov/grants/guide/rfa-files/rfa-mh-19-150.html), and CHR network sites outside of the U.S.

The minimal requirements of a CHR Network under this FOA are as follows:

1. Research Project(s): A CHR Network application must present a conceptual model of CHR for psychosis clinical features and propose measures of clinical trajectories and predictive biomarkers for various clinical outcomes, including methods for identifying subgroups of subjects based on their predicted trajectories that could be applied in a future treatment trial. The proposed network must have a “hub and spoke” structure, consisting of a centralized hub which serves administrative and organizational functions for multiple clinical research sites. Proposed networks also must include (a) multiple sites to rapidly implement the acquisition of a common set of biomarker and clinical outcome measures which will be finalized in conjunction with NIMH and an external working group and (b) the capability of collecting more specialized or exploratory biomarker and digital technologies at one or more sites to be determined in conjunction with NIMH and an external working group.

Each network will submit one U01 application that includes subawards to the collaborating sites.

2. Partnership with Data Processing, Analysis and Coordination Center (DPACC): Network(s) funded under this FOA must agree to partner with a DPACC (to be funded under RFA-MH-20-341 (//grants.nih.gov/grants/guide/rfa-files/rfa-mh-20-341.html)) which will be functionally separate from the network. The DPACC will, in partnership with the network(s), design and conduct data processing and analyses and oversee all data management, including organizing and performing on-site monitoring. In addition, DPACC staff will provide program support and generate standard operating procedures that include assisting in the design of protocols, data collection forms, data collection/distribution systems, quality assurance and monitoring systems, data sharing, and report generation.

3. Partnership with Steering Committee (SC) and External Working Group (EWG): Network(s) funded under this FOA must agree to partner with an SC and an EWG. The SC will include the PD(s)/PI(s), the PD(s)/PI(s) of the DPACC, External Working Group members, NIMH Project Scientist(s), and the NIMH Program Officer and will serve as the operational governing board for the CHR Network(s) and the DPACC. The External Working Group (EWG) will be composed of four to six senior scientists with relevant expertise and whom are not directly involved with the DPACC or CHR network(s).

4. Sharing of Data Generated by the Consortium Project: All data resulting from projects funded under this FOA will be transferred from the network sites to the DPACC in near real-time using processes to be established by the DPACC in conjunction with NIMH and an external working group. All data collected will be deposited into the NIMH Data Archive (https://nda.nih.gov/) (NDA) within 6 months of collection and made available to qualified investigators. The DPACC and the network of research sites will use the NIMH Global Unique Identifier (GUID) (https://data-archive.nimh.nih.gov/ndct/s/sharedcontent/plan/project-startup.html) infrastructure to create unique identifiers that protect the anonymity of the individual-level patient data. Staff at the NDA will be responsible for helping to distribute the GUID infrastructure to all the network research sites.

If a network or a collaborating network site is located in a country in which sharing of subject-level data via the NDA is not allowed, alternative approaches for analysis of network data and sharing of data resources are allowable.

Technical Assistance

Applicants are strongly encouraged to consult with NIMH staff when developing plans for an application (see Agency Contacts, Section VII). This early contact will provide an opportunity to clarify NIMH policies and guidelines and identify whether the proposed project is consistent with the purpose of this FOA.

A technical assistance teleconference will be held for potential applicants on Tuesday, December 17, 2019 at 3:00 pm EST. NIH staff will be available to answer questions related to this FOA during this teleconference. To obtain call-in information, please send a request to chrfoas@mail.nih.gov (mailto:chrfoas@mail.nih.gov) 24 hours in advance of the call. Prospective applicants are encouraged to submit their questions or comments in advance to chrfoas@mail.nih.gov (mailto:chrfoas@mail.nih.gov). Participation in the teleconference is neither required nor necessary for a successful application. A summary of the teleconference will be available upon request via chrfoas@mail.nih.gov (mailto:chrfoas@mail.nih.gov). For more information on the teleconference see https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-high-risk-for-psychosis.shtml (https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-high-risk-for-psychosis.shtml).

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

Section II. Award Information

Funding Instrument

Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this FOA.

Application Types Allowed

New
The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

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.htm?id=82370)

Funds Available and Anticipated Number of Awards

NIMH intends to commit up to a total of $11,000,000 in FY20 to fund 1-2 awards under this FOA.

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 5 years.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions

- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Governments

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

Foreign Institutions

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

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

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

Required Registrations

Applicant organizations

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

- Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.

- eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

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

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

Eligible Individuals (Program Director/Principal Investigator)

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

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

PD/PIs submitting an application under this FOA will not be eligible to submit an application as a PD/PI under RFA-MH-20-341 (//grants.nih.gov/grants/guide/rfa-files/rfa-mh-20-341.html).

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.
The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

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

Section IV. Application and Submission Information

1. Requesting an Application Package

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

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

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

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

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

The letter of intent should be sent to: nimhpeerreview@mail.nih.gov (mailto:nimhpeerreview@mail.nih.gov)

Page Limitations

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

Instructions for Application Submission

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

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

SF424(R&R) Senior/Key Person Profile

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

R&R or Modular Budget

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

The application must include only its own budget, including any subcontract budgets associated with it. Separate itemized budgets must be prepared for each anticipated subcontract.

The costs associated with attending annual in person meetings and monthly teleconferences should be included in the proposed budget.

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

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

Research Strategy

Significance: Explain why the proposed approach to establishing a research network focused on rapid recruitment of a large number of CHR individuals is optimal to achieve the scientific objectives of the FOA.

Innovation: Describe plans to employ unique or novel methodologies that will enhance the establishment and functioning of a CHR research network and collection of multimodal biomarker data. Explain how the research team plans to use current best practices to recruit, assess, track, and retain participants and partner with the DPACC for the purpose of centralized data analysis and resource sharing.

Approach:

Management plan

Applicants should present a Management Plan that describes the following:

- How the PD(s)/PI(s) will manage the proposed project, who will oversee the day-to-day activities (e.g., a project manager if not a PD/PI). A project manager may, in addition, strengthen the CHR network administration.
- How the management will support achievement of the proposed goals and milestones.
- Organization of the CHR network, including its coordination and communication functions among sites, key personnel, reporting relationships, a management plan for fiscal accountability and communication.
- How collaborations or subcontracts, if proposed, will be managed
- How the structure, governance, and mechanisms to ensure close collaboration among the “hub” anchor site and “spoke” clinical programs sites will support scientific integration of research procedures, overall managerial and administrative responsibilities, appropriate quality control and reliability assurance, and planning for data management.
- Plans for shared decision making among the PD/PI, Steering Committee, and clinical program sites regarding personnel, clinical decisions, changes in study protocol, and authorship.

Biomarker, trajectory, and outcome assessment

- The application should indicate how the proposed network defines CHR and how CHR status will be determined;
- Applicants should propose a preliminary core assessment battery, including measures of baseline characteristics and illness features, multimodal biomarkers, and symptomatic and functional outcomes and justify the proposed measures in terms of reliability and validity, participant burden, and utility for dissecting the heterogeneity of CHR outcomes. The applicant should describe the frequency and method of assessment, training required to administer measures, and the appropriateness of the measures for use in diverse populations. The final assessment battery will be determined in partnership with the NIMH and external working groups.
- Applicants should outline a strategy for feasibly and efficiently collecting the assessment battery data in a standardized fashion across CHR network sites. The application should include a clear plan for how the network’s information technology systems will support this data collection and ensure interoperability among the network sites.
- Applicants should identify possible challenges in enrolling CHR participants and implementing the core assessment battery and propose strategies to overcome these challenges.

Applicants should present a detailed set of milestones and a timeline covering all aspects of the CHR network’s activities. Include annual milestones with metrics that will document progress towards the achievement of the ultimate goals. Applications should include plans for critically evaluating and revising these milestones on a regular basis.

Workflow for Data Sharing

- Applicants should describe the data security processes and privacy procedures to be used for collecting, storing, and sharing data from CHR participants, including establishing a Global Unique Identifier number (GUID) for each patient to de-identify and protect the anonymity of individual-level data. Regional hubs should use the NIMH Global Unique Identifier (GUID) (https://nda.nih.gov/contribute/harmonization-standards.html#guid) infrastructure as the subject identifier. Staff at the NIMH Data Archive will be responsible for helping regional hubs to export GUID infrastructure to all network sites.
- The data workflow should be designed to facilitate sharing of subject-level data to the DPACC, however, if local privacy regulations do not allow for sharing of subject-level data, the workflow should facilitate combined analysis of network data to be coordinated by the DPACC and data sharing as allowable.

- Applicants should present a plan for maintaining high standards for data completeness and integrity, including establishing data quality metrics and data submission procedures to ensure appropriate quality control.

Collaboration with the DPACC and Steering Committee

Applicants should outline a strategy for maintaining a high level of collaboration with the DPACC on key tasks, including the following:

- Participating as a member of the Steering Committee, including monthly phone calls and an annual in-person meeting;
- Sharing common data elements, standard measures, and data collection procedures with the DPACC
- Submitting de-identified, patient-level data to the DPACC which will become part of a readily accessible CHR data resource that can be widely used by the extramural research community.

Study Team Expertise: The PD/PI (or Multi-PDs/PIs) of the network must be experienced in the establishment, coordination, and management of multi-site clinical research networks, including success in meeting milestones and timelines. The experience of each PD/PI and all Key Personnel must be carefully documented, and roles and responsibilities must be well-defined. Network(s) require a multidisciplinary team and the application should reflect the team's background in hands-on involvement in the steps needed for rapid recruitment and assessment of CHR participants, acquisition of multi-modal biomarker and clinical data, as well as study coordination.

Describe the study team members' experience and expertise in the following areas:

- establishment, coordination, and management of clinical research networks;
- recruitment and retention of individuals who meet CHR criteria; and
- collection of multi-modal biomarker and clinical and functional outcome data.

Environment*:* Describe features of the network and its constituent sites that promote enrollment and retention of a large number of CHR individuals.

Provide evidence of the ability of the sites to (1) enroll the proposed numbers of CHR participants; (2) adhere to the data collection protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.
The following modifications also apply:

The instructions for the Resource Sharing Plan specified in NOT-MH-19-033 (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-033.html) do not need to be followed since the data to be collected will not be known at the time of application. However, all applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan. This plan should focus on the collection of data required for generation of a NIMH Global Unique Identifier (GUID) (https://data-archive.nimh.nih.gov/ndct/s/sharedcontent/plan/project-startup.html) and procedures for quickly providing data to the DPACC for centralized quality control, analysis, and archiving.

Appendix:

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

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:
If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

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

Foreign Institutions

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

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

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

4. Submission Dates and Times

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

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

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

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

5. Intergovernmental Review (E.O. 12372)

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

6. Funding Restrictions

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

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

7. Other Submission Requirements and Information

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

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). 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 Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements.

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

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

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

Post Submission Materials

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

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?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 review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

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

Significance

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

Is the proposed approach to establishing a research network focused on rapid recruitment of a large number of CHR individuals optimal to achieve the scientific objectives of the FOA?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage

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

Is the PD/PI (or Multi-PDs/PIs) of the network experienced in the establishment, coordination, and management of multi-site clinical research networks, including successfully meeting milestones and timelines? Is the experience of each PD/PI and all Key Personnel carefully documented and roles and responsibilities well-defined? Does the study team have multidisciplinary expertise and background in hands-on involvement in the steps needed for rapid recruitment and assessment of CHR participants, acquisition of multi-modal biomarker and clinical and functional outcome data, as well as study coordination? #160;

Innovation

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

Does the application include plans to employ unique or novel methodologies that will enhance the establishment and functioning of a CHR research network and collection of multimodal biomarker and clinical and functional outcome data? Does the research team plan to use current best practices to recruit, assess, track, and retain participants and partner with the DPACC for the purpose of centralized data analysis and resource sharing?

Approach

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

Management Plan

Does the application include a detailed management plan that describes the following?

- How the PD(s)/PI(s) will manage the proposed project, who will oversee the day-to-day activities (e.g., a project manager if not a PD/PI);
- How the management will support achievement of the proposed goals and milestones;
- Organization of the CHR network, including its coordination and communication functions among sites, key personnel, reporting relationships, a management plan for fiscal accountability and communication;
- How collaborations or subcontracts, if proposed, will be managed;
- How the structure, governance, and mechanisms to ensure close collaboration among the “hub” anchor site and “spoke” clinical programs sites will support scientific integration of research procedures, overall managerial and administrative responsibilities, appropriate quality control and reliability assurance, and planning for data management; and
- Plans for shared decision making among the PD/PI, Steering Committee, and clinical program sites regarding personnel, clinical decisions, changes in study protocol, and authorship.

Biomarker, trajectory, and outcome assessment

Does the application include a description of how the proposed network will define CHR and how CHR status will be determined?

Is the proposed preliminary core assessment battery (including measures of baseline characteristics and illness features, multimodal biomarkers, and symptomatic and functional outcomes) well justified in terms of reliability and validity, participant burden, and utility for dissecting the heterogeneity of CHR outcomes? Is information provided about the frequency and method of assessment, training required to administer measures, and the appropriateness of the measures for use in diverse populations?

Does the application include a strategy for feasibly and efficiently collecting the assessment battery data in a standardized fashion across CHR network sites and a plan for how the network's information technology systems will support this data collection and ensure interoperability among the network sites?

Does the application identify possible challenges in enrolling CHR participants and implementing the core assessment battery and propose effective strategies to overcome these challenges?

Is a detailed set of milestones and a timeline covering all aspects of the CHR network's activities included? This should include annual milestones with metrics that will document progress towards the achievement of the ultimate goals and plans for critically evaluating and revising these milestones on a regular basis.

Workflow for Data Sharing

Does the application include a data workflow designed to collect and aggregate data and provide data to the DPACC? Are processes for ensuring data security and privacy in collecting, storing, and sharing data from CHR participants (including establishing a Global Unique Identifier) provided?

Is there a plan for maintaining high standards for data completeness and integrity, including establishment of data quality metrics and data submission procedures to ensure appropriate quality control?

Collaboration with the DPACC and Steering Committee

Does the application include a strategy for maintaining a high level of collaboration with the DPACC on key tasks, including participating as a member of the Steering Committee, sharing common data elements, standard measures, and data collection procedures with the DPACC, and submitting de-identified, patient-level data to the DPACC?

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

Environment

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

Are the features of the network and its constituent sites optimal for promotion of enrollment and retention of a large number of CHR individuals?

Is evidence of the ability of the sites to (1) enroll the proposed numbers of CHR participants; (2) adhere to the data collection protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure provided?

Additional Review Criteria

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

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects

and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

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

Inclusion of Women, Minorities, and Individuals Across the Lifespan

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

Vertebrate Animals

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

Biohazards

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

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

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

Applications from Foreign Organizations

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

Select Agent Research

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

Resource Sharing Plans

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

Authentication of Key Biological and/or Chemical Resources:

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

Budget and Period of Support

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the National Institute of Mental Health, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria (file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1._Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

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

Appeals (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) of initial peer review will not be accepted for applications submitted in response to this FOA.
Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Mental Health Council.
The following will be considered in making funding decisions:

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

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.
Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157).
A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

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

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

Institutional Review Board or Independent Ethics Committee Approval: Grantee 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 awardee must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158).
Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

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

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

individuals/special-topics/limited-english-proficiency/index.html). The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html (https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html)https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html (https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html). Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see https://www.hhs.gov/civil-rights/for-individuals/disability/index.html (https://www.hhs.gov/civil-rights/for-individuals/disability/index.html). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 75, and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below.

The PD(s)/PI(s) will have the primary responsibilities as described below:

- Provide scientific and administrative leadership and coordination of the project at the awardee and sub-awardee institutions and among collaborators.
- Oversee and perform the scientific activities within the guidelines of this FOA.
- Accept close coordination, cooperation, and participation of NIMH program staff in the scientific, technical, and administrative management of the grant.
- Provide milestones and cost for the grant to the NIMH program staff as requested (usually at the outset of the award and annually thereafter, but also at other times as requested by the program staff).
- Provide periodic progress reports summarizing CHR network activities and achievement of project milestones to NIMH staff as requested.
- Serve as a voting member of the CHR Steering Committee (SC) and fulfill related duties outlined below in Areas of Joint Responsibility.
- Attend at least monthly SC meetings and one yearly in person meeting.
- Demonstrate capability and flexibility for acquiring different types of biomarker data from participants in the CHR network.
- Share data and resources according to the data release and resource sharing policies developed for and by this project as appropriate and consistent with achieving the rapid and broad sharing goals of the program.
- Adhere to NIMH policies regarding intellectual property and other policies that might be established during the course of this activity.
- Accept and implement the common guidelines and procedures approved by the Steering Committee, External Working Group, and NIMH.

NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

The NIH Project Scientist(s) will:

- Provide relevant scientific expertise to the CHR network(s) and DPACC.
- Participate as a voting member of the SC, attend SC meetings, and assist in developing network study protocols and data collection procedures, quality control processes, and coordinating with the DPACC.
- Participate with other SC members in the group process of setting research priorities (key questions) for aggregation and harmonization of existing data and collection of new data by the CHR network and for analyses of CHR biomarker and clinical data, annual milestones for the project, and periodic adjustments of research protocols or approaches as warranted.
- Assist with coordination of network activities with the development of evolving tools and technologies in data science, database management, and analysis, with the scientific mission and evolving goals of the NIMH, and with other U.S. and international efforts that focus on sharing research resources for CHR biomarkers.
- Assist in promoting and encouraging the sharing of unique research resources for studies of CHR biomarkers by the scientific community at large.
- Assist in developing timetables for the timely, open, and free sharing of data and research resources received and produced by the network and DPACC to the scientific community.
- Participate in SC activities, including conference calls, working groups and special committees.
- Participate in the project update meetings and conference calls with the PD(s)/PI(s) on a weekly or monthly basis, as dictated by the needs of the project.
- It is anticipated that decisions in all activities will be reached by consensus of the SC and that NIMH staff will be given the opportunity to offer input to this process. One NIH Project Scientist will participate as a member of the SC and will have one vote.

The NIH Program Officer will:

- Be responsible for the normal scientific and programmatic stewardship of the award, including programmatic monitoring of the overall project.
- Be responsible for negotiating, monitoring, and implementing the data and research resource sharing plans and the milestones to ensure that the goals of the project are being met.
- Monitor the conduct and progress of the project to ensure milestones (go/no go and annual milestones) are accomplished in accordance with the timeline.
- Participate in SC meetings and conference calls as a non-voting participant.
- Approve modifications to the research plan and/or study protocol(s), in consultation with the SC, based on emerging data and/or other issues that impact progress of the project.
- Reserve the right to obtain periodic external peer review and recommend reviewers for an assessment of progress and achievement of milestones and deliverables.
- Monitor performance and compliance with NIH procedures.
- Negotiate the selection of existing cohorts for aggregation and harmonization of biomarker, clinical, and functional outcome measures with the awardee based on research priorities and associated cost.
- Negotiate the data types and frequency of new data collection by the CHR network, quality control, and cost goals with the awardees, including options to modify protocols for data collection when certain objectives of this FOA are not being met or as scientific goals evolve.
- Participate in SC, SC working group and/or special committee meetings and conference calls as a nonvoting member and serve as an administrative liaison.

Areas of Joint Responsibility include:

CHR Steering Committee. The CHR Steering Committee (SC) will serve as the operational governing board for the CHR Network(s) and the DPACC. The SC will include: the PD(s)/PI(s), the PD(s)/PI(s) of the DPACC, External Working Group members (to be named after award), NIMH Project Scientist(s), and NIMH Program Officer.

The CHR SC will:

- Coordinate the activities of the DPACC and CHR network as well as the distribution of data, algorithms, and other resources to the wider scientific community.
- Facilitate the development of uniform procedures for CHR data acquisition, data quality, and nomenclature and annotation conventions for data depositions to the NIMH Data Archive (NDA) or other shared analysis platform if local regulations prohibit deposition to the NDA.
- Advise on research priorities, optimal research designs, and project milestones.
- Discuss scientific progress and make recommendations regarding the enhancement of research activities

and the facilitation of free and open sharing of resources.
- Convene an External Working Group of outside experts, as needed, to address new scientific goals.
- Participate in reviewing scientific progress of the project, assessing CHR network recruitment, and progress of the go/no go and annual milestones.
- The DPACC SC will vote to elect a chair, who will be responsible for developing meeting agendas and chairing meetings.
- The SC will meet, at least monthly via teleconference and plan to hold an annual in-person investigators' meeting that includes NIMH staff and External Working Group members as appropriate. Further meetings can be convened on an *ad hoc* basis around specific issues. The network PD(s)/PI(s) will provide funds for travel for themselves to attend the annual in-person meeting.
- Hold teleconferences to address operational issues on a weekly or monthly basis, or as dictated by the needs of the project.
- External Working Group (EWG) members will be selected by the PD(s)/PI(s) and approved by the NIMH Program Officer.
- Establish workgroups for specific tasks as the SC deems appropriate. The workgroups will make recommendations to the SC and may include representatives from the DPACC and CHR network(s), NIMH Project Scientists, and external experts. Workgroups may be formed to address relevant issues such as: developing standards for integrating extant CHR data sets and information; addressing submission of newly acquired data from the CHR network(s); data management and analysis issues; developing quality standards and methods for quality control and assurance; and selection of common informatics tools for analyses of diverse biomarker and clinical data types.

The External Working Group (EWG) will be composed of four to six senior scientists with relevant expertise and whom are not directly involved with the DPACC or CHR network(s); the membership may be adjusted on an ad hoc basis as needed.

The EWG will:

- Participate in the selection of biomarkers and outcome measures to be implemented by the network.
- Provide consultation to the DPACC regarding the types of data analyses to be conducted.
- Provide recommendations about the progress and scientific direction of all components of the program (including the DPACC and CHR network(s) and will make recommendations about changes, if any, that may be necessary in the overall program.
- Meet at least twice a year in person or by teleconference.
- Participate once a year in a joint meeting with the SC for the members of both the EWG and SC to interact directly.

Dispute Resolution: Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened. It will have three members: a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special dispute resolution procedure does not alter the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161)
A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative

agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

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

Section VII. Agency Contacts

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

Application Submission Contacts

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

Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-945-7573

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

Scientific/Research Contact(s)

Sarah Morris, Ph.D.
National Institute of Mental Health (NIMH (http://www.nimh.nih.gov/index.shtml))
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Peer Review Contact(s)

Nick Gaiano, Ph.D.
National Institute of Mental Health (NIMH (http://www.nimh.nih.gov/index.shtml))
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Email: nick.gaiano@nih.gov (mailto:nick.gaiano@nih.gov)

Financial/Grants Management Contact(s)

Rita Sisco
National Institute of Mental Health (NIMH (http://www.nimh.nih.gov/index.shtml))
Telephone: 301-443-2805
Email: siscor@nih.gov (mailto:siscor@nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

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

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?11-29-19)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

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