Notice of Intent to Publish a Funding Opportunity Announcement for A Practice-Based Research Network to Transform Mental Health Care: Science, Service Delivery & Sustainability (U19 Clinical Trial Required)

Notice Number: NOT-MH-18-014

Key Dates

**Release Date:**January 24, 2018  
**Estimated Publication Date of Funding Opportunity Announcement**: 03/01/2018   
**First Estimated Application Due Date:** 06/01/2018   
**Earliest Estimated Award Date:** 03/01/2019   
**Earliest Estimated Start Date:** 03/01/2019   
  
Related Announcements  
None

Issued by  
National Institute of Mental Health ([NIMH](http://www.nimh.nih.gov/))

Purpose

The NIMH intends to publish a Funding Opportunity Announcement (FOA) Cooperative Agreement (U19) to solicit applications for a practice-based research network to transform mental health care.  
   
The planned FOA will support a practice-based research network in the United States to transform the development, delivery, and sustainability of evidence-based mental health practices and services. Through a research consortium embedded within large and integrated healthcare delivery systems, this Network would result in a continuously learning healthcare system as defined by the Institute of Medicine, to create “a continuous cycle or feedback loop in which scientific evidence informs clinical practice while data gathered from clinical practice and administrative sources inform scientific investigation.” The Network will support a wide range of practice-based research, including pragmatic and comparative effectiveness trials focused on optimizing and testing scalable preventive and therapeutic interventions and services research focused on identifying and intervening on mutable factors to increase access, engagement, continuity, equity, efficiency/value, and quality of mental health care. Leveraging practice-based networks as platforms for launching large-scale studies offers an efficient alternative to those conducted de novo trials.  
   
Demonstrable capacities and efficiencies are needed to accomplish the following:

* Rapidly identify, recruit and enroll large and representative patient populations into effectiveness and pragmatic trials that align with NIMH priorities;
* Harmonize electronic health record (EHR) data across multiple integrated systems for research use, to include EHR phenotyping;
* Collect biologic material for future analyses;
* Provide rapid responses to address urgent questions from federal, state, and other key stakeholders (e.g., questions related to the clinical epidemiology of mental disorders and/or questions related to the uptake of and outcomes associated with mental health interventions and best practices);
* Study low base-rate events (e.g., suicide, autism spectrum disorders, first episode psychosis, or other mental health conditions which are difficult to identify, predict, treat, or manage) by using and advancing innovative methodologies (e.g., predictive analytics) or resources which capitalize on the network’s unique sophistication in health information technology, overall size, or research efficiencies;
* Test strategies to reduce disparities in mental health status, service utilization, quality of care, and treatment outcomes in the health of people with mental illness, including disparities in medical comorbidities among adults with serious mental illness and youth with serious emotional disturbance;
* Develop strategies using implementation science to secure stakeholder commitment to adopt, implement, scale-up, and sustain best practices at the patient, provider, and health system levels.

This Notice is being provided to allow potential applicants sufficient time to develop meaningful collaborations and appropriate projects.   
  
The FOA is expected to be published in March 2018 with an expected application due date in June 2018.    
  
  
The FOA will utilize the U19 activity code. Details of the planned FOA are provided below.

Research Initiative Details

This Notice encourages investigators with expertise and insights into this area to begin to consider applying for this new FOA.  
  
**NETWORK GOALS**  
   
The Network is expected to function as a resource to the broad mental health research community, and its impact will be assessed through achievement of the following activities:

* Maintaining accessibility to relevant patient, provider, and health system data;
* Facilitating and coordinating access to these data for research conducted by Network-affiliated and non-affiliated investigators using approaches and solutions that optimize the use of the Network and are conducive to collaborative efforts;
* Maintaining high levels of expertise and competency in scientific areas relevant to the Network, US healthcare system stakeholders, and federal, state, and other key stakeholders;
* Facilitating interactions and research collaborations among (non-network affiliated) mental health researchers who might benefit from these data;
* Increasing participation of Network-affiliated and non-affiliated investigators in independently funded research, including efforts to increase the number, scope, and scientific impact of research projects conducted by external investigators in collaboration with the Network;
* Ensuring study samples include adequate representation of disparity populations to examine disparity reductions in mental health status, service utilization, and treatment outcomes in the health of people with mental illness, including disparities in medical comorbidities among adults with serious mental illness and youth with serious emotional disturbance;
* Building from established relationships with relevant constituent groups (e.g., patients, providers, administrators, payors, relevant federal and state agencies) to inform research questions, and attending to front-end infrastructure to secure stakeholder commitment to adopt, implement and sustain successful practices and products developed within this Network;
* Developing and testing strategies (using implementation science) to encourage adoption, quality, scale-up, and sustainability of new innovations and existing best practices;
* Developing and maintaining capacity to rapidly respond to and address urgent questions from Network-affiliated healthcare system partners, as well as federal, state, and other key stakeholders;
* Advancing expertise in research methodology and “big data” science, with attention to implementing findings from these advances into routine practice;
* Conducting well-powered studies, to include at least one large-scale pragmatic trial (described below) to definitively answer a research question of high importance and impact and whose findings, whether positive or negative, will be used by the Network’s healthcare system(s) to improve practice in an identifiable and measurable way;
* Conducting pilot projects (described below and directly funded by the Network) that will allow Network and external investigators to develop competitive applications for funding large-scale research projects;
* Including mid-career investigators in positions of leadership and fostering the careers of junior investigators;
* Developing and utilizing simulation approaches to model the potential public health impact of implementing research informed approaches and to guide decision making; and
* Harnessing perspectives from new and emerging fields (e.g., health information and communications technology, health systems engineering, decision science, behavioral economics) to transform clinical research and practice.

This practice-based research network for mental health will capitalize on the successes of and lessons learned from other such networks in mental health and other disease areas.    
   
**OVERALL STRUCTURE OF THE NETWORK**  
   
To effectively conduct the large and pilot projects and to achieve the aforementioned network goals, the proposed practice-based research network structure will be encompassed within an Administrative and Methods Core.   
   
**Administrative Core** (three functional units):  
1) The Organizational Unit will coordinate the Network’s administrative functions, provide organizational and administrative support for activities, and coordinate an evaluation of the Network's research, efficiencies created by the Network, and public health impact of its activities.   
   
2) The Outreach and External Collaboration Unit will work to increase the usage of the Network by Network and non-Network investigators, manage requests for data and resources, coordinate opportunities for junior and mid-career investigators, and disseminate approaches and research findings and products.  
   
3) The Emerging Issues Unit will develop a rapid and systematic capability for response to real-time inquiries to policy and practice relevant requests from Network and federal, state, and other stakeholders and leaders.  These rapid responses will capitalize on Network data and thus must include data pulls and data analysis from network healthcare systems.  It will also require some synthesis of available literature.  This capacity will include a transparent process to clarify the key question(s) being asked, the level of detail in the response, and the format and timeline for a response.    
   
**Methods Core** (two functional units):   
   
1) The Informatics Unit is the key component for the Network resource function. This Unit should be organized to support Network informatics infrastructure, notably including a data warehouse, and to continue improvements in data development, informatics tools, etc. The Informatics Unit should coordinate informatics-related efforts at individual Network member sites as well as interact with other Units and Projects (see below) to support their functions.  
   
2) The Scientific Analysis Unit is organized to generate new methodology and apply state of the art analytic approaches to the fields of big data science, health services research, and implementation science.  The unit should provide consultation and analytic support for network and affiliated projects to develop, identify, and engage putative change mechanisms in health system research.  
   
**Large Pragmatic Trial** (clinical trial required):  
   
At least one large pragmatic trial should be proposed as part of the application. The trial should address a significant problem in the prevention, treatment, management, and/or the delivery of services to people with mental disorders served by the health systems affiliated with the Network. The topic should align closely with NIMH strategic research priorities, and the topic should be demonstrated to be of such value to the affiliated healthcare system(s) that a priori, there is a well-developed plan for how definitive findings (whether they are positive or negative) will affect practice. The trial should be similar in scope to an R01 in terms of the research question(s), and because the Network infrastructure will be leveraged, there should significant and demonstrative efficiencies created than if the study was conducted *de novo*.      
   
To be responsive, the trial design must follow the NIMH experimental therapeutics approach; applicants are strongly encouraged to model the RCT on the NIMH R01 funding announcement for clinical trials to test the effectiveness of treatment, preventive, and services interventions (<http://www.nimh.nih.gov/about/director/2012/experimental-medicine.shtml> and <https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-17-608.html>).  
   
The trial should be a pragmatic clinical trial which, depending upon level of evidence and implementation readiness, should be designed as a hybrid effectiveness-implementation clinical trial Type I, II, or III.   
   
**Pilot Projects:**  
   
Applications for pilot projects should include innovative approaches consistent with the goals of this current announcement. The pilots should seek to optimize and improve care for a diverse population of patients within defined healthcare systems of the network; develop and/or test new IT platforms, risk algorithms, decision support systems, and preventive, therapeutic, or services interventions; reduce health disparities by engaging intervention targets; and improve methodologies in systems research, and/or seek strategies to continuously improve the accessibility, quality, continuity, equity and value of services delivered within the network.  
   
The pilots should be modeled on the NIMH R34 funding announcement for clinical trials (<https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-16-410.html>) or non-trial services research (<https://grants.nih.gov/grants/guide/pa-files/PAR-15-323.html>).  Pilots may or may not be clinical trials. For any pilot that is a clinical trial, the NIMH experimental therapeutics paradigm must be followed and research questions should be similar in type and scope to those supported by the NIMH R34 mechanism.  
   
It is expected that by leveraging the infrastructure of the network and the healthcare systems, efficiencies will be created by an order of magnitude when compared to similar studies conducted de novo. Pilot projects should involve network-affiliated as well as non-affiliated investigators wherever possible.  
   
**Markers of Successful Practice Based Research Network**  
   
A successful network will accomplish the following tasks within the period of the award:

* Build and extend capacity of the network to conduct prospective trials via the successful completion of multiple pilot studies of types of interventions not yet studied in such networks.
* Successfully complete at least one large pragmatic trial of high impact on the mental health and functioning of a large and representative population, where positive or negative findings will lead to measurable improvements in practice across the Network sites.
* Benchmark the costs of conducting a range of studies on the network compared to historical norms and progress toward network-involved trials to be completed with costs at an order of magnitude below prior norms relative to similar studies conducted *de novo*.
* Expand tools to create efficiency in the rapid conduct of effectiveness, services, and implementation research studies on the network.
* Use business models which foster data sharing, create efficiencies when collaborating with network-affiliated and non-network-affiliated healthcare systems, and strengthen the self-sustainability of the Network.
* Successfully disseminate trial results to health system Network partners resulting in significant change of policy and/or practice as a direct result of study findings.
* Rapidly disseminate research findings in high quality journals consistent with NOT-OD-16-149 and NOT-OD-18-011.
* Dissemination of Network generated research products, including methodological/analytic approaches, assessment and intervention approaches and materials, sharable programing (e.g., for technology based applications), and de-identified data.

NIMH will invest $2 million per year for this 5-year project (i.e., $10 million total costs over the project period).  
   
Foreign institutions will NOT be eligible to apply.  
   
It is planned that foreign components of U.S. institutions will be eligible to apply.

Funding Information

**Estimated Total Funding** TBD  
**Expected Number of Awards**TBD  
**Estimated Award Ceiling**TBD  
**Primary CFDA Numbers**TBD

Anticipated Eligible Organizations

Non-domestic (non-U.S.) Entity (Foreign Organization)

**Applications are not being solicited at this time.**

Inquiries

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