U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Maternal and Child Health Bureau

Office of Epidemiology and Research, Division of Research

U3D Measurement Research Network (MRN)

Funding Opportunity Number: HRSA-19-071

NOTICE OF FUNDING OPPORTUNITY CLARIFICATION

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Introduction

The purpose of this Notice of Funding Opportunity (NOFO) Clarification Document is to provide supplemental background information to eligible applicant organizations interested in **HRSA-19-071 Measurement Research Network.** Information in this document are necessary for the submission of a competitive proposal. All applicants should review this document while preparing their proposals. Please refer to the full announcement on grants.gov for critical information pertaining to this grant opportunity.

HRSA MCH Research Network Program

The Measurement Research Network is part of HRSA's Maternal and Child Health (MCH) Research Network Program which supports the establishment and maintenance of interdisciplinary, national, multi-site, collaborative research networks (RNs) which lead, promote, and coordinate national research activities on broad and specific fields of pediatrics and MCH. HRSA MCH RNs have contributed to improving the lives and health of MCH populations by: 1) enrolling and serving approximately 1.4 million participants in research studies; 2) publishing 420 peer-reviewed publications in leading journals; and 3) developing and putting 84 clinical guidelines, tools, and toolkits collectively in the hands of over 260,000 practitioners and families.

Organization, Functions, and Expectations of the Network Coordinating Center (NCC) and Clinical Research Entities (CREs):

Organization and Functions:

The NCC will be located at the Principal Investigator's (PI) institution, which is the recipient of the cooperative agreement. The NCC provides a core of administrative and operational functions that include the following:

- Support the Network infrastructure for partnership among CREs;
- Provide the Network with administrative and operations support in activities including, but not limited to, meetings, multidisciplinary educational activities, and development of research studies;
- Facilitate the process for the development, selection, implementation, and oversight of scientific research studies;
- Coordinate a plan to enhance the research training and mentorship of junior/new investigators through the use of innovative mentorship/research experiences and manuscript development; and
- Coordinate the dissemination of findings to health professionals, researchers, policymakers, family members and the greater public.

All major scientific decisions are determined by majority vote of the Network Advisory Board or Steering Committee. All participating CREs must agree to abide by the study designs and policies approved by the Network Advisory Board or Steering Committee.

The Network Advisory Board or Steering Committee will be constituted by representatives of the CREs. The PI will serve as Chair of the Network Advisory Board or Steering Committee. This body will meet monthly by phone and in-person at least once a year.

Data Collection and Management. The NCC will facilitate data gathering, data management training, and data quality assurance. CREs must follow the Network policies and procedures to (1) monitor adverse events; (2) report data and other information to the NCC in a timely and accurate manner; and (3) ensure good clinical practice and/or other applicable regulatory requirements.

Expectations of the NCC and CREs

The Network Coordinating Center (NCC) is responsible for overseeing the Clinical Research Entities (CREs) or sites established nationwide. The Network provides the CREs with guidance to ensure:

- Availability of staff and training needed for the CREs to implement a study protocol and participate in Network activities;

- Establishment of a data acquisition system needed to collect relevant outcome data for all study participants according to protocol-specific requirements; and
- Existence of support such as quality control to ensure the successful completion of the Network scientific goals, projects, and activities.
- You should include budgets for CRE travel support to Network meetings in your applications. **You do not need to include detailed budget forms and indirect cost agreement forms for each CRE proposed in your application.**

Each CRE Site Principal Investigator (PI) should, as appropriate, in conducting studies and participating in Network activities:

- Describe his/her plan to establish and sustain the CRE;
- Participate in Network subcommittees and agree to attend Network monthly teleconferences and in-person meetings;
- Participate in the development of concept and protocols of research studies to be conducted by the Network;
- Agree to participate in research studies, including subject enrollment, data collection, patient record maintenance, adherence to good clinical practice, compliance with protocol requirements, randomization methods, as appropriate, for assignment of patients to experimental or control groups or randomization of care delivered to different conditions;
- Participate in Network activities that enhance the research training and mentorship of junior/new investigators; and
- Inform the translation of critical Network findings to practice settings and educational training that will result in advancing and strengthening the evidence base and further develop the field of MCH measurement research and other related outcomes.

Application and Submission Information (Section IV of the NOFO)

Program-Specific Instructions

ii. Project Narrative

NEEDS ASSESSMENT

SECTION II – SPECIFIC GOALS AND OBJECTIVES -- Corresponds to Section V's Review Criteria #2 Response, #4 Impact, and #5 Resources/Capabilities

This section of the narrative must include:

- A numbered list of the specific goals and objectives that address the major network activities listed in the Purpose section of this notice to be accomplished during the funding period. The specific objectives should be succinctly stated. You should be

innovative with respect to specific objectives, but direct attention to the scope of expected activities listed.

- The process for developing an integrated research network and present a plan of proposed activities that shows progressive implementation during the 3-year period of performance.
- A description of the activities or steps that will be used to achieve each of the project goals. Please use a timeline that includes each activity and identifies responsible staff.
- A description of how proposed activities will build upon ongoing efforts, and not duplicative of existing efforts. As appropriate, identification of meaningful support and collaboration with key stakeholders and partners in planning, designing, and implementing all activities.
- A logic model for designing and managing the project in this section of the narrative. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements. While there are many versions of logic models, for the purposes of this notice, the logic model should summarize the connections between the:
  Goals of the project;
  - Theoretical approach;
  - Inputs (e.g., organizational profile, collaborative partners, other resources);
  - Target population(s);
  - Activities;
  - Outputs (i.e., products); and
  - Outcomes (i.e., the results of the project, typically describing a change in people or systems).

You may discuss all of the elements of the logic model in this section, but the diagram should be included as Attachment 4.

Provide documentation (letters of agreement) of participation of Collaborating Research Entities (CREs) sites that will collaborate to fulfill the goals and objectives of the research network, with descriptions of each CRE's characteristics, including patient population characteristics, average patient numbers, types of treatment or services currently delivered, number, characteristics and structure of staff. Include letters of agreement from CRE sites in Attachment 1. At least one CRE should demonstrate success in recruiting from underserved population(s) such as low-income, racial/ethnic minorities, immigrants, individuals who have limited access to services, and/or other underserved populations as defined by your organization.

Application Review Criteria (Refers to Section V of the NOFO)

Criterion 1: NEED

The extent to which the application describes:

- An approach using interdisciplinary collaborative multi-site research to address the identified needs, including the needs of underserved populations, such as low-income, racial/ethnic minorities, immigrants, individuals who have limited access to services, and/or other underserved populations;
- The current research gaps in the evidence base related to measurement research focusing on those with limited research and evidence, and for which prevailing policy and practice environments call for increased attention given their potential to improve health outcomes for MCH populations; and
- The national significance and impact of a MRN and how the coordination of multi-site research can advance the field.

Grant Application Completeness Checklist

Funding Opportunity Number: ————————————

Application Due Date in Grants.gov: _____

Requirement	Yes	No	Comments
Are you applying to the **correct funding opportunity (HRSA-19-071)**?			
Do you meet the **eligibility criteria**?			
Did you read the **R&R Application Guide?**			HRSA's SF-424 R&R Application Guide: https://www.hrsa.gov/grants/apply/application guide/sf424rrguidev2.pdf
Do you have a **DUNS number**?			Dun and Bradstreet number: http://www.dnb.com/duns-number.html
Did your Authorized Organization Representative register in **SAM and Grants.gov?**			• This process can take up to 1 month to complete. • System for Award Management (SAM:) https://www.sam.gov/ • Grants.gov: http://www.grants.gov/
In the **INTRODUCTION** section, did you demonstrate knowledge of MCH measurement research, identified gaps in research, and included a literature review?			

Requirement	Yes	No	Comments
In the **NEEDS ASSESSMENT** section, did you fully address unmet needs?			
In the **PROJECT DESIGN: METHODS AND EVALUATION** section did you include methods, a plan for sustainability, and a plan for dissemination of findings?			
In the **WORKPLAN** section did you include the steps to achieve objectives and logic model, process to develop research network, plan of proposed activities, and logic model?			
In the **RESOLUTION OF CHALLENGES** section, did you discuss challenges to designing and implementing described activities?			
In the **EVALUATION AND TECHNICAL SUPPORT CAPACITY** section, did you include a plan for program evaluation, tracking systems and processes, staff knowledge, skills, published research, and potential obstacles to program evaluation?			
In the **ORGANIZATIONAL INFORMATION** section, did you describe the organization's mission, structure, and scope of activities, and include an organizational chart in Attachment 3 and staffing plan and job descriptions in Attachment 2?			
In the **BUDGET** section, did you accurately complete the Budget and Budget Justification to include logistical support for the HRSA MCH RN/SIIP Meeting? Did you follow the budget instructions in the **NOFO and R&R Application Guide**?			The directions offered in the **SF-424 R&R Application Guide** differ from those offered by Grants.gov. Please follow the instructions included in the R&R Application Guide and, *if applicable*, the additional budget instructions in the **NOFO**. Your institution's indirect cost rate is negotiated by the institution with the
Do you know your institution's **indirect cost rate**?			U.S. Department of Health and Human Services (HHS). Check with your sponsored programs office for further information about the indirect cost rate.

Requirement	Yes	No	Comments
In the **PROGRAM ASSURANCES Section,** did you fully address: • Feasibility? • Evaluation and Technical Support Capacity? • Protection of Human Subjects? • Targeted/Planned Enrollment?			
Is your **Project Summary/Abstract** one page in length **and** single-spaced?			
Did you clearly label your **attachments**?			
Are your **page borders** no more than 1 inch wide?			Bio sketches can have .5" margins.
Did you include **Bio sketches**?			
Did you use 12-point **font**?			
Are your **pages**, including attachments and bio sketches, within the 80-page limit?			Face page, Standard OMB-approved forms, Indirect Cost Rate Agreement, proof of non-profit status (if applicable), and budget pages **do not count** toward the 80-page limit.
Is the **PROJECT DESIGN: METHODS AND EVALUATION Section** strictly within the 12-page limit?			
Is the **budget** within the funded limit per year?			
Did you experience system glitches or a qualified emergency and need to request an **exemption/waiver**?			Submit exemption request in writing to: DGPWaivers@hrsa.gov

Relevant Websites

Bright Futures
http://brightfutures.aap.org/

Healthy People 2020
http://www.healthypeople.gov/2020/
Human Subjects Assurances
http://www.hhs.gov/ohrp
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Inclusion of Children - Policy Implementation
http://grants.nih.gov/grants/funding/children/children.htm

National Academy of Medicine
https://nam.edu/

Making Websites Accessible: Section 508 of the Rehabilitation Act
http://www.section508.gov/

MCH Training Website
http://www.mchb.hrsa.gov/training

National Center for Cultural Competence
http://nccc.georgetown.edu/

National Center for Medical Home Implementation
http://www.medicalhomeinfo.org/

Logic Models
https://www.cdc.gov/eval/tools/logic_models/index.html

Tips for Writing a Strong Application

See Section 4.7 of HRSA's *SF-424 R&R Application Guide*.