# U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Maternal and Child Health Bureau
Office of Epidemiology and Research
Maternal and Child Health (MCH) Research Network Program

# U5D MCH Pediatric Research Network Program (PedsRN)

Funding Opportunity Number: HRSA-20-061 Funding Opportunity Type(s): New Assistance Listings (CFDA) Number: 93.110

## NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2020

Application Due Date: April 23, 2020

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!

HRSA will not approve deadline extensions for lack of registration.

Registration in all systems, including SAM.gov and Grants.gov,

may take up to 1 month to complete.

Issuance Date: January 24, 2020

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Authority: Social Security Act, Title V, § 501(a)(2) (42 U.S.C. § 701(a)(2)), as amended

# **EXECUTIVE SUMMARY**

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2020 Maternal and Child Health (MCH) Pediatric Research Network Program (PedsRN). The purpose of this program is to establish and maintain an interdisciplinary, national, multi-site research platform for scientific collaboration and infrastructure building. The Research Network will provide the platform for conducting original research studies (funded by HRSA), and leveraging external support and resources for conducting other research studies and implementing research-related activities within the scope of the Network. The Research Network will provide national leadership for applied and translational practice-based pediatric research and interventions<sup>1</sup> to advance the evidence base for pediatric practice. PedsRN will accomplish this by supporting: collaborative practice-based research aimed at enhancing primary care practice, the development of evidence-based guidelines based on network research findings, and dissemination of findings in order to accelerate the translation of research into practice.

Funding Opportunity Title:	U5D MCH Pediatric Research Network	
	Program (PedsRN)	
Funding Opportunity Number:	HRSA-20-061	
Due Date for Applications:	April 23, 2020	
Anticipated Total Annual Available	\$300,000	
FY 2020 Funding:		
Estimated Number and Type of Award(s):	One cooperative agreement	
Estimated Award Amount:	Up to \$300,000 total cost per year	
	dependent on the availability of	
	appropriated funds	
Cost Sharing/Match Required:	No	
Period of Performance:	September 1, 2020 through	
	August 31, 2025 (5 years)	

<sup>&</sup>lt;sup>1</sup>For the purpose of this NOFO, an "intervention" is defined as a manipulation of the subject or subject's environment to modify one or more health-related biomedical or behavioral processes and/or endpoints or outcomes for children and adolescents. Examples include, but are not limited to, delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior(s) (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; and prevention strategies. A manipulation or task would be regarded as an intervention if it is used to modify a health-related biomedical or behavioral outcome. A manipulation or task used expressly for measurement, and not modification, would not be considered as an intervention. National Institutes of Health, Office of Extramural Research. Frequently Asked Questions: NIH clinical trial definition. Available at: <a href="https://grants.nih.gov/grants/policy/faq\_clinical\_trial\_definition.htm#5226">https://grants.nih.gov/grants/policy/faq\_clinical\_trial\_definition.htm#5226</a>. Accessed August 27, 2019.

Eligible Applicants:

Only domestic public or nonprofit institutions of higher learning and public or private nonprofit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs are eligible to apply. See 42 CFR Part 51a.3(b). Domestic faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

See Section III.1 of this notice of funding opportunity (NOFO) for complete

## **Application Guide**

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in HRSA's *SF-424 R&R Application Guide*, available online at <a href="http://www.hrsa.gov/grants/apply/applicationguide/sf424rrguidev2.pdf">http://www.hrsa.gov/grants/apply/applicationguide/sf424rrguidev2.pdf</a>, except where instructed in this NOFO to do otherwise.

eligibility information.

## **Technical Assistance**

HRSA has scheduled the following technical assistance:

#### Webinar

Day and Date: Tuesday, February 4, 2020

Time: 1:30-2:30 p.m. ET

Call In Number: 1-800-779-7168

Participant Code: 4968

Weblink: https://hrsa.connectsolutions.com/fy20 pedsrn ta/

In an attempt to more effectively utilize our TA webinar time, if you have questions about the NOFO, please send them beforehand via email to Maura Maloney at <a href="MMaloney@hrsa.gov"><u>MMaloney@hrsa.gov</u></a> and Erica Caesar at <a href="ECaesar@hrsa.gov"><u>ECaesar@hrsa.gov</u></a>. We will compile and address these questions during the TA webinar.

HRSA will record the webinar and make it available at: https://hrsa.connectsolutions.com/fy20 pedsrn ta/.

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# I. Program Funding Opportunity Description

## 1. Purpose

This notice announces the opportunity to apply for funding under the U5D MCH Pediatric Research Network (PedsRN) Program. The purpose of this program is to establish and maintain an interdisciplinary, national, multi-site research platform for scientific collaboration and infrastructure building. The Research Network will provide national leadership for applied and translational practice-based pediatric research and interventions to advance the evidence base for pediatric practice. PedsRN will accomplish this by supporting: collaborative practice-based research aimed at enhancing primary care practice, the development of evidence-based guidelines based on network research findings, and dissemination of findings in order to accelerate the translation of research into practice.

The Research Network will identify effective practices to promote children's health in primary care settings. This will be accomplished through the establishment and ongoing development of a national network of primary care and child health professionals. These health care professionals will collaborate in the development and implementation of research designed to increase knowledge of pediatric care.

The Research Network will:

- Lead, promote, and coordinate national research activities to improve the physical health and well-being of the pediatric population and their families;
- Develop and maintain an infrastructure to support a portfolio of multi-site, interdisciplinary research specifically focused on fostering practice-based research studies, translating this research into policy and practice, and providing a mentoring environment to train clinical and non-clinical researchers in applied and translational practice-based pediatric research;
- Advance health equity by providing outreach to, and conducting research that, addresses the needs of underserved and safety net populations (e.g., families and children living in poverty, in rural and urban areas, or at high risk of poor developmental outcomes in physical, social, emotional, or cognitive domains);
- Address, where applicable, the U.S. Department of Health and Human Services' (HHS) and Health Resources and Services Administration's (HRSA) priorities; namely, mental health, opioid use disorder, prescription drug pricing, maternal mortality, and telehealth.

The recipient of the cooperative agreement is encouraged to leverage and extend, as appropriate, the impact of HRSA's existing programs and resources in the areas of child health and development.

For cooperative agreement activities please see Project Narrative Section IV.

### 2. Background

This program is authorized by the Social Security Act, Title V, § 501(a)(2) (42 U.S.C. § 701(a)(2)), as amended.

The PedsRN is a multi-site Research Network focused on building the evidence base for pediatric primary care practice by engaging practicing pediatric health care providers in practice-based research. The providers will conduct collaborative practice-based research to enhance primary care practice; develop evidence-based guidelines based on network research findings; disseminate findings; and accelerate the translation of research into practice. HRSA/MCHB has supported the PedsRN Program since 1986.

Persistent and pervasive disparities in child health and health care by race, ethnicity, and socioeconomic status mean that many children are not reaching their potential.<sup>2</sup> For example, social determinants of health can lead to adverse health outcomes in childhood and across the life course, negatively affecting physical health, socioemotional development, and educational achievement.<sup>3</sup> Pediatric providers are an essential part of national efforts to reduce and eliminate health disparities, as they can influence a child's health, development, and life course trajectory by promoting effective strategies and approaches in practice.<sup>4,4</sup> However, changes in primary and specialty practice, increasing family needs, and demographic diversity mean that pediatricians and other child health care professionals lack readily-available evidence to effectively assess and address health disparities in practice.<sup>2</sup> Practice-based research advances knowledge by drawing upon lessons learned from primary care delivery with the potential to improve the health of pediatric populations.<sup>5</sup> In the absence of adequate infrastructure designed to support primary care research, primary care is unlikely to be grounded in an adequate scientific base and knowledge. 6 Moreover, the National Academy of Medicine recommends the development of robust research infrastructures in order to address emerging public health challenges and to generate or advance the evidence base for the translation of research into practice. Multi-site research networks have been critical to health care advances across the spectrum of pediatric and adult care, yielding landmark studies on such topics as secondary sexual characteristics, smoking cessation, body mass index reduction, and immunization.8

The Research Network will bring together a group of practicing primary care providers, and draw upon their experiences and insights to identify community-based research

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<sup>&</sup>lt;sup>2</sup>Cheng TL, Emmanuel MA, Levy DJ, Jenkins RR. Child Health Disparities: What Can a Clinician Do? *Pediatrics*. 2015; 136(5), 961-

<sup>&</sup>lt;sup>3</sup>American Academy of Pediatrics, Council on Community Pediatrics. Poverty and Child Health in the United States (Policy Statement). *Pediatrics*. 2016; 137(4), e20160339.

<sup>&</sup>lt;sup>4</sup>American Academy of Pediatrics (AAP). *AAP Agenda for Children: Health Equity*. <a href="https://www.aap.org/en-us/about-the-aap/aap-facts/AAP-Agenda-for-Children-Strategic-Plan/Pages/AAP-Agenda-for-Children-Strategic-Plan-Health-Equity.aspx.">https://www.aap.org/en-us/about-the-aap/aap-facts/AAP-Agenda-for-Children-Strategic-Plan-Health-Equity.aspx.</a> Accessed September 1, 2019.

<sup>&</sup>lt;sup>5</sup>Institute of Medicine. For the Public's Health: Investing in a Healthier Future. Washington, DC: The National Academies Press; 2012. <a href="http://www.nationalacademies.org/hmd/Reports/2012/For-the-Publics-Health-Investing-in-a-Healthier-Future.aspx">http://www.nationalacademies.org/hmd/Reports/2012/For-the-Publics-Health-Investing-in-a-Healthier-Future.aspx</a> Accessed September 1, 2019.

<sup>&</sup>lt;sup>6</sup>Institute of Medicine. *Primary Care: America's Health in a New Era.* Washington, DC: The National Academies Press; 1996. https://www.nap.edu/read/5152/chapter/1 Accessed September 1, 2019.

<sup>&</sup>lt;sup>7</sup>Institute of Medicine. For the Public's Health: Investing in a Healthier Future. Washington, DC: The National Academies Press; 2012. <a href="http://www.nationalacademies.org/hmd/Reports/2012/For-the-Publics-Health-Investing-in-a-Healthier-Future.aspx">http://www.nationalacademies.org/hmd/Reports/2012/For-the-Publics-Health-Investing-in-a-Healthier-Future.aspx</a> Accessed September 1, 2019.

<sup>&</sup>lt;sup>8</sup>Lindbloom EJ, Ewigman BG, Hickner JM. Practice-based research networks: the laboratories of primary care research. *Medical Care*, 2004; 42(4), 45-49.

questions, and translate research findings, with the aim of improving primary care practice.<sup>6, 7</sup> By linking these questions with rigorous research methods, in settings accessible to the target populations of interest, the PedsRN program will produce research findings that are immediately relevant to the primary care clinician and easily translated into everyday practice.<sup>9</sup>

The majority of U.S. children receive care from primary care clinicians in community settings. The PedsRN cooperative agreement is positioned to generate and develop knowledge essential to the maintenance and advancement of the health of a sizeable proportion of the pediatric population.

### The HRSA Maternal and Child Health Research Network Program

The PedsRN is part of the HRSA-MCHB Research Network Program. The Research Network Program, administered by the Division of Research in MCHB's Office of Epidemiology and Research, supports the establishment and maintenance of interdisciplinary, multi-site, collaborative, national Networks that lead, promote, and coordinate national research activities on broad and specific MCH topics. As of June 2019, HRSA MCH Research Networks have contributed to improving the lives and health of MCH populations by:

- Enrolling and serving approximately 3.9 million participants in research studies;
- Publishing 837 peer-reviewed articles in leading scholarly journals; and
- Developing and placing 84 clinical guidelines, tools, and toolkits collectively in the hands of over 260,000 practitioners and families.

For more information about the MCH Research Program and the MCH PedsRN Program, visit our website: http://www.mchb.hrsa.gov/research.

# **Objectives and Functions**

The PedsRN will forge partnerships with pediatric health professionals, researchers, educators, advocates, families, local public health programs, and other organizations/agencies critical to translating the Network's research into practice.

The following describes multiple aspects of the Network that you should consider in the development of your application:

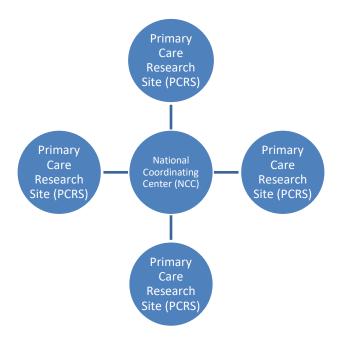
#### Organization and Functions

The PedsRN structure<sup>10</sup> will consist of a Network Coordinating Center (NCC) and collaborating primary care research sites (PCRS). The NCC is the administrative center

<sup>&</sup>lt;sup>9</sup>Agency for Healthcare Research and Quality. *Fact Sheet. Primary Care Practice-Based Research Networks.* Rockville, MD: Agency for Healthcare Research and Quality; 2001. <a href="https://www.ahrq.gov/sites/default/files/publications/files/pbrn.pdf">https://www.ahrq.gov/sites/default/files/publications/files/pbrn.pdf</a> Accessed September 1, 2019.

<sup>&</sup>lt;sup>10</sup>This structure ensures that all the Research Network's activities encompass an approach to address population needs to "accelerate, upstream, together." **Accelerate:** An acknowledgement that although progress has been made in a variety of areas, much remains to be done. RNs must continue to innovate, grow the evidence base, and strive to address health disparities in maternal and child health by considering ways to reduce the gap between populations—whether those defined by race, place, age,

of the Research Network, providing leadership and maintaining a partnership with its PCRS. A sample of this structure is depicted in the following diagram:



# **Research Network Organizational Structure with the NCC**

The NCC will be located at the cooperative agreement recipient's institution. The NCC provides the core administrative and operational functions that include the following:

- 1) Support the Research Network infrastructure for partnerships among the PCRS;
- 2) 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 diverse emerging investigators through the use of mentorship/research experiences and manuscript development;
- 4) Coordinate the dissemination of findings to health professionals, researchers, policymakers, family members and the public;
- 5) Establish and foster partnerships with programs and organizations serving underserved populations, and recruit study participants from these populations;
- 6) Establish a plan to ensure parent, family, and/or consumer involvement and input in Research Network activities; and
- Collaborate with pertinent partners including the other MCHB-supported Research Network recipients and other programs related to child health and development.

or gender. **Upstream:** A consideration of the social determinants of health—a broader and more expansive way of looking at contributors to health beyond health care. RNs must think about primary prevention, but recognize the importance of secondary and tertiary prevention for some MCH populations. **Together:** A need to strategically engage stakeholders who understand the needs and priorities of the maternal and child health population. RNs must collaboratively develop solutions to the current and emerging health and development challenges.

### Research Network Advisory Board or Steering Committee

The Research Network Advisory Board or Steering Committee will be comprised of representatives of the PCRS and HRSA/MCHB. The PI will serve as Chair of the Research Network Advisory Board or Steering Committee. All major scientific decisions (e.g., study designs and policies) are determined by majority vote of the Research Network Advisory Board or Steering Committee. All participating PCRS must agree to abide by these approved decisions. The Research Network Advisory Board or Steering Committee will meet monthly by telephone or other online platforms, and in person at least once a year at a location accessible to Network members. The PI will meet annually with HRSA/MCHB leadership and other key stakeholders including, but not limited to: Title V directors, clinical interest groups, state and local education districts, Centers for Medicare and Medicaid Services, and Department of Education agencies, as applicable, to brief them on the existence and progress of the Research Network and to leverage their networks for translating Research Network findings into practice and policy.

<u>Data Collection and Management</u>. The NCC will facilitate data gathering, data management training, and data quality assurance according to previously developed protocol. PCRS must follow the Research Network policies and procedures to (1) monitor adverse events; (2) report data and other information to the NCC; (3) ensure good clinical practice or other applicable regulatory requirements; and (4) participate in the national evaluation of HRSA/MCHB's Research Networks.

#### **II. Award Information**

# 1. Type of Application and Award

Type(s) of applications sought: New

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement, as opposed to a grant, is an award instrument of financial assistance in which substantial involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

In addition to the usual monitoring and technical assistance provided under the cooperative agreement, **HRSA Program responsibilities shall include**:

- Assurance of the availability of HRSA/MCHB personnel or designees to participate in the planning and development of all phases of this activity;
- 2) Review of policies and procedures established for carrying out project activities;
- 3) Participation in meetings and regular communications with the award recipient to review mutually agreed-upon goals and objectives and to assess progress;
- 4) Facilitation of effective communication and accountability to HRSA/MCHB regarding the project, with special attention to new program initiatives and policy developments that have the potential to advance the utility of PedsRN;
- 5) Assistance in establishing and maintaining federal interagency and interorganizational contacts necessary to carry out the project;

- Review of all documents and products prior to submission for publication or public dissemination; and
- Participation in project activities such as meetings, webinars, presentations, publications, and other forms of disseminating information regarding project results and activities.

# The cooperative agreement recipient's responsibilities will include:

- Establishing and maintaining an interdisciplinary network of practice-based pediatric primary care researchers, providers, and other stakeholders, (including families) which will accelerate the translation of science into pediatric practice, promote scientific collaboration, and support additional research capacity in the field of pediatric health and health care;
- 2) Designing and implementing multi-site research protocols to develop evidence-based practices for interventions (including innovative models for reaching underserved populations), address disparities in physical health interventions, and treatment of individuals, and treatment of the pediatric population;);
- Establishing partnerships with programs or pediatric primary care practices in different settings serving, and recruiting study participants from underserved populations including but not limited to, the HRSA Health Center Program or the HRSA MIECHV Program;
- 4) Developing and instituting a plan to ensure dissemination of Research Network findings via peer-reviewed publications and other formats (e.g., presentations, tools, toolkits, guidelines) to diverse stakeholders in order to increase the evidence base and accelerate the adoption of effective interventions into practice;
- 5) Providing a research environment that supports the professional development and mentorship of emerging or new investigators in the field of practice-based pediatric primary care research;
- 6) Fostering the translation of Research Network findings into interventions, guidelines, tools, toolkits, and systems management approaches in practice settings and communities to promote the translation of evidence-based practices that will result in improved care;
- 7) Developing and implementing procedures to store and share, after a 3-year embargo period, de-identified data with members of the research community in a manner that protects the privacy of participants and providers, while enabling the full utilization of those data to improve the health and well-being of the pediatric population;
- Leveraging Research Network capacity to compete for grant opportunities from other federal and private sources to bolster support and extend implementation of research protocols; and
- 9) Providing an electronic copy of any products supported by award funds (including guidelines, assessment tools, publications, books, pamphlets, PowerPoint presentations, curricula, videos, etc.) to the public and to the MCH Research Program.

### 2. Summary of Funding

HRSA estimates approximately \$300,000 to be available annually to fund one recipient. The actual amount available will not be determined until enactment of the final FY 2020 federal appropriation. You may apply for a ceiling amount of up to \$300,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is September 1, 2020 through August 31, 2025 (5 years). Funding beyond the first year is subject to the availability of appropriated funds for PedsRN Program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

All HRSA awards are subject to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements at <u>45 CFR part 75</u>.

Please note that if indirect costs are requested, the applicant must submit a copy of the latest negotiated rate agreement. This project supports an infrastructure from which to conduct research, but is not a research project in and of itself, therefore, it is not eligible for research indirect rates. The indirect costs rate refers to the "Other Sponsored Program/Activities" rate and to neither the research rate, nor the education/training program rate. Those applicants without an established indirect cost rate for "other sponsored programs" may only request 10 percent of salaries and wages, and must request an "other sponsored programs" rate from Cost Allocation Services (CAS).

Direct cost amounts for equipment (capital expenditures), tuition and fees, and contracts in excess of \$25,000 are excluded from the actual direct cost base for purposes of this calculation.

# **III. Eligibility Information**

# 1. Eligible Applicants

Only domestic public or nonprofit institutions of higher learning and public or private nonprofit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs are eligible to apply. See 42 CFR § 51a.3(b). Domestic faith-based and community-based organizations, tribes, and tribal organizations are also eligible to apply.

# 2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

#### 3. Other

HRSA will consider any application that exceeds the ceiling amount of \$300,000 total costs per year non-responsive and will not consider it for funding under this notice.

HRSA will consider any application that fails to satisfy the deadline requirements referenced in <u>Section IV.4</u> non-responsive and will not consider it for funding under this notice.

The <u>Methods</u> section of the Project Narrative is limited to 12 pages in length. Applications that exceed this 12-page limit for the Methods section will be deemed nonresponsive, and will **not** be considered for funding under this notice.

NOTE: Multiple applications from an organization are allowable. In order to diversify the HRSA/MCHB research grant portfolio, an individual cannot serve as the project director (PD) or PI on more than one active HRSA MCH Research Network. To foster interdisciplinary collaboration and increase opportunities for mentorship for emerging MCH researchers, a PD/PI on an active HRSA MCH research grant is allowed up to 10 percent effort as a co-investigator on an existing HRSA MCH research grant. HRSA allows one PD/PI to be named on the cover page of the SF-424 R&R application, who will serve as the key point of contact. The application can include co-investigators as key personnel on the project. It does not apply to being a PI on grants from other agencies. However, if selected for funding, the new recipient will need to verify that percent effort across all federally-funded grants does not exceed 100 percent.

Please make sure you submit your application to the correct NOFO number: HRSA-20-061, the U5D MCH PedsRN Program competition. Applications submitted to the wrong competition will be deemed nonresponsive and will not be considered for funding under this notice.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates) an application is submitted more than once prior to the application due date, HRSA will only accept your **last** validated electronic submission, under the correct funding opportunity number, prior to the <u>Grants.gov</u> application due date as the final and only acceptable application.

# IV. Application and Submission Information

#### 1. Address to Request Application Package

HRSA **requires** you to apply electronically. HRSA encourages you to apply through <u>Grants.gov</u> using the SF-424 Research and Related (R&R) workspace application package associated with this notice of funding opportunity (NOFO) following the directions provided at <a href="http://www.grants.gov/applicants/apply-for-grants.html">http://www.grants.gov/applicants/apply-for-grants.html</a>.

The NOFO is also known as "Instructions" on Grants.gov. You must provide your email address when reviewing or preparing the workspace application package in order to receive notifications including modifications and/or republications of the NOFO on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are ultimately responsible for reviewing the For Applicants page for all information related to desired opportunities.* 

### 2. Content and Form of Application Submission

Section 4 of HRSA's <u>SF-424 R&R Application Guide</u> provides instructions for the budget, budget justification, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the *R&R Application Guide* in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA's <u>SF-424 R&R Application Guide</u> except where instructed in the NOFO to do otherwise. You must submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

See Section 8.5 of the <u>SF-424 R&R Application Guide</u> for the Application Completeness Checklist.

### **Application Page Limit**

The total size of all uploaded files may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments including biographical sketches and letters of commitment and support required in HRSA's <u>SF-424 R&R Application Guide</u> and this NOFO. Standard Office of Management and Budget (OMB)-approved forms that are included in the workspace application package do not count in the page limit. Biographical sketches **do** count in the page limitation. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.** 

Applications must be complete, within the specified page limit, and validated by Grants.gov under the correct funding opportunity number prior to the deadline to be considered under this notice.

#### Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- You, on behalf of the applicant organization, certify, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
- 3) Where you are unable to attest to the statements in this certification, an explanation shall be included in *Attachment 8: Other Relevant Documents*.

See Section 4.1 viii of HRSA's <u>SF-424 R&R Application Guide</u> for additional information on all certifications.

## **Program-Specific Instructions**

In addition to application requirements and instructions in Section 4 of HRSA's <u>SF-424</u> <u>R&R Application Guide</u> (including the budget, budget justification, staffing plan and personnel requirements, assurances, certifications, and abstract), include the following:

#### i. Project Abstract

See Section 4.1.ix of HRSA's SF-424 R&R Application Guide.

Include the information requested at the top of the abstract. Because the abstract is often distributed to provide information to the public and Congress, please prepare this so that it is clear, accurate, concise, and without referring to other parts of the application. Briefly state the principal needs and problem, goals, proposed activities including target population(s), planned coordination, anticipated products, and plans for evaluation.

**Abstract content:** The following describes the different section headers (capitalized) and suggested content, which should be included in the abstract in the corresponding order. The abstract must be limited to **one page.** 

- FUNDING OPPORTUNITY NUMBER: HRSA-20-061
- FUNDING OPPORTUNITY TITLE: U5D Maternal and Child Health Pediatric Research Network Program (MCH PedsRN)
- PROBLEM: Briefly state the principal needs and problems that are addressed by the project.
- GOAL(S) AND OBJECTIVES: Identify the major goal(s) and objectives for the period of performance. Typically, the goal is stated in a sentence or paragraph, and the objectives are presented in a numbered list.
- PROPOSED ACTIVITIES AND TARGET POPULATION(S): Describe the programs and activities used to attain the objectives, the target population(s) addressed, and comment on innovations and other characteristics of the proposed plan.
- COORDINATION: Describe the coordination planned with, and participation of, appropriate national, regional, state, and/or local health agencies, interdisciplinary professional groups and providers, and/or organizations that function as stakeholders or partners in the proposed project.
- PRODUCTS: Provide a brief description of the anticipated products of this Network, including modes of dissemination of project activities and findings.
- EVALUATION: Briefly describe the evaluation methods used to assess program outcomes as well as the effectiveness and efficiency of the project in attaining goals and objectives.
- KEY TERMS: From <u>Appendix B</u> select: (a) significant content terms that describe your project (maximum of 10 content terms), (b) targeted populations (select all that apply), and (c) age ranges (select all that apply), and include at the end of your abstract.

#### ii. Project Narrative

This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory, consistent with forms and attachments, and well-organized so that reviewers can understand the proposed project.

Successful applications will contain the information below. Please use the following section headers for the narrative:

**SECTION I – BACKGROUND AND SIGNIFICANCE-**CORRESPONDS TO SECTION V'S REVIEW CRITERIA #1 NEED, #2 RESPONSE, AND #4 IMPACT

Demonstrate/Include the following:

- A thorough knowledge and understanding of the gaps in evidence-based practices for interventions to improve pediatric health;
- Critical evaluation of the national significance of this Research Network;
- Knowledge and identification of the health needs and issues for children and adolescents across the life course;
- How proposed interdisciplinary research studies may fill gaps in research and advance the field of practice-based primary care research; and
- How the interdisciplinary, national, multi-site Research Network may address the identified needs of children and adolescents, including those of underserved populations.

**SECTION II – SPECIFIC GOALS AND OBJECTIVES -** CORRESPONDS TO SECTION V'S REVIEW CRITERIA <u>#2 RESPONSE</u>, <u>#4 IMPACT</u>, AND #5 RESOURCES/CAPABILITIES

Include the following:

- A numbered list of objectives and goals that address the major network activities listed in the <u>Purpose</u> section of this notice to be accomplished during the period of performance. Specific objectives should be succinctly stated and innovative, and direct attention to the scope of expected activities listed. In addition, each objective should be specific, measurable, achievable, realistic, time-bound (SMART), and tied to a distinct goal;
- A detailed plan for completing several pediatric primary care and practicebased intervention studies, including studies on emerging health topics affecting children and adolescents in consultation with HRSA/MCHB stakeholders;
- The process for developing an integrated Research Network and a plan of proposed activities showing progressive implementation to ensure national reach during the 5-year period of performance;
- · A description of the activities or steps that will be used to achieve each of

- the project goals. Please provide a timeline that includes each activity and identifies responsible staff;
- A description of how proposed activities will build upon ongoing efforts, and not be duplicative of existing funded efforts (including HRSA/MCHB projects). As appropriate, identification of meaningful support and collaboration with key stakeholders and partners in planning, designing, and implementing all activities; and
- A logic model utilized 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. The creation of a logic model is a requirement of this Application, as described in the <a href="Attachments Section">Attachment Section</a> of this NOFO (Attachment 5). HRSA's expectations and goals for the logic model is further illustrated in <a href="Appendix D">Appendix D</a> of this NOFO.

Provide documentation (letters of agreement) of participation of nationally-distributed PCRS from across HRSA regions that will collaborate to fulfill the goals and objectives of the Research Network, with descriptions of each research site's characteristics that include patient population characteristics; average patient numbers; intervention; or services currently delivered; and characteristics and structure of staff. Include letters of agreement from PCRS in *Attachment 2*. It is expected that no fewer than four PCRS are recruited from different HRSA regions working in collaboration with partnering programs are required and should demonstrate existing partnerships in recruiting from underserved population(s) with limited access to services, and/or other underserved populations.

To assist you in demonstrating a plan for collaboration with programs serving underserved populations, this section describes the expected documentation that would demonstrate commitment of both your organization and the partnering programs. Examples of collaboration with HRSA's Health Center Program and the MIECHV Program are given. For collaboration with other programs, you should provide similar documentation relevant to their application and program.

The HRSA Health Center Program: Submit a letter of agreement from a Primary Care Association (PCA) that will serve as the mediator for research involving recruitment from Health Centers. The PCA will document a commitment to working with your organization in identifying Health Centers that demonstrate the patient population needed to support Research Network research endeavors. They will support staff leadership and commitment to the project and collaboration with your organization to fulfill the purpose of the Research Network program. The PCA will facilitate the arrangements between your organization and the Health Centers.

Link to find Primary Care Associations:

https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/ncapca/associations.html

Establish subcontract arrangements between your organization and Health Centers identified by the PCA for Research Network participation that will provide funding for Health Center Program liaison(s), such as a research project coordinator. The Health Center Program liaison will facilitate the research coordination and recruitment of Health Center patients for Research Network research studies.

The HRSA MIECHV Program: Submit a letter of agreement from a MIECHV State Program that will facilitate connections with MIECHV local implementing agencies (LIAs). The MIECHV State Program must document a commitment to working with your organization in the identification of LIAs that demonstrate the patient population needed to support Research Network research endeavors. They will support staff leadership and commitment to the project and collaboration with your organization to fulfill the purpose of the Research Network program. The MIECHV State Program will facilitate arrangements between your organization and the MIECHV LIAs.

Link to find MIECHV State Programs: <a href="https://mchb.hrsa.gov/maternal-child-health-initiatives/home-visiting/fy18-home-visiting-awards">https://mchb.hrsa.gov/maternal-child-health-initiatives/home-visiting/fy18-home-visiting-awards</a>

Establish subcontract arrangements between your organization and the MIECHV LIAs that will provide funding for a LIA liaison. The LIA liaison will facilitate the research coordination and recruitment of participants served by the MIECHV LIAs for Research Network research studies.

Responsibility of the NCC overseeing the PCRS: Address how the Research Network will manage PCRS. The Research Network provides the PCRS with guidance to ensure:

- Staff and training needed for the PCRS to implement a study protocol and participate in Research Network activities;
- A data acquisition system to collect intake, treatment, and outcome data for all study participants, according to protocol-specific requirements and
- Additional support such as quality control to ensure the successful completion of the scientific goals of a research project and other Research Network activities. Include budgets for PCRS travel support to Research Network meetings in your applications.

<u>Responsibility of Each PCRS</u>: Each PCRS should, as appropriate, in conducting studies and participating in Research Network activities:

- Describe plan to establish and sustain the PCRS;
- Participate in Research Network subcommittees and agree to attend Research Network monthly teleconferences and in-person meetings;
- Participate in the development of concept and protocol of observational and clinical trial studies to be conducted by the Research Network;

- Agree to participate in observational studies and clinical trials, including subject enrollment, data collection, patient record maintenance, adherence to good clinical practice, compliance with protocol requirements, randomization methods for assignment of patients to experimental or control groups or randomization of care delivered to different conditions;
- Participate in Research Network activities that enhance the research training and mentorship of junior/new investigators; and,
- Participate in the translation of critical Research Network findings into practice settings and educational training that will result in advancing and strengthening the evidence base on primary care pediatric research.

SECTION III – PROJECT DESIGN: METHODS AND EVALUATION CORRESPONDS TO SECTION V'S REVIEW CRITERIA #2 RESPONSE,
#3 EVALUATIVE MEASURES, #4 IMPACT, AND #5
RESOURCES/CAPABILITIES

#### 1. Methods:

#### This section has a strict 12-page limit.

Provide detailed descriptions of the methodology for accomplishing the work of the Research Network and each of its distinct objectives. Provide sufficient technical detail to demonstrate the necessary steps to accomplish each objective and to convey to reviewers adequate information to assess the methodology.

Indicate the specific methods that will be used to evaluate progress in each activity area. List and discuss anticipated obstacles that may be encountered and indicate how these will be overcome.

It is important that you describe how the interdisciplinary team will function in true partnership/collaboration within the Research Network to accomplish their objectives and meet their goals. Anticipate potential problems and challenges that may arise in this process, and propose mechanisms for collaborative resolution.

Successful participation in the Research Network includes the ability to work collaboratively to achieve the goals of the Research Network, address challenges, and fulfill commitments to the project as indicated in the proposal and Letters of Agreement.

In addition, describe plans to disseminate findings to stakeholders, including health professionals, policymakers, family members, and the greater public. These include:

 Peer-reviewed publications: Produce at least three peer-reviewed publications per year. In addition, it is expected that a new or

- updated national research agenda for the Research Network will be published in a peer-reviewed journal;
- Research Network website: Maintain a public Research Network website to disseminate research findings, generate interest in the Research Network, and expand Research Network membership;
- Research acceleration: Disseminate findings to help accelerate the synthesis, analysis and translation of existing and future knowledge so that it can be applied to practice and policy at the state and national levels:
- Stakeholder engagement: Showcase informational products and educational opportunities, including webinars, website material, plenary sessions, abstracts, conference presentations, annual Research Network meetings, and consumer materials, etc.

#### **2.** Evaluation:

Describe a plan for program performance evaluation that will contribute to continuous quality improvement. The program performance evaluation should monitor ongoing processes and progress towards the goals and objectives of the project.

Also indicate the specific methods that will be used to evaluate progress in each activity area. List and discuss anticipated obstacles to implementing the program performance evaluation that may be encountered and describe plans to overcome these obstacles.

Describe the systems, processes, and staff that will support the organization's performance management requirements through effective tracking of performance outcomes, including a description of how the organization will collect and manage data (e.g., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes. As appropriate, describe the data collection strategies that will be used to collect, analyze, and track data to measure progress and impact/outcomes with different sociocultural groups (e.g., race, ethnicity, language, rural versus urban, socioeconomic, gender), and explain how the data will be used to inform program development and service delivery.

For each described objective, include an evaluation measure. The evaluation measure should be SMART with a timeline for evaluation and should be presented consistent with the plan and schedule of implementation of the goals and objectives

#### 3. Cooperative Agreement Activities

## **Infrastructure Development**

- Develop and maintain a national network of pediatric clinical practices across
  the country that will collaborate to advance clinical science and accelerate
  the translation of research into practice, in accordance with the objectives
  and functions outlined in this NOFO; and
- Establish an interdisciplinary Network Advisory Board or Steering Committee comprised of a broad representation of diverse key stakeholders, including but not limited to, health professionals, national experts, research entities, and family members (including those from underserved populations),<sup>11</sup> in accordance with the guidance outlined in this NOFO.

#### **Research Network Activities**

- Create an interdisciplinary Research Network of pediatric providers for practice-based pediatric research;
- Conceptualize, or update and publish a national research agenda for practice-based pediatric primary care research in a peer-reviewed journal;
- Design, implement, and complete several multi-site intervention research studies, clearly identifying the number of studies and how these address disparities in access to pediatric health care, models of care delivery (including innovative models serving underserved populations), and emerging issues affecting the pediatric population in consultation with HRSA/Maternal Child and Health Bureau (MCHB) leadership;<sup>12</sup> Accelerate the adoption, expansion, and distribution of evidence-based interventions addressing pediatric health and development, while pursuing the development of new interventions;
- Engage family members in the planning, design, and implementation of Research Network studies;
- Recruit diverse participants in research, ensuring that a robust number of Research Network study participants are from underserved populations;
- Develop and foster partnerships with several programs serving underserved populations (e.g., Health Center Program; Maternal, Infant and Early Childhood Home Visiting Program (MIECHV));
- Engage key audiences that serve children and adolescents in order to advance the translation of Network studies, such as policymakers, researchers, school systems, health professionals, families, community members, and state, tribal, territorial, and local agencies;
- Develop and evaluate resources such as guidelines, tools, or toolkits for use in clinical practice or intervention-based research in communities;
- Develop and implement strategies to sustain the Research Network infrastructure beyond the funding period;
- Train and mentor diverse emerging investigators in practice-based pediatric research; and

<sup>&</sup>lt;sup>11</sup>Underserved populations include low-income, racial/ethnic minorities, immigrant, tribal, the geographically remote, and other groups that are not already well represented in current pediatric research.

<sup>&</sup>lt;sup>12</sup>For this NOFO, HRSA/MCHB is particularly interested in the exploration of emerging issues such as, but not limited to, adolescent and youth mental health including suicides; adolescent and youth substance use, including vaping; social determinants of health and health disparities, including the role of implicit bias in health care access and service delivery.

- Develop and maintain a public website for engaging multiple stakeholders.
- Prepare and submit grant applications for external funding opportunities outside of HRSA/MCHB's research grant program.

#### Communications:

• Translate research findings into formats that are beneficial for the constituent/research community for policy and practice.

#### Dissemination:

- Disseminate critical information on Research Network activities and research findings to a broad audience, including researchers, health professionals, policymakers, educators, community members, and families.
- Consistent with HRSA's mission to improve access to quality services for underserved populations, the Research Network should ensure that research activities will be responsive to the cultural and linguistic needs of underserved populations such as partnering with programs that serve these populations in Research Network activities. These services should be family-centered, accessible to consumers, and represent the needs of the populations described above.

SECTION IV – PLAN AND SCHEDULE OF IMPLEMENTATION, AND CAPABILITY OF THE APPLICANT - CORRESPONDS TO SECTION V'S REVIEW CRITERIA #3 EVALUATIVE MEASURES, #4 IMPACT, #5 RESOURCES/CAPABILITIES, AND #6 SUPPORT REQUESTED

Provide a description of the organizational plan for management of the project, including an explanation of the roles and responsibilities of interdisciplinary project personnel and collaborators. Provide a draft organizational chart as **Attachment 4** describing the leadership structure of the Research Network demonstrating collaboration between the PI, co-investigators, and PCRS.

In addition, provide an implementation schedule for each activity described in previous sections. The material should be presented in a succinct manner, with a brief listing of specific milestones and expected outcomes.

In demonstrating capability to fulfill the goals of the Research Network program, describe your organization's significant experience and the publication record of key personnel in carrying out interdisciplinary collaborative research and related projects relating to the goals and objectives of the Research Network. Describe experience in working with underserved populations and key stakeholder groups, as available.

Include reference citations for publications and works cited following the end of the Project Narrative, not as an attachment.

#### NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria. Any attachments referenced in a narrative section may be considered during the objective review.

Narrative Section	Review Criteria
	(1) Need
Background and Significance	(2) Response
	(4) Impact
	(2) Response
Specific Goals and Objectives	(4) Impact
	(5) Resources/Capabilities
Project Design: Methods and Evaluation	(2) Response
	(3) Evaluative Measures
	(4) Impact
	(5) Resources/Capabilities
Plan and Schedule of	(3) Evaluative Measures
Implementation, and Capability of	(4) Impact
Applicant	(5) Resources/Capabilities
' '	(6) Support Requested
Biographical Sketches	(5) Resources/Capabilities
	(6) Support Requested – the budget section
Budget and Budget Justification	should include sufficient justification to allow
Narrative (below)	reviewers to determine the reasonableness
	of the support requested.

The (PedsRN) Program has seven review criteria. A summary of the points is below. See Section V. Application Review Information for details.

Criterion 1.	Need	10 points
Criterion 2.	Response	20 points
Criterion 3.	Evaluative Measures	20 points
Criterion 4.	Impact	20 points
Criterion 5.	Resources/Capabilities	10 points
Criterion 6.	Support Requested	10 points
Criterion 7.	Program Assurances	10 points
TOTAL:		100 points

# iii. Budget

See Section 4.1.iv of HRSA's SF-424 R&R Application Guide.

Please note: the directions offered in the <u>SF-424 R&R Application Guide</u> may differ from those offered by <u>Grants.gov</u>. Follow the instructions included in the *R&R Application Guide* and the additional budget instructions provided below. A budget that follows the *R&R Application Guide* will ensure that, if HRSA selects the application for funding, you will have a well-organized plan, and by carefully following the approved plan, you can avoid audit issues during the implementation phase.

**Reminder:** The Total Project or Program Costs are the total allowable costs (inclusive of direct **and** indirect costs) incurred by the recipient to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement, as applicable.

In addition, the maximum number of budget periods allowed is five (5). A budget period represents 12 months of project effort.

The budget should reflect travel expenses associated with participating in meetings that address MCH research efforts and other proposed trainings or workshops. The following travel is required for the Network budget:

- Annual in-person meeting of the Research Network leadership at a location convenient to the majority of the leadership members;
- Annual in-person meeting of the PI and/or co-PIs with HRSA/MCHB leadership and other pertinent stakeholder groups to provide updates on the work of the Research Network; and
- Annual in-person meeting for up to two people (the PI and one key personnel) for 2 days at the HRSA MCH RN and Single Investigator Innovation Programs Grantee Meeting in the Washington, D.C. metropolitan area.

NOTE: Travel outside of the United States is not supported for the MCH PedsRN Program.

The Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, § 202 states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II. . . ." See Section 4.1.iv Budget – Salary Limitation of HRSA's <u>SF-424 Application Guide</u> for additional information. Note that these or other salary limitations may apply in the following fiscal years, as required by law.

### iv. Budget Justification Narrative

See Section 4.1.v of HRSA's SF-424 R&R Application Guide.

In addition, the MCH PedsRN program requires the position descriptions (roles, responsibilities, and qualifications of proposed project staff) in the Budget Justification under Personnel costs. The budget justification is uploaded into the Budget Narrative Attachment Form. Biographical sketches for any key employed personnel that will be assigned to work on the proposed project must be included as *Attachment 1*. Due to the HRSA 80-page limit, it is recommended that all biographical sketches are no more than two pages in length and must follow the HRSA font/margin requirements. Biographical sketches should document education, skills, and experience that are relevant, necessary, and demonstrate capability to fulfill the assigned roles for the proposed project.

## v. Program-Specific Forms

Program-specific forms are not required for application.

#### vi. Attachments

Provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. You must clearly label **each attachment**.

## Attachment 1: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying key positions. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch. Given the 80-page limit, it is recommended that biographical sketches be no more than two pages in length per person. Biographical sketches should document education, skills, and experience that are relevant, necessary, and demonstrate capability to fulfill the assigned roles for the proposed project. Please follow the system prompts to upload biographical sketches.

# Attachment 2: Letters of Agreement/Letters of Support

Provide any documents that describe working relationships between your agency and other agencies and programs cited in the proposal. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the collaborators and any deliverables. Include only letters of support that specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.). Letters of agreement and letters of support must be dated.

#### Attachment 3: List of Citations for Key Publications

A list of citations for key publications by your key personnel that are relevant to the proposal can be included. Do not list unpublished theses, or abstracts/manuscripts submitted (but not yet accepted) for publication. In consideration of the 80-page limitation, a list of citations only may be included.

# Attachment 4: Project Organizational Chart, Including Partners and Collaborators

Provide a project organizational chart that describes the functional structure of the Research Network. The chart should provide the following information for key personnel: Institution, Responsibilities/Activities.

### Attachment 5: Logic Model

Submit a logic model for designing and managing the project. 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 HRSA does not endorse any organization/website, the following reference may be helpful when developing a logic model: http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf.

<u>Appendix D</u> contains an example of a logic model. There are many versions of logic models, however, for the purpose of this NOFO, the logic model should, at a minimum, address the following areas:

- 1. Identify the Problem(s), Target Population(s), and Program Purpose:
  - O What problem does the program address?
  - Target population(s):
    - Who does the program target?
    - Who gets the intervention, and (if different) who is the intervention eventually supposed to impact?
    - Are there primary and secondary target populations?
  - o Program Purpose:
    - How does the program offer a solution?
    - What does the program do to address the problem?
- 2. Identify Activities and Clarify Outputs:
  - Activities:
    - What does the program do?
    - What services does the program deliver?
  - Products:
    - What does the program create?
    - What are the outputs of the program?
- 3. Identify Program Outcomes:
  - Short-Term and Intermediate Outcome(s):
    - May include changes in skills, attitudes, knowledge or changes in behaviors and decision-making.
    - Should directly result from the program outputs.
  - Long-Term Outcome(s):
    - May include changes related to health status, health conditions, or systems changes.
    - Should directly result from short-term/intermediate outcomes.

See Appendix D: Logic Models for further details.

Attachment 6: Proof of Non-Profit Status (Not counted in the page limit)

Attachment 7: Indirect Cost Rate Agreements (Not counted in the page limit)

Check with your sponsored programs office for further information about the indirect cost rate. Your institution's indirect cost rate is negotiated by the institution with HHS. <u>Limitations on indirect cost rates</u> are discussed earlier in this NOFO.

Attachments 8–15: Other Relevant Documents
Include here any other documents that are relevant to the application.

# 3. Dun and Bradstreet Data Universal Numbering System Number and System for Award Management

You must obtain a valid DUNS number, also known as the Unique Entity Identifier, for your organization/agency and provide that number in the application. You must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d)).

HRSA may not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine that the applicant is not qualified to receive an award and use that determination as the basis for making an award to another applicant.

If you have already completed Grants.gov registration for HRSA or another federal agency, confirm that it is still active and that the Authorized Organization Representative (AOR) has been approved.

The Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (http://www.dnb.com/duns-number.html)
- System for Award Management (SAM) (https://www.sam.gov)
- Grants.gov (http://www.grants.gov/

For further details, see Section 3.1 of HRSA's SF-424 R&R Application Guide.

<u>SAM.GOV</u> ALERT: For your SAM.gov registration, you must submit a <u>notarized letter</u> appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018.

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial

assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM located at <u>SAM.gov</u>.

If you fail to allow ample time to complete registration with SAM or Grants.gov, you will not be eligible for a deadline extension or waiver of the electronic submission requirement.

#### 4. Submission Dates and Times

#### **Application Due Date**

The due date for applications under this NOFO is *April 23, 2020 at 11:59 p.m. ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadline** to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's <u>SF-424 R&R Application Guide</u> for additional information.

### 5. Intergovernmental Review

The MCH PedsRN Program is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

See Section 4.1 ii of HRSA's SF-424 R&R Application Guide for additional information.

## 6. Funding Restrictions

You may request funding for a period of performance of up to 5 years, at no more than \$300,000 per year (inclusive of direct **and** indirect costs). Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

Funds under this announcement may not be used for travel outside the United States.

The General Provisions in Division A of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) apply to this program. Please see Section 4.1 of HRSA's <u>SF-424</u> <u>Application Guide</u> for additional information. Note that these or other restrictions will apply in the following fiscal years, as required by law.

You are required to have the necessary policies, procedures, and financial controls in place to ensure that your organization complies with all legal requirements and restrictions applicable to the receipt of federal funding including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like those for all other applicable grants requirements, the effectiveness of these policies, procedures, and controls is subject to audit.

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative applied to the award(s) under the program will be the addition/additive alternative. You can find post-award requirements for program income at 45 CFR § 75.307.

# V. Application Review Information

#### 1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation.

These criteria are the basis upon which the reviewers will evaluate and score the merit of the application. The entire proposal will be considered during objective review.

Review criteria are used to review and rank applications. The MCH PedsRN Program has seven review criteria. See the review criteria outlined below with specific detail and scoring points.

Criterion 1: NEED (10 points) – Corresponds to Section IV's <u>Background and Significance</u>

The extent or degree to which the application describes:

- The current research gaps in evidence-based practices for interventions to improve the health of children and adolescents and addressing disparities in effective interventions, treatment, and access to care, including underserved populations;
- An approach using interdisciplinary, collaborative, multi-site research to address the identified health care needs of children and adolescents; and
- The national significance and impact of MCH PedsRN and how the coordination of multi-site research can advance the field by developing guidelines, fostering the adoption of innovative treatment models, and disseminating findings.

Criterion 2: RESPONSE (20 points) – Corresponds to Section IV's <u>Background and</u> <u>Significance</u>; <u>Specific Goals and Objectives</u>; <u>Project Design: Methods and Evaluation</u>

## **Intervention Studies (10 points)**

The degree to which the application:

• Proposes intervention studies and discusses how these studies will address physical health outcomes in pediatric populations.

## Other Response Areas (10 points)

The degree to which the application responds to, and its abilities to implement, all activities described in the "Purpose" section for this competition. How well the application articulates its proposed goals and objectives and their relationship to the identified project. How clearly the application aligns its activities (scientific or other) described with addressing the identified problem(s) and attaining the project objectives. The degree to which the application:

- Demonstrates awareness of previous work in the area of this project, including citation of relevant literature and justification of the need for the Research Network;
- Describes clear, concise, and appropriate goals and objectives;
- Includes project aims that will advance scientific knowledge, technical capability, and/or clinical practice or other services and act as a catalyst in developing methodology, treatments, practice, services, or preventive interventions that advance the field;
- Describes critical research and methodology that challenge and seek to shift current research, practice, or service paradigms by utilizing innovative theoretical concepts, approaches or methodologies, instrumentation, or interventions;
- Proposes refining, improving, or applying new theoretical concepts, approaches or methodologies, instrumentation, or interventions;
- Describes a plan to ensure successful collaboration with all key partners identified in the proposal;
- Clearly articulates the project in a logic model; and
- Describes collaboration with several partnering programs serving underserved populations, such as the Health Center or the MIECHV Program and includes documentation of agreement from the partnering programs.

Criterion 3: EVALUATIVE MEASURES (20 points) – Corresponds to Section IV's <u>Project Design: Methods and Evaluation</u>; <u>Plan and Schedule of Implementation, and Capability of Applicant</u>

The strength and effectiveness of the methods proposed to monitor and evaluate project results. Evidence that the evaluative measures will be able to assess: (1) how well the program objectives have been met, and (2) the degree to which these can be attributed to the project. The effectiveness of the application plan to ensure that:

- Proposed activities are capable of attaining project goals and objectives;
- The plan and methodology for establishing and managing the Research Network described in the proposal are appropriate, feasible, and of high quality;
- An implementation plan for the proposed intervention studies is clearly articulated;
- Experience and familiarity with data gathering procedures as they relate to collaborative multi-site research are well described; and
- Scalable evaluation measures are included for each described objective, including intervention research studies, with a timeline for evaluation consistent

with the plan and schedule of implementation.

The extent to which the description in the application methods section includes:

- An effective and robust dissemination plan that includes, three peer-reviewed publications a year, disseminating information to scientific and professional audiences, Research Network website and webinars; and
- Other dissemination strategies to research and practice communities, as well as families and communities that will promote the transfer of findings to improve care.

Criterion 4: IMPACT (20 points) – Corresponds to Section IV's <u>Background and Significance</u>; <u>Specific Goals and Objectives</u>; <u>Project Design: Methods and Evaluation</u>; Plan and Schedule of Implementation, and Capability of Applicant

- The quality of the applicant's plan for establishing a Research Network and the nature and technical quality of the activities proposed;
- The significance of the project in terms of its potential impact in creating a multisite, collaborative, interdisciplinary Research Network that will advance and strengthen the evidence base related to health outcomes for pediatric populations;
- The potential impact of project results in advancing and strengthening the evidence base for health interventions and treatments and access to care for children and adolescents, including underserved populations;
- The effectiveness of the dissemination plan to facilitate the translation of Research Network findings to a broad audience of researchers, health professionals, policymakers, educators, and families; and
- The feasibility of the applicant's plan for delivering at least three peer-reviewed publications each year resulting from the award.

Criterion 5: RESOURCES/CAPABILITIES (10 points) – Corresponds to Section IV's Specific Goals and Objectives; Project Design: Methods and Evaluation; Plan and Schedule of Implementation, and Capability of Applicant; Biographical Sketches

The strength of the application's plan in regards to project personnel and collaborators' training qualifications and/or experience to implement and carry out the project. This includes evaluation of the capabilities of the applicant organization and collaborators, the quality and availability of facilities, and personnel to fulfill the needs and requirements of the proposed project.

The strength of the PI and project team's documented history of leadership in the conduct of multi-site, national, interdisciplinary, collaborative research and publication record on advancing the field of pediatric health.

#### Implementation of a National Research Network (5 points)

The extent to which the applicant proposes:

 Key personnel such as co-investigators, study coordinator, data manager, and other key personnel for the successful implementation of a national Research Network.

### Other Resource/Capabilities Areas (5 points)

The extent to which:

- The PI, staff, and collaborators are well-qualified by training and/or expertise to develop the infrastructure of the Network and to accomplish the activities of the Research Network as described in this NOFO;
- The PI and other key personnel demonstrate current and/or past success in publishing the findings of their research;
- The applicant has the existing resources/facilities to achieve project objectives and to successfully support the proposed Research Network described; and
- The partnering programs, such as HRSA's Health Center Program or the MIECHV Program, demonstrate the ability and commitment to collaborate with the applicant organization and ability to recruit from their patient population for Research Network research studies.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's Budget and Budget Justification Narrative

The reasonableness of the proposed budget for each year of the period of performance in relation to the objectives, the complexity of the research, related activities, and the anticipated results. A sufficient description, which includes:

- Costs, as outlined in the budget and required resources sections, are reasonable given the scope of work;
- Budget line items that are well described and justified in the budget justification;
   and
- Time allocated by key personnel is appropriate to achieve project objectives.

Criterion 7: PROGRAM ASSURANCES (10 points) -- Corresponds to Feasibility; Evaluation and Technical Support Capacity; Protection of Human Subjects; Targeted/Planned Enrollment

#### Feasibility

The applicant should demonstrate the feasibility of its proposal to implement the Network. This should include a documented strategy to indicate that the project can be completed as proposed and approved, sharing key timelines and strategies to address challenges.

# **Proposed Sequence or Timetable**

A sufficient description, which includes:

- A clear and feasible timeline;
- A proposed project that is feasible to conduct within the project time frame;
- A project that is feasible in terms of meeting targeted participant enrollment, given recruitment methods and frequent difficulties of recruiting among hard-toreach populations; and
- A project that demonstrates the feasibility of reaching targeted/planned enrollment levels within the timeline provided.

### **Resolution of Challenges**

The reasonableness of the application plan to:

- Anticipate and address potential barriers to project progress:
- Provide assurance that a research platform can be sustained as proposed; and
- Demonstrate the feasibility of reaching targeted/planned enrollment levels within the timeline provided.

# **Evaluation and Technical Support Capacity**

 Describe plans in place to evaluate whether the project objectives are being met according to the timeline provided.

# **Protection of Human Subjects**

- The extent to which the application description includes: Adequate protections afforded to human subjects, including children and youth, and the adequacy of measures in place to ensure the security of the research data (data security);
- Compliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR Part 46). See the instructions in HRSA's <u>SF-424 R&R Application Guide</u>, Appendix: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan; and
- Plans to seek Institutional Review Board (IRB) approval (IRB approval is not required at the time of application submission, but must be received prior to initiation of any activities involving human subjects).

# Targeted/Planned Enrollment

The quality of the plan to:

- Provide details regarding the Targeted/Planned Enrollment for their proposed studies, including information on anticipated sociocultural groups (e.g., race, ethnicity, language, rural versus urban, socioeconomic, gender) categories;
- Plan and meet recruitment targets to ensure a robust representation of participants from underserved populations; and
- Provide assurance regarding cultural competence as appropriate.

#### 2. Review and Selection Process

The objective review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

See Section 5.3 of HRSA's SF-424 R&R Application Guide for more details.

#### 3. Assessment of Risk

HRSA may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements (45 CFR § 75.205).

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional programmatic or administrative information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine whether HRSA can make an award, if special conditions are required, and what level of funding is appropriate.

Award decisions are discretionary and are not subject to appeal to any HRSA or HHS official or board.

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider any of your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

HRSA will report to FAPIIS a determination that an applicant is not qualified (45 CFR § 75.212).

### VI. Award Administration Information

#### 1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of September 1, 2020. See Section 5.4 of HRSA's <u>SF-424 R&R Application Guide</u> for additional information.

#### 2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's SF-424 R&R Application Guide.

### **Requirements of Subawards**

The terms and conditions in the NOA apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NOA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients under awards. See 45 CFR § 75.101 Applicability for more details.

### **Data Rights**

All publications developed or purchased with funds awarded under this notice must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the recipient owns the copyright for materials that it develops under an award issued pursuant to this notice, and HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for federal purposes, and to authorize others to do so. In addition, pursuant to 45 CFR § 75.322(d), the Federal Government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes, e.g., to make it available in government-sponsored databases for use by others. If applicable, the specific scope of HRSA rights with respect to a particular grant supported effort will be addressed in the NOA. Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government's copyright license and data rights.

# **Human Subjects Protection**

Federal regulations (<u>45 CFR part 46</u>) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

 Please refer to instructions provided in HRSA's <u>SF-424 R&R Application Guide</u>, Appendix Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy for specific instructions on preparing the human subjects section of the application.  Discuss plans to seek IRB approval or exemption. IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent the page limits of the <u>Methods</u> portion of the <u>Project Narrative</u> Section.

# 3. Reporting

Award recipients must comply with Section 6 of HRSA's <u>SF-424 R&R Application Guide</u> and the following reporting and review activities:

1) Discretionary Grant Information System (DGIS) Performance Reports.

Available through the Electronic Handbooks (EHBs), the DGIS is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report annually, by the specified deadline. To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are available on <a href="https://grants6.hrsa.gov/MchbExternal/DgisApp/formassignmentlist/U5D.html">https://grants6.hrsa.gov/MchbExternal/DgisApp/formassignmentlist/U5D.html</a> the type of report required is determined by the project year of the award's period of performance.

Type of Report	Reporting Period	Available Date	Report Due Date
New Competing Performance Report	September 1, 2020- August 31, 2025  (administrative data and performance measure projections, as applicable)	Period of performance start date	120 days from the available date
Non-Competing Performance Report	September 1, 2021- August 31, 2022 September 1, 2022- August 31, 2023 September 1, 2023- August 31, 2024	Beginning of each budget period (Years 2– 4, as applicable)	120 days from the available date
Project Period End Performance Report	September 1, 2024- August 31, 2025	Period of performance end date	90 days from the available date

The full OMB-approved reporting package is accessible at <a href="https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection">https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection</a> (OMB Number: 0915-0298 | Expiration Date: 06/30/2022).

- 2) Progress Report(s). The recipient must submit a progress report narrative to HRSA annually via the Non-Competing Continuation Renewal in the EHBs, which should address progress against program outcomes (e.g., accomplishments, barriers, significant changes, plans for the upcoming budget year), and include annual data on performance measures identified in the Project Narrative, if not captured by DGIS. Submission and HRSA approval of a progress report will trigger the budget period renewal and release of each subsequent year of funding. Further information will be available in the NOA.
- Integrity and Performance Reporting. The NOA will contain a provision for integrity and performance reporting in <u>FAPIIS</u>, as required in <u>45 CFR part 75</u> <u>Appendix XII</u>.
- 4) **Final Report Narrative.** The recipient must submit a final report narrative to HRSA after the conclusion of the project.

# VII. Agency Contacts

You may request additional information and/or technical assistance regarding business, administrative, or fiscal issues related to this NOFO by contacting:

Tonya Randall
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857

Telephone: (301) 594-4259

Fax: (301) 443-6343

Email: Tonya.Randall@hrsa.hhs.gov

You may request additional information regarding the overall program issues and/or technical assistance related to this NOFO by contacting:

Maura Maloney PhD, MS and Erica Caesar MSPH, MBA Program Officers, Office of Epidemiology and Research, Division of Research

Attn: MCH PedsRN Network Maternal and Child Health Bureau Health Resources and Services Administration 5600 Fishers Lane, Room 18-11

Rockville, MD 20857

Telephone: (301) 443-1087 and (301) 594-4227 Email: MMaloney@hrsa.gov and ECaesar@hrsa.gov You may need assistance when working online to submit your application forms electronically. Always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, 7 days a week, excluding federal holidays at:

Grants.gov Contact Center

Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)

Email: <a href="mailto:support@grants.gov">support@grants.gov</a>

Self-Service Knowledge Base: <a href="https://grants-portal.psc.gov/Welcome.aspx?pt=Grants">https://grants-portal.psc.gov/Welcome.aspx?pt=Grants</a>

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's EHBs. For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday–Friday, 8 a.m. to 8 p.m. ET, excluding federal holidays at:

HRSA Contact Center Telephone: (877) 464-4772 TTY: (877) 897-9910

Web: <a href="http://www.hrsa.gov/about/contact/ehbhelp.aspx">http://www.hrsa.gov/about/contact/ehbhelp.aspx</a>

#### VIII. Other Information

#### **Technical Assistance**

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Tuesday, February 4, 2020

Time: 1:30-2:30 p.m. ET

Call-In Number: 1-800-779-7168

Participant Code: 4968

Weblink: https://hrsa.connectsolutions.com/fy20\_pedsrn\_ta/

In an attempt to more effectively utilize our TA webinar time, if you have questions about the NOFO, please send them beforehand via email to Maura Maloney at <a href="MMaloney@hrsa.gov"><u>MMaloney@hrsa.gov</u></a> and Erica Caesar at <a href="ECaesar@hrsa.gov"><u>ECaesar@hrsa.gov</u></a>. We will compile and address these questions during the TA webinar.

HRSA will record the webinar and make it available at: <a href="https://hrsa.connectsolutions.com/fy20">https://hrsa.connectsolutions.com/fy20</a> pedsrn ta/.

#### <u>Tips for Writing a Strong Application</u>

See Section 4.7 of HRSA's <u>SF-424 R&R Application Guide</u>.

#### **Appendix A: Relevant Websites**

While HRSA does not endorse any organization/website, the following list, although not exhaustive, may be helpful references:

#### **Bright Futures**

http://brightfutures.aap.org/

#### Healthy People 2020 / Developing Healthy People 2030

http://www.healthypeople.gov/2020/

https://www.healthypeople.gov/2020/About-Healthy-People/Development-Healthy-People-2030

#### **HRSA/MCHB** Division of Workforce Development Website

http://www.mchb.hrsa.gov/training

#### **Human Subjects Assurances**

http://www.hhs.gov/ohrp

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

#### Inclusion Across the Lifespan- Policy Implementation

http://grants.nih.gov/grants/funding/children/children.htm

#### **Logic Models**

https://www.cdc.gov/eval/tools/logic models/index.html

### Making Websites Accessible: Section 508 of the Rehabilitation Act

http://www.section508.gov/

#### **National Academy of Medicine**

https://nam.edu/

#### **National Center for Cultural Competence**

http://nccc.georgetown.edu/

National Resource Center for Patient/Family-Centered Medical Home (formerly the National Center for Medical Home Implementation)

http://www.medicalhomeinfo.org/

#### **Appendix B: Key Terms for Project Abstracts**

#### a) Content Terms (maximum of 10) Health Care Systems & Delivery

- Access to Health Care
- Capacity & Personnel
- Clinical Practice
- Health Care Quality
- Health Care Utilization
- Health Disparities
- Health Information Technology
- Home Visiting
- Innovative Programs and Promising New Practices
- Perinatal Regionalization
- Telehealth

#### **Primary Care & Medical Home**

- Adolescent Health
- Coordination of Services
- Community-Based Approaches
- Integration of Care
- Medical Home
- Oral Health
- Preconception/Interconception Health & Well-Woman Care
- Primary Care
- Well-Child Pediatric Care

#### **Insurance & Health Care Costs**

- Cost Effectiveness
- Health Care Costs
- Insurance Coverage

#### Prenatal/Perinatal Health & Pregnancy Outcomes

- Cesarean
- Labor & Delivery
- Low Birthweight
- Perinatal
- Postpartum
- Pregnancy
- Prenatal Care
- Preterm

#### **Nutrition & Obesity**

- Breastfeeding
- Nutrition & Diet
- Obesity & Weight
- Physical Activity

#### **Parenting & Child Development**

- Cognitive & Linguistic Development
- Fathers
- Parent-Child Relationship
- Parenting
- Physical Growth
- Social & Emotional Development

#### School Settings, Outcomes & Services

- Child Care
- Early Childhood Education
- School Health Programs
- School Outcomes & Services

#### **Screening & Health Promotion**

- Early Intervention
- Illness Prevention & Health Promotion
- Immunization
- Health Education & Family Support
- Screening
- Sleep

#### Illness, Injury & Death

- Emergency Care
- Infant Illness & Hospitalization
- Maternal Illness & Complications
- Mortality
- Safety & Injury Prevention
- Sudden Infant Death Syndrome/Sudden Unexpected Infant Death
- Trauma & Injury

#### Mental/Behavioral Health & Well-being

- Bullying & Peer Relationships
- Depression
- Mental Health & Well-being
- Risk Behaviors
- Sexually Transmitted Diseases
- Smoking
- Stress
- Substance Use
- Violence & Abuse

#### **Special Health Care Needs & Disabilities**

- Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder
- Asthma
- Chronic Illness

- Developmental Disabilities
- Special Health Care Needs
- Youth with Special Health Care Needs Transition to Adulthood

#### **Life Course & Social Determinants**

- Neighborhood
- Life Course
- Social Determinants of Health

#### b) Targeted Population(s) (as many as apply):

- African American
- Asian/Pacific Islander
- Hispanic/Latino
- Immigrant
- Low-income
- Native American/Alaskan Native
- Rural
- Special Health Care Needs

#### c) Targeted Age Range(s) (as many as apply):

- Women's Health & Well-being (Preconception/Interconception/Parental)
- Prenatal (until 28th week of gestation)
- Perinatal (28th week of gestation to 4 weeks after birth)
- Infancy (1–12 months)
- Toddlerhood (13–35 months)
- Early Childhood (3–5 years)
- Middle Childhood (6–11 years)
- Adolescence (12–18 years)
- Young Adulthood (19–25 years)

# **Appendix C: Title V MCH Services Block Grant—National Performance Domains**

No.	Performance Domain	MCH Population Domain
1	Well-Woman Visits and	Maternal Health
	Preconception/	
	Interconception Health	
2	Low-Risk Cesareans	Maternal Health
3	Breastfeeding	Perinatal and Infant Health
4	Perinatal	Perinatal and Infant Health
	Regionalization	
5	Safe Sleep	Perinatal and Infant Health
6	Developmental	Child Health
	Screening	
7	Injury Prevention	Child Health
8	Physical Activity	Child Health
9	Adolescent Well-Visits	Adolescent Health
	and Preventive	
	Services	
10	Bullying	Adolescent Health
11	Medical Home	Children with Special Health Care Needs
12	Transition to Adulthood	Children with Special Health Care Needs
13	Oral Health	Cross-Cutting/Life Course
14	Smoking	Cross-Cutting/Life Course
15	Adequate Insurance	Cross-Cutting/Life Course
	Coverage	

### **Appendix D: Logic Models**

The following logic model illustrates HRSA's expectations and goals for the MCH PedsRN.

DDOCD ANA	PROGRAM	OUTPUTS	PROGRAM OUTCOMES		
PROGRAM INPUTS	ACTIVITIES	PRODUCTS / SYSTEMS	SHORT-TERM / INTERMEDIATE	LONG-TERM / IMPACT	
Eligible Entities, Stakeholders & Key Resources	Activities to create/improve health/service systems and infrastructure	Health/service systems and infrastructure created to support desirable systems or behaviors	Health/service systems or behaviors that lead to improved health outcomes	Improved health or health care outcomes	
Domestic public or non-profit institutions of higher learning and public or private non-profit agencies engaged in research or in programs relating to maternal and child health and/or services for	Create and maintain an interdisciplinary research network focused on improving practice-based pediatric care.	Multi-site, interdisciplinary research network for practice-based pediatric care.	Increase the number of resources on health issues available to help clinicians and other researchers.  Increase collaboration and coordination of research on current and emerging health problems among children and adolescents.	Advance the evidence base and further develop the field of practice-based pediatric health  Increase the translation of research findings into practice.  Increase MCH practice-based pediatric research sustainability.	
children with special health care needs  Interdisciplin ary network of national experts and research entities  Federal staff  Families and community members	Form an interdisciplinary Network Steering Committee / Advisory Board composed of diverse professionals and family members	Interdisciplinary and diverse Network Steering Committee / Advisory Board established, and annual in-person meetings convened	Increase the number of multidisciplinary investigators trained/mentored in the field of pediatric research.  Increase the active contribution and incorporation of stakeholders (researchers, practitioners, and community members) into activities advancing pediatric health.		

DD00D4::	PROGRAM OUTPUTS		PROGRAM OUTCOMES	
PROGRAM INPUTS	ACTIVITIES	PRODUCTS / SYSTEMS	SHORT-TERM / INTERMEDIATE	LONG-TERM / IMPACT
	Create a national research agenda for MCH PedsRN research (in collaboration with MCHB)	National research agenda for MCH PedsRN research	Increase the number of resources on physical health issues available to help clinicians and other researchers.  Increase the active contribution and incorporation of stakeholders (researchers, practitioners, and community members) in pediatric health activities.	
	Design and implement several multi-site intervention research studies to examine and improve upon the health of children and adolescents.	Multi-site intervention research studies designed and implemented	Increase the number of resources on physical health issues available to help clinicians and other researchers.	Advance the evidence base and further develop the field of physical health interventions for underserved children and adolescents.
	Develop and evaluate resources such as guidelines, tools, study protocols, or toolkits for use in clinical practice or intervention-based research in community settings	Resources developed, evaluated, and utilized in clinical practice or intervention-based research in community settings		Increase the translation of research findings into practice.  Increase MCH pediatric research sustainability.
	Develop and implement a dissemination plan for communicating research findings to diverse stakeholders	Dissemination plan with a timeline and list of proposed products.  Manuscripts published in peer- reviewed journals		

	PROGRAM	OUTPUTS	PROGRAM OUTCOMES		
PROGRAM INPUTS	ACTIVITIES	PRODUCTS / SYSTEMS	SHORT-TERM / INTERMEDIATE	LONG-TERM /	
	Engage family members in MCH PedsRN practice- based research network studies.  Engage key audiences (e.g., researchers, clinicians, Title V populations, Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV) populations, families, community members, policymakers) in translating MCH PedsRN research	Non-peer-reviewed publications aimed at stakeholders beyond the scientific research community (e.g., reports, blogs, web posting, videos, infographics, lay summary of research publications)  Family members engaged as members of the Network Steering Committee  Input from family members incorporated in the design and implementation of MCH PedsRN research network studies  Key audiences engaged  Resources developed that include the input of key audiences and are shared broadly and in varying formats	Increase the active contribution and incorporation of stakeholders (researchers, practitioners, and community members) into activities advancing health interventions for children and adolescents.	IMPACT	
	findings into practice  Develop and maintain a public website for engaging multiple stakeholders and communicating work of the MCH PedsRN research network  Prepare and submit grant applications for external funding opportunities outside of HRSA/MCHB's research grant program	Website representing the work of the MCH PedsRN research network developed and maintained  Grant applications completed and submitted for external funding opportunities			

DDOCDAM	PROGRAM OUTPUTS		PROGRAM OUTCOMES		
PROGRAM INPUTS	ACTIVITIES	PRODUCTS / SYSTEMS	SHORT-TERM / INTERMEDIATE	LONG-TERM / IMPACT	
	Train and mentor junior/new investigators in practice-based pediatric research	Junior/new investigators trained/mentored	Increase the number of grant applications submitted for external funding opportunities outside of MCH Research Network program.  Increase the capacity of recipients to expand/sustain research initiated by the MCH Research Network program.  Increase the number of multidisciplinary investigators trained/mentored in	Advance the evidence base and further develop the field of physical health interventions for underserved children and adolescents.  Increase the translation of research findings into practice.  Increase MCH pediatric research sustainability.	
			the field of pediatric research.		
PERFORMANCE MEASURES	Process Measures  DGIS Core 2 DGIS Core 3 # of studies developed # of participants (including demographic data) enrolled in MCH PedsRN research network studies # of total researchers involved in the MCH PedsRN research network # of junior/new investigators being trained or mentored through MCH PedsRN Research Network		Outcome / Impact Measures  • # of tools, toolkits, and clinical guidelines • # of research sites	Outcome / Impact Measures  • # of peer- reviewed publications • # of non peer- reviewed publications • DGIS Core 1	

You can find additional information on developing logic models at the following website: <a href="http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf">http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf</a>.

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a time line used during program implementation; the work plan provides the "how to" steps. You can find information on how to distinguish between a logic model and work plan at the following website: <a href="http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf">http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf</a>.

mtp://www.cdc.gov/neaitriyyodtri/evaluation/pdi/brief5.pdf

#### **Appendix E: Frequently Asked Questions (FAQs)**

#### 1. Where do I find application materials for the MCH PedsRN Program?

All application materials are available through Grants.gov

### 2. How can I download the complete application package for the MCH PedsRN Program NOFO?

You can download the application from Grants.gov.

#### 3. What is Grants.gov?

<u>Grants.gov</u> is the website that the U.S. Government uses to inform citizens of grant opportunities and provide a portal for submitting applications to government agencies. More information can be found on the <u>Grants.gov</u> website.

## 4. Is there anything that we need to do immediately to better prepare for our new grant application?

Yes, make sure that the Authorized Organization Representative (AOR) at your university or institution has registered the university/organization and himself/herself in <u>Grants.gov</u>. In order to submit your application (new or continuation), your university and your AOR MUST be registered in <u>Grants.gov</u>. When your AOR registers in Grants.gov, he/she will receive a Credential User Name and Password which will allow that individual to submit application forms in <u>Grants.gov</u>.

#### 5. What are the key take-home messages about Grants.gov?

- Make sure that the AOR from your university/organization is registered in <u>Grants.gov</u> NOW. This process can take up to 1 month and it is better to complete it and have it out of the way before starting any grant application.
- 2) Read the instructions on <u>Grants.gov</u> carefully and allow time for corrections. Enter information in fields even if it is 0 or the form will remain incomplete. Required fields are highlighted in yellow.
- 3) There are resources available on the Grants.gov website to help you navigate this new system. Please visit <u>Grants.gov</u> to access these resources.
- 4) Some business practices will change with the introduction of the new SF-424 R&R Form.
  - With the HRSA SF-424 R&R, you will be reporting faculty and staff time in calendar month equivalents.
  - Budget details about subcontracts will now be described in a section of the SF-424 R&R called sub-awards.
  - New applications will now fill out detailed budgets for each of the years in the period of performance. Therefore, submit detailed budgets for each of the 5 years.

#### 6. What types of institutions can apply?

Only domestic public or non-profit institutions of higher learning and public or private non-profit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs are eligible to apply. Domestic faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

## 7. We are a foreign organization interested in applying for the MCH PedsRN Program. Are foreign entities eligible to apply?

The MCH PedsRN Program is a domestic grant program and open only to U.S. entities that meet the eligibility criteria as outlined in the NOFO.

## 8. We are trying to apply for the announced grants, but our organization does not have an Indirect Cost Rate Agreement. What should we do?

According to the <u>HRSA SF-424 R&R Application Guide</u> (as aligned with the Uniform Administrative Requirements at <u>45 CFR part 75</u>), "any non-federal entity that has never received a negotiated indirect cost rate, (except a governmental department or agency unit that receives more than \$35 million in direct federal funding) may elect to charge a de minimis rate of 10 percent of modified total direct costs (MTDC) which may be used indefinitely. The HRSA SF-424 R&R Application Guide also contains information on how to negotiate the indirect cost rate.

#### 9. How do I know what my institution's indirect cost rate is?

The applicant institution's indirect cost rate is negotiated by the institution with the U.S. Department of Health and Human Services (HHS). Your sponsored programs office will be able to provide further information about your institution's indirect cost rate.

#### 10. Is there a requirement regarding minimum or maximum effort for the PI?

In general, the NOFO does not specify any minimum or maximum time requirement for the PI, but we anticipate that applicant PIs should allocate and devote sufficient time to justify their commitments to the project. Under Review Criteria 5 and 6 of the NOFO, it states that applications will be assessed regarding:

- Key personnel such as co-investigators, study coordinator, data manager, and other staff are identified. Applications that do not propose PI, co-investigator, and other key personnel for the successful implementation of a national research network will be deemed non-responsive to this section of the NOFO;
- The PI, staff, and collaborators are well-qualified by training and/or expertise to develop the infrastructure of the Network and to accomplish the activities of the Network as described in this NOFO;
- The PI and other key personnel demonstrate current and/or past success in publishing the findings of their research;

- The applicant has the existing resources/facilities to achieve project objectives and to successfully support the Network described in the proposal;
- The partnering programs demonstrate the ability and commitment to collaborate with the applicant organization and ability to recruit from their patient population for Network research studies;
- Costs, as outlined in the budget and required resources sections, are reasonable given the scope of work;
- Budget line items that are well described and justified in the budget justification narrative; and
- Time allocated by key personnel is appropriate to achieve project objectives.

### 11. Can someone who is currently a PI on another agency grant be a PI of the MCH PedsRN Program?

Yes, however, if selected for funding, the new recipient will need to verify that percent effort across all federally funded grants does not exceed 100 percent.

## 12. We have more than one investigator in our institution planning to apply to this NOFO. Is more than one application per institution allowable?

Yes, more than one application per institution is allowable.

#### 13. Which format should we follow for the biographical sketch?

Include biographical sketches for persons occupying key positions. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch. Given the 80-page limit, it is recommended that biographical sketches be no more than two pages in length per person. Biographical sketches should document education, skills, and experience that are relevant, necessary, and demonstrate capability to fulfill the assigned roles for the proposed project

#### 14. Are there any page limitations to the narrative?

- The NOFO requires a 12-page limit for Section III Project Design: Methods and Evaluation section of the narrative.
- The research strategy includes: Significance, Innovation, and Approach.
- Preliminary studies can be included in the Approach section of the Research Strategy if applicable and would be included in the 12-page limit as described above.
- Please consult the NOFO and/or the <u>HRSA R&R Application Guide</u>, referenced throughout the NOFO, for more specific information.
- If an application exceeds required page limitations, it will not be considered for funding.

#### 15. Are there font/margin requirements?

Specifications regarding fonts and margins can be found in the NOFO, but typically follow HRSA guidelines, which call for 1" margins and 12-point font. Please consult the NOFO and/or the HRSA R&R Application Guide, referenced throughout the NOFO, for more specific information.

#### 16. Where do I include the staffing plan?

The staffing plan information is included in the budget narrative attachment that should be uploaded into the budget form Box K.

#### 17. When will you announce your other research NOFOs?

Please join our listserv at <a href="http://mchb.hrsa.gov/research">http://mchb.hrsa.gov/research</a> to receive an alert whenever our NOFOs are released.

#### 18. Who should I talk to if I have further questions?

#### Please contact:

- For programmatic questions, the program officers listed in the NOFO via email.
- For budget questions, the grants management specialist listed in the NOFO via email.

### **Appendix F: Application Completeness Checklist**

Funding Opportunity Number: HRSA-20-061 Application Due Date in Grants.gov: April 23, 2020

Requirement	Yes	No	Comments
Are you applying to the <b>correct</b>			
funding opportunity?			
Do you meet the eligibility			
criteria?			
Did you read the HRSA <b>R&amp;R</b>			HRSA's SF-424 R&R Application Guide:
Application Guide?			https://www.hrsa.gov/grants/apply/
			applicationguide/sf424rrguidev2.pdf
De you have a DUNC number?			DUNS number:
Do you have a <b>DUNS number</b> ?			http://www.dnb.com/duns-number.html
Did your Authorized Organization			SAM: https://www.sam.gov/
Did your Authorized Organization Representative (AOR) register in			SAIVI. IIIIps.//www.saiii.gov/
SAM?			
Did your AOR register in			Grants.gov: http://www.grants.gov/
Grants.gov?			Granto.gov. <u>ntep.//www.granto.gov/</u>
In the <b>Need Section</b> , did you fully			
address Needs and Alignment?			
In the <b>Methods</b> , did you fully			
address:			
<ul><li>Goals and Hypotheses?</li></ul>			
<ul> <li>Significance of</li> </ul>			
Methodology/Researc			
h Strategy?			
In the Evaluative Measures			
Section, did you fully address			
your Work Plan Approach?			
In the <b>Impact Section</b> , did you			
fully address:			
Scientific Innovation			
and Importance?			
Impact and Dissemination?  In the Becourse Conshilities.			
In the Resources Capabilities			
Section, did you fully address Organizational Information/			
Environment?			
In the Support Requested			The directions offered in the HRSA SF-
Section, did you accurately			424 R&R Application Guide differ
complete the Budget and			from those offered by Grants.gov.
Budget Justification?			Please follow the instructions included
			in the R&R Application Guide and, if
Did you follow the budget			applicable, the additional budget
instructions in the NOFO and			instructions in the <b>NOFO</b> .
R&R Application Guide?			
			Your institution's indirect cost rate is
			negotiated by the institution with HHS.

Do you know your institution's indirect cost rate?	Check with your sponsored programs office for further information about the indirect cost rate.
In The Program Assurances Section, did you fully address:      Feasibility?     Evaluation and     Technical Support     Capacity?     Protection of Human     Subjects?     Targeted/Planne     d Enrollment?	
Is your <b>Project Summary/Abstract</b> one page in length <u>and</u> single- spaced?	
Did you clearly label your attachments?	
Are your <b>page borders</b> no more than 1 inch wide?	Biosketches can have .5 inch margins.
Did you include Biosketches?	
Did you use 12-point <b>font</b> ?	Face years Chandend OMD annual d
Are your <b>pages</b> , including attachments and biosketches, 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 <b>do not count</b> toward the 80-page limit.
Is the Project Design: Methods and Evaluation within the 12-page limit?	
Is the <b>budget</b> within the funded limit per year?	
Did you experience system glitches or a qualified emergency and need to request an <b>exemption/waiver</b> ?	Submit exemption request in writing to: <u>DGPWaivers@hrsa.gov</u>