U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

HRSA
Health Resources & Services Administration

Maternal and Child Health Bureau
Office of Epidemiology and Research
Maternal and Child Health Research Network Program

U4D Maternal and Child Health (MCH)
Pregnancy-Related Care Research Network (PRC-RN) Program

Funding Opportunity Number: HRSA-20-058
Funding Opportunity Type(s): New
Assistance Listings (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2020

Application Due Date: March 10, 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 3, 2020

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2020 Maternal and Child Health (MCH) Pregnancy-Related Care Research Network (PRC-RN) Program. The purpose of this program is to establish and maintain the infrastructure and forum for interdisciplinary, national, multi-center practice-based research and scientific collaboration. The PRC-RN will provide the platform for conducting original research studies (funded by HRSA), and leveraging of external support and resources for conducting other research studies and implementing research-related activities within the scope of the PRC-RN. The PRC-RN will provide national leadership to advance the evidence base on effective interventions that address maternal health including, but not limited to, pregnancy, pre-conception care, inter-conception care, maternal morbidity, maternal mortality, and current and emerging issues and gaps in research and practice, such as innovative models of delivery of pregnancy-related care in settings with limited resources in the United States.

The FY 2020 President's Budget does not request funding for this program. This notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. You should note that this program may be cancelled prior to award.

Funding Opportunity Title:	U4D Maternal and Child Health (MCH) Pregnancy-Related Care Research Network (PRC-RN) Program
Funding Opportunity Number:	HRSA-20-058
Due Date for Applications:	March 10, 2020
Anticipated Total Annual Available FY 2020 Funding:	$300,000
Estimated Number and Type of Award(s):	Up to one cooperative agreement
Estimated Award Amount:	Up to $300,000 per year subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2020 through August 31, 2025 (5 years)
Eligible Applicants:	Eligible applicants include any domestic public or private entity, including research centers or networks. 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 eligibility information.

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 http://www.hrsa.gov/grants/apply/applicationguide/sf424rrguidev2.pdf, except where instructed in this NOFO to do otherwise.

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Monday, January 13, 2020
Time: 3–4 p.m. ET
Call-In Number: 1-888-566-6351
Participant Code: 3672361
Weblink: https://hrsa.connectsolutions.com/fy20_prcrn_ta/

HRSA will record the webinar and make it available at:
https://mchb.hrsa.gov/fundingopportunities/default.aspx.

In an attempt to most effectively utilize our TA webinar time, if you have questions about the NOFO, please send them via email to Fulera Salami at FSalami@hrsa.gov and Jessica DiBari at JDiBari@hrsa.gov. We will compile and address these questions during the TA call.

Table of Contents

I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the U4D Maternal and Child Health (MCH) Pregnancy-Related Care Research Network Program (PRC-RN). The purpose of this program is to establish and maintain an interdisciplinary, national, multi-center practice-based research forum for scientific collaboration and infrastructure building. The PRC-RN will provide national leadership to advance the evidence base on effective interventions[1] that address maternal health including, but not limited to, pregnancy, pre-conception care, inter-conception care, maternal morbidity, maternal mortality, and current and emerging issues and gaps in research and practice, such as models of delivery of pregnancy-related care in settings with limited resources in the United States.

The PRC-RN will:

- Lead, promote, and coordinate national research activities to improve pregnancy-related health care and maternal health, especially addressing barriers to access quality services for underserved populations;
- Develop and maintain an infrastructure to support a portfolio of multi-site, interdisciplinary research focused on fostering the implementation of multi-site intervention research studies, translating of research to policy and practice, and providing a mentoring environment to train a new generation of clinical and non-clinical researchers in applied and translational pregnancy-related research; and
- Address, where applicable, the following U.S. Department of Health and Human Services' (HHS) and Health Resources and Services Administration (HRSA) priority areas namely, mental health, opioid use disorder, prescription drug pricing, maternal mortality, and telehealth.
- Indicate how study findings will further develop the evidence base, where relevant for this program.

The recipient of the cooperative agreement is encouraged to leverage existing work in the field, as appropriate, and extend the impact of HRSA's existing programs and resources in the areas of maternal and women's health. For example, the Alliance for Innovation on Maternal Health (AIM) assists state-based teams with the implementation of maternal safety bundles.[2] Safety bundles are small, straightforward sets of evidence-based practices, that, when performed collectively and reliably, have been shown to improve patient outcomes. These bundles improve the quality and safety of maternity care with the goal of reducing maternal morbidity and mortality. As of August 2019,

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[1]For the purpose of this NOFO, an intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints or outcomes. Examples include, but 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; prevention strategies; and, diagnostic strategies. For this definition, a manipulation or task would be regarded as an intervention if it is used to modify a health-related biomedical or behavioral outcome. However, a manipulation or task used expressly for measurement, and not modification, would not be considered an intervention for this NOFO. Source: Frequently Asked Questions, NIH clinical trials questions. https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5226 Accessed August 27, 2019.

[2] U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau, Maternal/Women's Health. https://mchb.hrsa.gov/maternal-child-health-topics/maternal-and-womens-health Accessed October 8, 2019.

there are 27 states enrolled in AIM and approximately 1,300 hospitals participating in bundle implementation. Additional information about other HRSA programs on maternal and women's health can be read at: https://mchb.hrsa.gov/maternal-child-health-topics/maternal-and-womens-health. Section IV provides more information about cooperative agreement activities.

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, and it is a component of the Special Projects of Regional and National Significance (SPRANS).

The PRC-RN is the only existing national collective of practicing obstetricians and gynecologists (OB/GYN) recruited to participate in practice-based research studies. The PRC-RN -affiliated practitioners develop and implement original, practice-based research studies to improve access to care, improve the quality of care, reduce costs, and test innovative care delivery models for obstetrics care. There is an urgent need for improved nationwide engagement of OB/GYNs and other health care professionals in research that addresses the critical and emerging issues affecting pregnancy-related care and maternal health across the life course (e.g., maternal morbidity, mortality, racial/ethnic disparities in maternal mortality, rural-urban disparities in access to OB/GYN care, in-utero opioid exposure and its consequences for mothers and children, etc.). In 2015, the U.S. pregnancy-related mortality ratio was estimated at 17.2 pregnancy-related deaths per 100,000 live births, and is one of the highest among developed countries.[3] There are significant and persistent disparities in pregnancy-related maternal mortality in the United States.[4] For instance, non-Hispanic Black or African American women are three to four times more likely to die from pregnancy-related complications than non-Hispanic White women.[5] Furthermore, the United States is experiencing a shortage of midwives and OB/GYNs, with a projected deficit of 8,800 OB/GYNs by 2020 and 22,000 OB/GYNs by 2050.[6]

In the last 20 years, the PRC-RN has conducted over 100 studies with about 8,000 study participants at 16 medical centers across the United States. The results from these research studies have informed health care provider practices, medical education, and service delivery aimed at improving health care for women. For example, several of these studies have resulted in a major Call to Action in the *American Journal of Obstetrics & Gynecology* on the underutilization of metabolic screening in patients with Polycystic Ovary Syndrome (PCOS).[7] Study results also prompted an editorial on provider familiarity with guidelines on weight gain during pregnancy in the *Journal of*

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[3]Petersen EE, Davis NL, Goodman D, et al. Vital Signs: Pregnancy-Related Deaths, United States, 2011–2015, and Strategies for Prevention, 13 States, 2013–2017. *Morbidity and Mortality Weekly Report*. 2019;68:423–429.

[4]Kassebaum NJ, et al. Global, regional, and national levels of maternal mortality, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet*. 2016;388(10053):1775–1812.

[5]Howell EA. Reducing Disparities in Severe Maternal Morbidity and Mortality. *Clin Obstet Gynecol*. 2018;61(2):387–399.

[6]Ollove M. A Shortage in the Nation's Maternal Health Care. *The Pew Charitable Trusts*. 2016. Available at: https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/08/15/a-shortage-in-the-nations-maternal-health-care. Accessed on October 30, 2018.

[7]Dhesi A., Murtough, K., Lim J., Schulkin J., Mcgovern P., Power M., & Morelli S. Metabolic Screening in Patients with Polycystic Ovary Syndrome is Largely Underutilized among Obstetrician-Gynecologists. *American Journal of Obstetrics and Gynecology*. 2016;215(5):579.e1-579.e5.

Women's Health by a former President of the American College of Obstetricians and Gynecologists.[8]

The existing PRC-RN has published papers with significant contributions to the knowledge, practices, and education of obstetricians and gynecologists.[9,10,11] The PRC-RN has also collaborated with providers from diverse disciplines, such as endocrinology, genetics, infectious disease, neonatology, pediatrics, nursing, internal medicine, family practice, and dentistry. The PRC-RN is expected to develop a practice-based intervention research infrastructure that focuses on interdisciplinary collaboration on the continuity of care around pregnancy and women's health. Results of studies from the PRC-RN have been published and disseminated across different fields.

For additional details regarding other HRSA initiatives, please see https://mchb.hrsa.gov/maternal-child-health-initiatives/mchb-programs.

The HRSA Maternal and Child Health Research Network Program

The PRC-RN is part of the HRSA-MCHB Research Network Program. Administered by the Division of Research in MCHB's Office of Epidemiology and Research, the RN Program supports the establishment and maintenance of interdisciplinary, national, multi-site, collaborative Networks which lead, promote, and coordinate national research activities on broad and specific fields of MCH. As of June 2019, HRSA MCH RNs 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

Objectives and Functions

The PRC-RN will forge partnerships with researchers, health care professionals, health professional educators, advocates, families, local public health programs, and other organizations/agencies critical to translating PRC-RN research into practice.

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

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[8]Brown HL. Providers' Familiarity with Guidelines for Weight Gain During Pregnancy Impacts Counseling and Compliance in Obese Women. *Journal of Women's Health.* 2017;26(11):1139–1140.

[9]Jones KM, Power ML, Queenan JT, Schulkin J. Racial and ethnic disparities in breastfeeding. *Breastfeeding Medicine.* 2015;10(4):186-196.

[10]Power ML, Schulkin J. Obstetrician/Gynecologists' Knowledge, Attitudes, and Practices Regarding Weight Gain During Pregnancy. *J Womens Health.* 2017;26(11):1169–1175.

[11]Dhesi AS, Murtough KL, Lim JK, Schulkin J, McGovern PG, Power ML, Morelli SS. Metabolic screening in patients with polycystic ovary syndrome is largely underutilized among obstetrician-gynecologists. Am J Obstet Gynecol. 2016;215(5):579.e1-579.e5.

Organization and Functions

The PRC-RN structure[12] will consist of a Network Coordinating Center (NCC) and multiple Collaborating Research Entities/Sites (CREs) from across the country. The NCC is the administrative center of the Research Network and provides leadership and maintains a partnership with its CREs. 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 principal investigator's (PI) institution, which is the recipient of the cooperative agreement. The NCC provides the core administrative and operational functions that include the following:

1) Support the Research Network infrastructure for partnership among CREs;
2) Facilitate the process for the development, selection, implementation, and oversight of scientific research studies;
3) Coordinate a plan to enhance the research training and mentorship of diverse emerging investigators through the use of innovative mentorship/research experiences and manuscript development;

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[12]This structure ensures that all Research Network's activities encompass a general 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 are defined by race, place, age, or gender. **Upstream:** A consideration of the social determinants of health—a broader and 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.

4) Coordinate the dissemination of findings to health care professionals, researchers, policymakers, family members, and the greater 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 family and/or consumer involvement and input in Research Network activities; and
7) Collaborate with pertinent partners including the other MCH Research Network recipients and other MCHB programs related to maternal/women's health, maternal morbidity, and maternal mortality.

All participating CREs must agree to abide by the study designs and policies approved by the Research Network Advisory Board or Steering Committee.

<u>Research Network Advisory Board or Steering Committee</u>

The Research Network Advisory Board or Steering Committee will be constituted by representatives of the CREs and HRSA/MCHB. This body will meet monthly by telephone or other online platforms, and in person at least once a year in the Washington, D.C. area. All major scientific decisions are determined by majority vote of the Research Network Advisory Board or Steering Committee. The PI will serve as Chair of the Research Network Advisory Board or Steering Committee. 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 health professional education bodies, Centers for Medicare and Medicaid Services, and other 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 developed protocols. CREs must follow the Research Network policies and procedures to (1) monitor adverse events; (2) report data and other information to the NCC; and (3) ensure good clinical practice or other applicable regulatory requirements.

II. Award Information

1. Type of Application and Award

Types of applications sought: New

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement is a financial assistance mechanism where 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**:

1) Assurance of the availability of 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 periodic meetings and/or communications with the award recipients to review mutually agreed-upon goals and objectives and to assess progress;
4) Assistance in establishing and maintaining federal interagency and inter-organizational contacts necessary to carry out the project;
5) Facilitation of effective communication and accountability to HRSA/MCHB regarding the project, with special attention to new program initiatives and policy development in the public health field relating to MCH;
6) Review of all documents and products prior to submission for publication or public dissemination;
7) Identification of emerging research issues or agency priority topics that warrant new Network research studies; and
8) 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:

1) Establishing and maintaining a national interdisciplinary Research Network of OB/GYNs and other health professionals and researchers who collaborate in the development and implementation of research designed to improve pregnancy-related care and maternal health;
2) Designing and implementing multi-site research protocols to develop evidence-informed practices for interventions, and examining disparities in pregnancy-related care and maternal health, including innovative models for reaching underserved populations;
3) Establishing partnerships with programs serving and recruiting study participants from underserved populations including, but not limited to, the Health Center Program or the MIECHV Program;
4) Providing a research environment that supports the professional development and mentorship of diverse emerging investigators in the field of pregnancy-related care and maternal health research;
5) Developing and instituting a plan to ensure dissemination of Research Network findings beyond peer-reviewed publications, and to diverse stakeholders, in order to accelerate the adoption of effective interventions into practice;
6) Fostering the transfer of Research Network findings on interventions, guidelines, tools, toolkits, and systems management approaches into practice and community settings to promote the translation of evidence-informed 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 interested 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 population;

8) Leveraging Research Network capacity to compete for grant opportunities from other federal and private sources to support and implement research protocols; and

9) Providing an electronic copy of any products supported by award funds (including guidelines, publications, books, pamphlets, slide sets, CD-ROMS, curricula, assessment tools, videos, etc.) to be made available to the general public through 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 FY 2020 President's Budget does not request funding for this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. 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 the MCH Pregnancy-Related Care Research Network Program (PRC-RN) 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 45 CFR part 75.

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

Eligible applicants include any domestic public or private entity, including research centers or networks. Domestic faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

You are required to submit proof of non-profit status as **Attachment 6**.

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 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 Section IV.4 non-responsive and will not consider it for funding under this notice.

NOTE: Multiple applications from an organization are allowable. In order to diversify our 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 face 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-20-058, the U4D MCH PRC-RN 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 Grants.gov 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 Grants.gov 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 http://www.grants.gov/applicants/apply-for-grants.html.

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 relevant to desired opportunities.*

2. Content and Form of Application Submission

Section 4 of HRSA's *SF-424 R&R Application Guide* 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 *SF-424 R&R Application Guide* 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 *SF-424 R&R Application Guide* 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 (biosketches), and letters of commitment and support required in HRSA's *SF-424 R&R Application Guide* 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 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

1) 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 *SF-424 R&R Application Guide* for additional information on all certifications.

Program-Specific Instructions
In addition to application requirements and instructions in Section 4 of HRSA's *SF-424 R&R Application Guide* (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 reference 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 suggested section headers (capitalized) and content. The abstract should not exceed one page in length.

- FUNDING OPPORTUNITY NUMBER: HRSA-20-058.
- FUNDING OPPORTUNITY TITLE: U4D Maternal and Child Health (MCH) Pregnancy-Related Care Research Network (PRC-RN) Program.
- PROBLEM: Briefly state the principal needs and problems which 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, and comment on innovations and other characteristics of the proposed plan.
- COORDINATION: Describe the coordination planned with appropriate national, regional, state, and/or local health agencies, professional groups, and/or organizations that function as stakeholders or partners in the proposed project.

- PRODUCTS: Provide a brief description of the anticipated products of this MCH Research Network, including modes of dissemination of project activities and findings.
- EVALUATION: Briefly describe the evaluation methods used to assess program outcomes and the effectiveness and efficiency of the project in attaining goals and objectives.
- KEY TERMS: From Appendix B 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 gaps in evidence-based practices for interventions to improve the pregnancy-related care and maternal health;
> - Critical evaluation of the national significance of this Research Network;
> - Knowledge and identification of the health needs and issues for women including, but not limited to, pregnancy, pre-conception care, inter-conception care, maternal morbidity, maternal mortality, and current and emerging gaps in research, such as models of delivery of pregnancy-related care in settings with limited resources;
> - How interdisciplinary research studies can fill the gaps in research and advance the field of pregnancy-related care; and
> - How an interdisciplinary, national, multi-site intervention Research Network can address the identified needs, including those of underserved populations.

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

Include the following:

- A numbered list of objectives and goals that address the major Research Network activities listed in the Purpose section of this notice to be accomplished during the period of performance. Specific objectives should be succinctly stated and innovative, but direct attention to the scope of expected activities listed. Objectives should be specific, measurable, achievable, realistic, time-bound (SMART), and tied to a distinct project goal;
- A detailed plan for completing several practice-based intervention studies, including one study per year on emerging pregnancy-related and maternal health topics 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 taken to achieve each of the project goals. Please use a timeline that includes each activity and identifies responsible staff;
- A description of how proposed activities will build upon ongoing efforts. As appropriate, identification of meaningful support and collaboration with key stakeholders and partners in planning, designing, and implementing all activities; and
- A logic model should be 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 the PRC-RN Application, as described in the Attachments Section of this NOFO (**Attachment 5**). HRSA's expectations and goals for the PRC-RN logic model is further illustrated in Appendix D of this NOFO.

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

To assist you in demonstrating a plan for collaboration with programs serving vulnerable and 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.

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 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 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 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: https://mchb.hrsa.gov/maternal-child-health-initiatives/home-visiting/fy18-home-visiting-awards

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 studies.

> Responsibility of the NCC overseeing the CREs: Address how the Research Network will manage CRE or sites. The Research Network provides the CREs with guidance to ensure the availability of:

- Staff and training needed for the CREs 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 the Research Network, data acquisition system to collect intake, treatment and outcome data for all study participants, according to protocol-specific requirements. You should include budgets for CRE travel support to Research Network meetings in your applications.

Responsibility of Each CRE Site: Each CRE should, as appropriate, in conducting studies and participating in Research Network activities:

- Describe the plan to establish and sustain the CREs;
- 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;
- 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 to practice settings and health professions' educational training that will result in advancing and strengthening the evidence base on pregnancy-related care and maternal health outcomes.

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

A. 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.

B. Dissemination:

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

- **Peer-reviewed publications:** It is expected that the Research Network will produce no less than three peer-reviewed publications per year. It is expected that a new or updated national research agenda for pregnancy-related care research be published in a peer-reviewed journal;
- **The Research Network website:** Maintain a Research Network website to disseminate research findings, generate interest in the Research Network, and expand Research Network membership;
- **Research acceleration:** Disseminate findings to 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; and
- **Stakeholder engagement:** Showcasing informational products and educational opportunities, including webinars, website material, plenary sessions, abstracts, conference presentations, annual Research Network meetings, and consumer materials, etc.

C. 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.

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 evaluative measure. The evaluative measure should be SMART with a timeline for evaluation and should be consistent with the plan and schedule of implementation of the goals and objectives.

D. Cooperative Agreement Activities:

Infrastructure Development:

- Develop and maintain a national Research Network of research entities from across the country that will collaborate to strengthen the evidence base for pregnancy-related care through an improved understanding of risk factors across the life course, in accordance with the objectives and functions outlined in this NOFO; and
- Establish an interdisciplinary Research Network Steering Committee comprised of a broad representation of diverse key stakeholders including, but not limited to, clinicians/ health care professionals, national experts, research entities, and family members, including those from underserved populations,[13] in accordance with the guidance outlined in this NOFO.

Research Network Activities:

- Create and maintain an interdisciplinary Research Network focused on research around pregnancy-related care and maternal health across the life course;
- Conceptualize, or update and publish, in a peer-reviewed journal, a national research agenda for intervention research on pregnancy-related care;
- Design and implement several multi-site intervention research studies clearly identifying the number of studies and how they address disparities in pregnancy-related care, including innovative models

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[13] In this NOFO, Underserved populations include low-income, racial/ethnic minorities, immigrant, disabled, female, tribal, the geographically remote, and other groups that are not already well represented in current research on pregnancy-related care.

serving underserved populations and populations disproportionately impacted by maternal morbidity and mortality;

- Design and implement multi-site intervention research studies addressing emerging pregnancy-related issues in consultation with HRSA/Maternal Child and Health Bureau (MCHB) leadership;
- Accelerate the adoption, scale-up, and distribution of evidence-based interventions for addressing pregnancy-related maternal health problems, while pursuing the development of new interventions;
- Engage family members in planning, design, and implementation of PRC-RN studies;
- Recruit diverse participants in research ensuring that a robust number of PRC-RN study participants represent underserved populations;
- Develop and foster collaborations with other HRSA-funded programs, that may include state Title V programs, Health Center Program, Maternal, Infant, and Early Childhood Home Visiting Program, rural health research program, etc.;
- Develop a dissemination plan for communicating research findings to diverse stakeholders;
- Engage key audiences that provide pregnancy-related care and services to advance the translation of PRC-RN research into practice. These include, but are not limited to, policymakers, researchers, health professional schools, health care and direct service professionals, families, community members, and state, tribal, territorial, and local agencies;
- Develop and evaluate resources such as guidelines, tools, study protocols, or toolkits for use in clinical practice or intervention-based research in community settings;
- Train and mentor diverse emerging investigators in pregnancy-related care research;
- Develop and maintain a public website for engaging multiple stakeholders and communicating the work of the PRC-RN; and
- 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 information on PRC-RN activities and research findings to a broad audience including researchers, health professionals, policymakers, educators, community members, families, and Title V populations.

- Consistent with HRSA's mission to improve access to quality services to underserved populations, the PRC-RN should ensure that research

activities will be responsive to the cultural and linguistic needs of special populations. These services should be family-centered, accessible to consumers and represent the aforementioned populations.

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, #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 CREs.

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 (Note: this is not the same as the publication records of your key personnel to be listed in attachment 3).

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
Background and Significance	(1) Need (2) Response (4) Impact
Specific Goals and Objectives	(2) Response (4) Impact (5) Resources/Capabilities
Project Design: Methods and Evaluation	(2) Response (3) Evaluative Measures (4) Impact (5) Resources/Capabilities (7) Program Assurances

Plan and Schedule of Implementation, and Capability of Applicant	(3) Evaluative Measures (4) Impact (5) Resources/Capabilities (6) Support Requested (7) Program Assurances
Biographical Sketches	(5) Resources/Capabilities
Budget and Budget Justification Narrative (below)	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

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 *SF-424 R&R Application Guide* may differ from those offered by Grants.gov. 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. 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 meetings are required for the Research Network:
* 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.

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 *SF-424 R&R Application Guide* for additional information. Note that these or other salary limitations may apply in the following FY, 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 PRC-RN 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 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 which 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.

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

1. Identify the Problem(s), Target Population(s), and Program Purpose:
   - 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?
   - Program Purpose:
     - How does the program offer a solution?

- o What does the program do to address the problem?

2. Identify Activities and Clarify Outputs:
   - Activities:
     - o What does the program do?
     - o What services does the program deliver?
   - Products:
     - o What does the program create?
     - o What are the outputs of the program?

3. Identify Program Outcomes:
   - Short-Term and Intermediate Outcome(s):
     - o May include changes in skills, attitudes, knowledge or changes in behaviors and decision-making.
     - o Should directly result from program outputs.
   - Long-Term Outcome(s):
     - o May include changes related to health status, health conditions, or systems changes.
     - o Should directly result from short-term/intermediate outcomes.

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. [Limitations on indirect cost rates](#) are discussed earlier in this NOFO.

Attachments 8–15: Other Relevant Documents, As Necessary

Include here any other documents that are relevant to the application.

3. Dun and Bradstreet Data Universal Numbering System (DUNS) 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*.

SAM.GOV ALERT: For your SAM.gov registration, you must submit a notarized letter 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 SAM.gov.

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 *March 10, 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 *SF-424 R&R Application Guide* for additional information.

5. Intergovernmental Review

The Research Network is not 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). The FY 2020 President's Budget does not request funding for this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately. 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.

Travel outside of the United States is not supported under this notice.

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 *SF-424 Application Guide* for additional information. Note that these or other restrictions will apply, as required by law in subsequent appropriations acts for the following fiscal year.

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 reviewers 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 PRC-RN 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 [Background and Significance](#)

The extent to which the application describes:

- The current research gaps in (1) evidence-based practices for interventions to improve pregnancy-related care and maternal health, and (2) health needs and issues for women including, but not limited to, pregnancy, pre-conception care, inter-conception care, maternal morbidity, maternal mortality, especially among underserved populations;
- An approach using interdisciplinary, collaborative, multi-site research to address the identified gaps and needs; and
- The national significance and impact of PRC-RN and how the coordination of multi-site research can advance the field by contributing to the development of practice guidelines, fostering the adoption of innovative treatment models, and disseminating findings.

Criterion 2: RESPONSE (20 points) – Corresponds to Section IV's [Background and Significance](#); [Specific Goals and Objectives](#); [Project Design: Methods and Evaluation](#)

Intervention Studies (10 points)

The degree to which the application:

- Proposes intervention studies and discusses how these studies will address health outcomes in pregnant women.

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 clearly articulates its proposed goals and objectives and their relationship to the identified project. How clearly the application aligns its activities (scientific or other) described in the application with addressing the identified problem(s) and attaining the project objectives. The degree to which the application/proposed project:

- 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 applications of 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 HRSA's Health Center Program or the MIECHV Program and includes documentation of agreement from the partnering programs.

Criterion 3: EVALUATIVE MEASURES (20 points) – Corresponds to Section IV's *[Project Design: Methods and Evaluation](#); [Plan and Schedule of Implementation, and Capability of Applicant](#)*

The strength and effectiveness of the method proposed to monitor and evaluate the 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 in regards to:

- Proposed activities 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;
- Clearly articulated implementation plan for the proposed intervention studies;
- Familiarity and experience with data gathering procedures as they relate to collaborative multi-site research are described; and
- Evaluative measures are included for each described objective, including intervention research studies, with a timeline for evaluation that aligns 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 several, but no fewer than three, peer-reviewed publications per 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 *[Background and Significance](#); [Specific Goals and Objectives](#); [Project Design: Methods and Evaluation;](#) [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 multi-site, collaborative, interdisciplinary Research Network that will advance and strengthen the evidence base related to care and health outcomes for pregnant

women;

- The feasibility and effectiveness of plans for disseminating project results;
- The potential impact of project results in advancing and strengthening the evidence base for pregnancy-related health interventions and treatments and access to care, including underserved populations;
- The effectiveness of the dissemination plan to facilitate the transfer of Research Network findings to a broad audience of researchers, health professionals, policymakers, educators, and families;
- The feasibility of the applicant's plan for delivering at least three peer-reviewed publications each year resulting from the award; and
- An effective plan for engaging other MCH programs (e.g., Research Networks) and other cooperative agreements pertinent to PRC-RN.

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 with regard 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 national, multi-site, interdisciplinary, collaborative research and publication record on advancing the field of pregnancy related 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, NCC staff 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 Research 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; and
- The partnering programs such as, but not limited to, 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 and related activities, and the anticipated results. A sufficient description that 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.

Criteria 7: PROGRAM ASSURANCES (10 points) -- Corresponds to Section III's Project Design: Methods and Evaluation and Section IV's Plan and Schedule of Implementation and Capability of Applicant

Feasibility

The applicant should demonstrate the feasibility of its proposal to establish the Research 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

The extent to which the application 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-to-reach 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's plan to:

- Anticipate and address potential barriers to project progress;
- Provide assurance that a Research Network 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 HHS regulations for protection of human subjects (45 CFR Part 46). See the instructions in HRSA's *SF-424 R&R Application Guide*, 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 of ensuring the enrollment of an adequate number 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 *SF-424 R&R Application Guide* 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 ([45 CFR part 46](#)) 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 *SF-424 R&R Application Guide*, 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 Methods portion of the Project Narrative Section.

3. Reporting

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

1) **Discretionary Grant Information System (DGIS) Performance Reports.** Available through the Electronic Handbooks (EHBs), the Discretionary Grant Information System (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 https://grants6.hrsa.gov/MchbExternal/DgisApp/formassignmentlist/U4D_1.html.

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
a) 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
b) 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
c) 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 https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection (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.

3) **Integrity and Performance Reporting.** The NOA will contain a provision for integrity and performance reporting in FAPIIS, as required in 45 CFR part 75 Appendix XII.

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
Office of Federal Assistance Management
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 594-4259
Email: Trandall@hrsa.gov

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

Fulera Salami, M.P.H. & Jessica DiBari, Ph.D., M.H.S.
Program Officers
Division of Research, Office of Epidemiology and Research
Attn: PRC-RN Program
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 18N-136A
Rockville, MD 20857
Telephone: (301) 443 6377 (Ms. Salami) & (301) 443-4690 (Dr. DiBari)
Fax: (301) 480-0508
Email: FSalami@hrsa.gov & JDiBari@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: support@grants.gov
Self-Service Knowledge Base:
https://grantsportal.psc.gov/Welcome.aspx?pt=Grants

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: http://www.hrsa.gov/about/contact/ehbhelp.aspx

VIII. Other Information

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Monday, January 13, 2020
Time: 3–4 p.m. ET
Call-In Number: 1-888-566-6351
Participant Code: 3672361
Weblink: https://hrsa.connectsolutions.com/fy20_prcrn_ta/

HRSA will record the webinar and make it available at:
https://mchb.hrsa.gov/fundingopportunities/default.aspx

In an attempt to most effectively utilize our TA webinar time, if you have questions about the NOFO, please send them beforehand via email to Fulera Salami at FSalami@hrsa.gov and Jessica DiBari at JDiBari@hrsa.gov. We will compile and address these questions during the TA webinar.

Tips for Writing a Strong Application

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

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
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: Application Completeness Checklist

Funding Opportunity Number: HRSA-20-058 Application Due Date in Grants.gov: March 10, 2020	
Requirement	**Yes**
Do you meet the eligibility criteria?	
Did you read the HRSA R&R Application Guide (https://www.hrsa.gov/sites/default/files/hrsa/grants/apply/applicationguide/sf-424-rr-app-guide.pdf)?	
Do you have a DUNS number (https://www.dnb.com/duns-number.html)?	
Did your Authorized Organization Representative (AOR) register in **SAM** (https://www.sam.gov/)?	
Did your AOR register in **Grants.gov** (https://www.grants.gov/)?	
Is your **Abstract** no more than one page in length **and** single spaced?	
Does the **Narrative Section** of your application fully address: • Background and Significance? • Specific Goals and Objectives? • Project Design, Methods, and Evaluation? • Plan/Schedule of Implementation and Capability of Applicant? • Feasibility? • Evaluation and Technical Support Capacity? • Protection of Human Subjects? • Targeted/Planned Enrollment?	
Did you confirm that your application addressed all of the NOFO **Review Criteria**?	
Is your **Methods Section** within the 12-page limit?	
Are your **budget** and **budget justification narrative** completed accurately and in the yearly funding limit? **NOTE:** The directions offered in the HRSA SF-424 R&R Application Guide differ from those offered by Grants.gov. Please follow the instructions included in the Guide and, *if applicable*, the additional budget instructions in the **NOFO**.	
Did you clearly label all of your **attachments**?	
Did you include the **Biographical Sketches of Key Personnel** in the Application?	
Do you know your institution's **indirect cost rate**?	
Did you use no less than 12-point font and are your **page borders** no more than 1 inch wide in the Narrative and Attachment Sections of the Application? **NOTE:** The Biographical Sketches of Key Personnel can have .5" margins.	
Are your **pages**, including attachments, within the 80-page limit? **NOTE:** Pages which **do not count** toward the 80-page limit include: Cover Page, Indirect Cost Rate Agreement, Proof of Non-Profit Status, Budget, and Standard OMB-approved forms.	
Did you experience system glitches or a qualified emergency and need to request an **exemption/waiver**, subject to HRSA discretion? NOTE: Submit exemption request in writing to: DGPWaivers@hrsa.gov.	

Appendix D: Logic Models

The following logic model illustrates HRSA's expectations and goals for the PRC-RN.

PROGRAM INPUTS	PROGRAM OUTPUTS		PROGRAM OUTCOMES	
	ACTIVITIES	PRODUCTS / SYSTEMS	SHORT-TERM / INTERMEDIATE	LONG-TERM / IMPACT
Eligible Entities, Stakeholders & Key Resources	Activities to create/improve health/service systems and infrastructure (What will program inputs do?)	Health/service systems and infrastructure created to support desirable systems or behaviors (What will be created as a result of the activity?)	Health/service systems or behaviors that lead to improved health outcomes (What will change as a result of the product/system implemented?)	Improved health or health care outcomes (What will change if short-term / intermediate outcomes are achieved?)
• Domestic public or private entities, including research centers or networks	Create and maintain an interdisciplinary Research Network focused on research around pregnancy-related care	Multi-site, interdisciplinary Research Network for pregnancy-related care	Establish, maintain, and increase a Research Network infrastructure to address current and emerging pregnancy-related care issues; such as rural/urban disparities in access to OB/GYN services, the national shortage of midwives, obstetricians, and gynecologists, etc.	Advance the evidence base to further develop the field for pregnancy-related care for mothers and children.
• Interdisciplinary Research Network of national experts and research entities • Federal staff • Families and community members	Form an interdisciplinary Research Network Steering Committee / Advisory Board composed of diverse professionals and family members	Interdisciplinary and diverse Research Network Steering Committee/ Advisory Board established, and annual in-person meetings convened	A national research agenda addressing current and emerging obstetric and gynecologic issues is published and disseminated. Practice-based interventions addressing maternal morbidity and mortality; such as postpartum depression, substance/opioid use disorder, etc. are conducted in obstetric/gynecologic offices nation-wide.	Improve maternal and child health outcomes.

PROGRAM INPUTS	PROGRAM OUTPUTS		PROGRAM OUTCOMES	
	ACTIVITIES	PRODUCTS / SYSTEMS	SHORT-TERM / INTERMEDIATE	LONG-TERM / IMPACT
Eligible Entities, Stakeholders & Key Resources	**Activities to create/improve health/service systems and infrastructure** **(What will program inputs do?)**	**Health/service systems and infrastructure created to support desirable systems or behaviors** **(What will be created as a result of the activity?)**	**Health/service systems or behaviors that lead to improved health outcomes** **(What will change as a result of the product/system implemented?)**	**Improved health or health care outcomes** **(What will change if short-term / intermediate outcomes are achieved?)**
			A pipeline of trained obstetrician/gynecologist researchers/ investigators committed to advancing the field of pregnancy-related care for women and children is established and increased.	
	Create a national research agenda for PRC-RN research (in collaboration with MCHB)	National research agenda for PRC-RN research		
	Design and implement several multi-site intervention research studies to examine and improve upon standards of pregnancy-related care	Multi-site intervention research studies designed and implemented		
	Develop and implement a dissemination plan for communicating research	Dissemination plan with a timeline and list of proposed products		

PROGRAM INPUTS	PROGRAM OUTPUTS		PROGRAM OUTCOMES	
	ACTIVITIES	PRODUCTS / SYSTEMS	SHORT-TERM / INTERMEDIATE	LONG-TERM / IMPACT
Eligible Entities, Stakeholders & Key Resources	**Activities to create/improve health/service systems and infrastructure** **(What will program inputs do?)**	**Health/service systems and infrastructure created to support desirable systems or behaviors** **(What will be created as a result of the activity?)**	**Health/service systems or behaviors that lead to improved health outcomes** **(What will change as a result of the product/system implemented?)**	**Improved health or health care outcomes** **(What will change if short-term / intermediate outcomes are achieved?)**
	findings to diverse stakeholders	Manuscripts published in peer-reviewed journals 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)		
	Engage key audiences (e.g., researchers, clinicians, Title V populations, Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV), families, community members, policymakers) to advance the	Key audiences engaged Resources developed that include the input of key audiences and are shared broadly and in varying formats		

PROGRAM INPUTS	PROGRAM OUTPUTS		PROGRAM OUTCOMES	
	ACTIVITIES	PRODUCTS / SYSTEMS	SHORT-TERM / INTERMEDIATE	LONG-TERM / IMPACT
Eligible Entities, Stakeholders & Key Resources	Activities to create/improve health/service systems and infrastructure (What will program inputs do?)	Health/service systems and infrastructure created to support desirable systems or behaviors (What will be created as a result of the activity?)	Health/service systems or behaviors that lead to improved health outcomes (What will change as a result of the product/system implemented?)	Improved health or health care outcomes (What will change if short-term / intermediate outcomes are achieved?)
	translation of PRC-RN research findings into practice			
	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		
	Prepare and submit grant applications for external funding opportunities outside of HRSA/MCHB's research grant program	Grant applications completed and submitted for external funding opportunities		
	Develop and maintain a public website for engaging multiple stakeholders and	Website representing the work of the PRC-RN developed and maintained		

PROGRAM INPUTS	PROGRAM OUTPUTS		PROGRAM OUTCOMES	
	ACTIVITIES	PRODUCTS / SYSTEMS	SHORT-TERM / INTERMEDIATE	LONG-TERM / IMPACT
Eligible Entities, Stakeholders & Key Resources	Activities to create/improve health/service systems and infrastructure (What will program inputs do?)	Health/service systems and infrastructure created to support desirable systems or behaviors (What will be created as a result of the activity?)	Health/service systems or behaviors that lead to improved health outcomes (What will change as a result of the product/system implemented?)	Improved health or health care outcomes (What will change if short-term / intermediate outcomes are achieved?)
	communicating work of the PRC-RN			
	Train and mentor junior/new investigators in pregnancy-related care research	Junior/new investigators trained/mentored		
	Engage family members in PRC-RN studies	Family members engaged as members of the Research Network Steering Committee Input from family members incorporated in the design and implementation of PRC-RN studies		

PROGRAM INPUTS	PROGRAM OUTPUTS		PROGRAM OUTCOMES	
	ACTIVITIES	PRODUCTS / SYSTEMS	SHORT-TERM / INTERMEDIATE	LONG-TERM / IMPACT
Eligible Entities, Stakeholders & Key Resources	**Activities to create/improve health/service systems and infrastructure** **(What will program inputs do?)**	**Health/service systems and infrastructure created to support desirable systems or behaviors** **(What will be created as a result of the activity?)**	**Health/service systems or behaviors that lead to improved health outcomes** **(What will change as a result of the product/system implemented?)**	**Improved health or health care outcomes** **(What will change if short-term / intermediate outcomes are achieved?)**

PERFORMANCE MEASURES		• # of studies developed
		• # of participants (including demographic data) enrolled in PRC-RN studies
		• # of total researchers involved in the PRC-RN
		• # of junior/new investigators being trained or mentored through PRC-RN
			• # of tools, toolkits, and clinical guidelines
			• DGIS Core 2
			• DGIS Core 3
			  # of research sites
				• # of peer-reviewed publications
				• # of non-peer-reviewed publications
				  DGIS Core 1

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

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

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

Appendix E: Frequently Asked Questions (FAQs)

1. Where do I find application materials for the PRC-RN Program?

All application materials are available through Grants.gov

2. How can I download the complete application package for the PRC-RN NOFO?

You can download the application from Grants.gov.

3. What is Grants.gov?

Grants.gov 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 Grants.gov 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 Grants.gov. In order to submit your application, your university or institution and your AOR MUST be registered in Grants.gov. 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 Grants.gov.

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

1) Make sure that the AOR from your university/organization is registered in Grants.gov 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 Grants.gov 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 Grants.gov 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?**

   Eligible applicants include any domestic public or private entity, including research centers or networks. 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 PRC-RN Program. Are foreign entities eligible to apply?**

   The PRC-RN 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 HRSA SF-424 R&R Application Guide (as aligned with the Uniform Administrative Requirements at 45 CFR part 75), "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 the 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 NCC 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 Research 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 Research 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 Research 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.
- 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 PRC-RN 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 page limits for the submitted application?**

Please consult the NOFO and/or the HRSA R&R Application Guide, referenced throughout the NOFO, for more specific information.

15. **Are there any page limitations to the narrative?**

The NOFO requires a 12-page limit for Section III - Project Design: Methods and Evaluation, of the narrative. Preliminary studies can be included if applicable and would be included in the 12-page limit as described above. Please consult the NOFO and/or the HRSA R&R Application Guide, referenced throughout the NOFO, for more specific information.

16. **Are there font/margin requirements?**

Specifications regarding fonts and margins can be found in the HRSA R&R Application Guide. Follow HRSA guidelines, which call for 1" margins and 12-point font.

17. 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.

18. When will you announce your other research NOFOs?

Please join our listserv at http://mchb.hrsa.gov/research to receive an alert whenever our NOFOs are released.

19. Whom 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.*