# **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**



# Health Resources & Services Administration

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

## UA6 Life Course Intervention Research Network (LCI-RN)

Funding Opportunity Number: HRSA-18-103 Funding Opportunity Type(s): New Catalog of Federal Domestic Assistance (CFDA) Number: 93.110

# NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2018

# Application Due Date: June 12, 2018

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: April 13, 2018

Jessica DiBari, PhD, MHS and Evva Assing-Murray, PhD, MA Program Officers, Division of Research, Office of Epidemiology and Research Telephone: DiBari: (301) 443-4690; Assing-Murray: (301) 594-4113 Email: JDiBari@hrsa.gov; EAssing-Murray@hrsa.gov

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

## **EXECUTIVE SUMMARY**

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2018 Life Course Intervention Research Network (LCI-RN) Program. The purpose of this program is to coordinate a national platform to support research studies and to advance knowledge in disease prevention and health promotion across the life course by supporting a national network of interdisciplinary maternal and child health (MCH) researchers who would design, plan, and implement multi-site life course intervention research studies that will contribute to the improvement of health outcomes for MCH populations, including children with special healthcare needs. Funding authorized for the LCI-RN will be used to principally coordinate applied and translational research studies in life-course that will be conducted at multiple sites under the coordination of the Network.

Funding Opportunity Title:	UA6 Life Course Intervention Research Network (LCI-RN)
Funding Opportunity Number:	HRSA-18-103
Due Date for Applications:	June 12, 2018
Anticipated Total Annual Available FY 2018 Funding:	\$1,200,000
Estimated Number and Type of Award(s):	Up to one cooperative agreement
Estimated Award Amount:	Up to \$1,200,000 per year dependent on the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2018 through August 31, 2023 (5 years)
Eligible Applicants:	Domestic public or non-profit institutions of higher learning and public or private non-profit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs are eligible to apply. See 42 CFR § 51a.3(b). See <u>Section III-1</u> 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 <u>http://www.hrsa.gov/grants/apply/applicationguide/sf424rrguidev2.pdf</u>, except where instructed in this NOFO to do otherwise. A short video explaining the *Application Guide* is available at <u>http://www.hrsa.gov/grants/apply/apply/applicationguide/</u>.

#### **Technical Assistance**

HRSA has scheduled the following pre-submission technical assistance webinar:

Day and Date: Thursday, May 3, 2018 Time: 3 p.m. – 4 p.m. ET Call-In Number: 888-790-3364 Participant Passcode: 7415078 Weblink: https://hrsa.connectsolutions.com/ta\_hrsa\_18\_103/

#### Replay

End date: July 3, 2018, 11:59 p.m. ET Number: 1-888-566-0478 Passcode: 4690

In an attempt to most effectively utilize our TA webinar time, if you have questions about the NOFO, please send them via email to Jessica DiBari at <u>JDiBari@hrsa.gov</u> and Evva Assing-Murray at <u>EAssing-Murray@hrsa.gov</u>. We will compile and address these questions during the TA call.

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# I. Program Funding Opportunity Description

#### 1. Purpose

This notice solicits applications for the Life Course Intervention Research Network (LCI-RN) Program. The life course theory posits that multiple determinants, such as health care, nutrition, stress, community/family supports, and environmental exposures, operating over the life course, are critical drivers of maternal and child health (MCH) outcomes.

The purpose of this program is to coordinate a national platform to support research studies to advance knowledge in disease prevention and health promotion across the life course by supporting a national network of interdisciplinary MCH researchers to design, plan, and implement **multi-site life course intervention research studies.**<sup>1</sup>

The LCI-RN is designed to accelerate the translation of the life course theory to MCH practice and policy, and foster its rapid adoption into clinical and public health settings through rigorous testing, systems integration, and collaboration among entities interested in improving MCH outcomes.

The cooperative agreement will establish and maintain an interdisciplinary, multi-site, collaborative Research Network (hereafter referred to as "the Network"). The Network will lead, promote, and coordinate national research activities to advance and strengthen the evidence base related to disease prevention and health promotion through an improved understanding of risk factors across the life course. The Network infrastructure will support the design of a portfolio of multi-site, interdisciplinary research that focuses on fostering the implementation of multi-site intervention research studies, translation of research to policy and practice, and provision of a mentoring environment to train a new generation of clinical and non-clinical researchers in applied and translational research, drawing upon life course theory and science. The Network should incorporate the HRSA clinical priorities that are relevant to life-course and aligned with Title V Maternal and Child Health Block Grant national performance measures including opioid and other substance abuse, mental health, and/or childhood obesity as part of its overall research strategy and study plan.

**Cooperative Agreement Activities** 

#### Infrastructure development:

• Develop and maintain a national Network of research entities that will collaborate to advance and strengthen the evidence base in disease prevention and health promotion through an improved understanding of risk factors across the life course; and

<sup>&</sup>lt;sup>1</sup> For the purpose of this NOFO, an "intervention" is defined to include behavioral, social, or structural / health systems approaches, as well as a combination of applied clinic-medical and behavioral, social, or structural / health system approaches that contribute to the prevention of diseases or improvement of health (including clinical) outcomes for mothers, children and families at a population level.

• Establish an interdisciplinary Network Steering Committee that will comprise a broad representation of diverse key stakeholders, including but not limited to, clinicians, national experts, research entities, and family members, including those from MCH and other vulnerable populations.

#### Network Activities:

- Create an interdisciplinary Network for life course intervention research;
- Engage family members in the planning and implementation of Network studies;
- Conceptualize a national research agenda for life course intervention research;
- Design and implement several multi-site intervention research studies<sup>1</sup> clearly identifying the number of studies and how the proposed studies apply life course theory and methodologies, and address the health needs of MCH, including children with special health care needs, and other vulnerable populations;
- Develop and implement a dissemination plan for communicating research findings to diverse stakeholders;
- Engage key audiences (e.g., researchers, clinicians, Title V Maternal and Child Health Services populations, families, policymakers) to advance the translation of life course research into practice;
- Develop and evaluate resources such as guidelines, tools, or toolkits for use in clinical practice or intervention-based research in communities;
- Develop and implement strategies to sustain the Network infrastructure and to expand the scientific knowledge generated from this grant;
- Train and mentor junior/new investigators in life course intervention research; and
- Develop and maintain a public website for engaging multiple stakeholders.

#### Communications:

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

#### Dissemination:

 Disseminate information on Network activities and research findings to a broad audience including researchers, clinicians, policymakers, educators, families, and Title V populations;<sup>2</sup>

Consistent with HRSA's mission to improve access to quality services to underserved populations, HRSA's intent is to ensure that research activities carried out by this Network will be responsive to the cultural and linguistic needs of special populations, ensure that services are family-centered and accessible to consumers, and that the broadest possible representation of culturally distinct and historically underrepresented groups is supported through programs and projects sponsored by HRSA.

<sup>&</sup>lt;sup>2</sup> Title V populations include women, mothers, infants, children, adolescents, children with special health care needs (CSHCN) and their families.

#### 2. Background

This program is authorized by the Social Security Act, Title V, § 501(a)(2) (42 U.S.C. § 701(a)(2)). The LCI-RN is an interdisciplinary research Network focused on improving the understanding of the socio-environmental determinants of health experienced at different life course stages for the maternal and child health (MCH) population through engagement of researchers, practitioners, policymakers and consumers in a collaborative, innovative, and multidisciplinary research project.

The life course model of health development posits that an individual's heath trajectory amounts to more than a combination of genetic endowment and adult lifestyle choices, and that social, psychological and environmental factors operating early in life could have major impacts on both short- and long-term health outcomes including chronic conditions such as cardiovascular diseases.<sup>3,4</sup> The improvement of these outcomes requires rethinking of current practice, policy, and investment strategies including workforce development that integrates biological, behavioral, and social perspectives before conception and continuing through the lifespan. The life course perspective provides us with vital information on how investments in MCH can be more effectively targeted.

The current challenge is how to advance MCH life course research through rigorous testing and intervention-based research, build the capacity to have a greater collective impact, and accelerate the translation of life course theory to practice.<sup>5</sup>

The Network infrastructure will provide a platform for the development and implementation of well-designed intervention studies to inform public health efforts in the prevention of disability and disease. This requires collaboration of an interdisciplinary network and the integration of multidimensional systems to intervene across multiple life stages.

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

<sup>&</sup>lt;sup>3</sup> Halfon, N, Larson, K, Lu, M, Tullis, E, Russ, S. Lifecourse Health Development: Past, Present and Future, *Maternal Child Health J*. 2014; 18(2):344-365.

 <sup>&</sup>lt;sup>4</sup> Pollitt, RA, Rose, KM, Kaufman, JS. Evaluating the evidence for models of life course socioeconomic factors and cardiovascular outcomes: a systematic review. BMC Public Health. 2005; 5:7.
 <sup>5</sup>Lu, MC. Improving maternal and child health across the life course: where do we go from here?. *Maternal Child Health J.* 2014; 18(2):339-43.

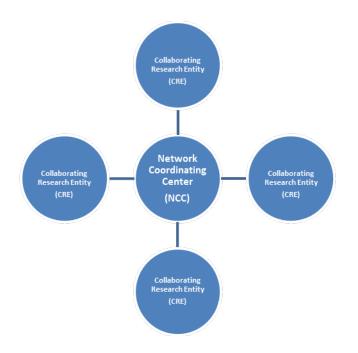
# Objectives and Function of the Life Course Intervention Research Network (LCI-RN)

The LCI-RN will forge partnerships with researchers, clinicians, educators, advocates, families, state public health programs, and other organizations/agencies critical to translating life course research into practice.

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

#### Organization and Functions

The LCI-RN will consist of a Network Coordinating Center (NCC) and multiple Collaborating Research Entities/Sites (CREs). The NCC is the administrative center of the 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 a core of administrative and operational functions that include the following:

- 1) Support the Network infrastructure for partnership among CREs;
- Provide the Network with administrative and operations support in activities including, but not limited to, meetings, multidisciplinary educational activities, and development of research studies;

- 3) Facilitate the process for the development, selection, implementation, and oversight of scientific research studies;
- Coordinate a plan to enhance the research training and mentorship of junior/new investigators through the use of innovative mentorship/research experiences and manuscript development;
- 5) Coordinate the dissemination of findings to health professionals, researchers, policymakers, family members and the greater public; and
- 6) Collaborate with other HRSA MCH Research Network recipients to assure synergy and to advance efforts to improve the system of services for children and adolescents with special health care needs.

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

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

<u>Data Collection and Management</u>. The NCC will facilitate data gathering, data management training, and data quality assurance according to developed protocol. CREs must follow the 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

Type(s) of applications sought: New

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

#### As a cooperative agreement, HRSA Program involvement will include:

• Assurance of the availability of HRSA personnel or designees to participate in the planning and development of all phases of this activity;

- Facilitation of effective communication and accountability to HRSA regarding the project, with special attention to new program initiatives and policy development that have the potential to advance the utility of the Network;
- Assistance in establishing and maintaining federal interagency and interorganizational contacts necessary to carry out the project;
- Review of documents developed by the Network such as Network operating procedures, authorship guidelines, etc. but excluding manuscripts for submission to peer-reviewed journals; and
- Participation, as appropriate, 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:

- Develop and maintain a national Network of collaborating research entities, who will collaborate in research designed to improve and advance the field of life course intervention research;
- Establish a Network Advisory Board or Steering Committee that will include broad representation from key stakeholders, including, but not limited to, national experts, research entities, and family members;
- Develop and publish a research agenda for scientific studies in the Network's focus areas;
- Coordinate and sustain a platform for multi-site research that is designed to advance the field's understanding of life course intervention theory and practice;
- Develop and implement several, multi-site intervention research studies that will address gaps and promote the research agenda identified by the Network within one project cycle;
- Develop and implement a robust plan to disseminate Network findings through publications and other dissemination activities such as webinars, annual Network meetings, conference presentations, and other related activities. These activities should serve to facilitate the transfer of Network findings to a broader audience including researchers, health professionals and providers, policy makers, educators, families, and State Title V programs;
- Engage with and ensure the participation of HRSA Project Officer in Network leadership meetings, such as Advisory / Steering Committee meetings;
- Collaborate with other HRSA MCH Research Networks or cooperative agreements to explore the feasibility of translating the Network's findings into practice and program development;

- Recruit study participants from diverse backgrounds including racial/ethnic, geographic, and socioeconomic diversity, and analysis of data from such efforts to determine the types of studies to be conducted;
- Engage in mentored research activities with diverse, emerging, or new investigators in fields relevant to the topics of this Network;
- Develop and implement strategies to sustain the Network infrastructure and to expand the scientific knowledge generated from this grant;
- Develop and submit a robust dissemination plan for the dissemination of Network findings several stakeholders including researchers, clinicians, policy makers, and the public, including family members;
- Ensure that Network research and activities address the needs of underserved populations, such as low-income, racial/ethnic minorities, individuals with limited English proficiency, individuals who have limited access to services, and/or other vulnerable populations;
- Translate research findings into policy or practice, as applicable per study findings;
- Develop and maintain a robust Network website.
- Participate in an annual national all-Research Network and cooperative agreement grantee meeting organized by HRSA. This meeting will take place in the Washington, DC area, and will be an opportunity to share best practices, disseminate results, and discuss research priorities with HRSA leadership, staff, and stakeholders.
- Provide to HRSA electronic copies of any products supported by award funds, including guidelines, publications, books, pamphlets, slide sets, CD-ROMs, curricula, assessment tools, videos, toolkits, guidance documents, etc., which will be made available to the general public and to HRSA staff and stakeholders;
- Adhere to HRSA guidelines pertaining to acknowledgement and disclaimer on all products produced by HRSA award funds. See "Acknowledgment of Federal Funding" in Section 2.1 of HRSA's SF-424 R&R Application Guide.
- Develop a schedule of on-going communication among Network members, and with the HRSA Project Officer; and
- Work with the HRSA Project Officer in the collection and reporting of ongoing Network impact data such as number of research sites, study enrollees, publications, investigators, mentees, etc.

#### 2. Summary of Funding

HRSA expects approximately \$1,200,000 to be available annually to fund one recipient. You may apply for a ceiling amount of up to \$1,200,000 total cost (including both direct and indirect, facilities, and administrative costs) per year. The period of performance is September 1, 2018 through August 31, 2023 (5 years). Funding beyond the first year is dependent on the availability of appropriated funds for "Life Course Intervention Research Network Program" in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

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

## **III. Eligibility Information**

#### 1. Eligible Applicants

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

#### 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. This ceiling includes both direct and indirect expenses.

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.

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 Principal Investigator (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 awardee will need to verify that percent effort across all federally-funded grants does not exceed 100 percent.

To foster innovation, maintain the uniqueness of this Network, avoid duplication, and ensure that Investigators devote substantial time and efforts to achieve Network goals, investigators should demonstrate how their work on this Network will not be duplicative of any other ongoing research project(s).

If for any reason (including submitting to the wrong NOFO 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 <u>Grants.gov</u> using the SF-424 Research and Related (R&R) workspace application package associated with this notice of funding opportunity (NOFO) following the directions provided at <u>http://www.grants.gov/applicants/apply-for-grants.html</u>.

HRSA recommends that you supply an email address to Grants.gov on the grant opportunity synopsis page when accessing this NOFO [also known as "Instructions" on Grants.gov] or workspace application package. This allows Grants.gov to email organizations in the event HRSA changes and/or republishes 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 nonresponsive 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 <u>SF-424 R&R Application Guide</u> provides instructions for the budget, budget justification, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the R&R Application Guide in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA's <u>SF-424</u> <u>R&R Application Guide</u> except where instructed in the NOFO to do otherwise. You must submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

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

#### Application Page Limit

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

Applications that exceed the 80-page limit will be deemed nonresponsive and will not be considered for funding under this notice. Please see the Frequently Asked Questions in <u>Appendix E</u> for more information on what does and does not apply to the 80-page limit.

As part of the overall 80-page limit, note that the Methodology/Research Strategy of the application narrative is STRICTLY LIMITED TO 12 PAGES. Applications that do not adhere to the stated page limit for this Section of their narrative will be deemed nonresponsive to the NOFO and marked ineligible for review.

# Applications must be complete, within the specified page limit, and validated by Grants.gov under the correct NOFO number prior to the deadline to be considered under this notice (see <u>Appendix D</u>).

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

- The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 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).
- Where the prospective recipient is unable to attest to the statements in this certification, an explanation shall be included in Attachment 7: Other Relevant Documents.

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

#### **Program-Specific Instructions**

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

#### i. Project Abstract

See Section 4.1.ix of HRSA's <u>SF-424 R&R Application Guide</u>. Include the information requested at the top of the abstract. Prepare the abstract so that it is clear, accurate, concise, and without reference to other parts of the application because it is often distributed to provide information to the public and Congress. Briefly state the principal needs and problem, goals, proposed activities including target population(s), planned coordination, anticipated products, and plans for evaluation.

Abstract content:

- Clearly indicate the NOFO number and title.
- 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, the target population(s) addressed, and comment on innovations and other characteristics of the proposed plan.
- COORDINATION: Describe the coordination planned with and participation of appropriate national, regional, state, and/or local health agencies, interdisciplinary professional groups and providers, and/or organizations that function as stakeholders or partners in the proposed project.
- PRODUCTS: Provide a brief description of the anticipated products of this Network, including modes of dissemination of project activities and findings.
- EVALUATION: Briefly describe the evaluation methods used to assess program outcomes and the effectiveness and efficiency of the project in attaining goals and objectives.
- KEY TERMS: From the Appendix select: (a) significant content terms that describe your project (maximum of 10 content terms), (b) targeted populations, and (c) age ranges, 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, 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 IN THIS SECTION -- Demonstrate a thorough knowledge and understanding of interdisciplinary research related to life course theory and research. In addition, you should critically evaluate the national significance of a research network. Identify issues of concern to, and needs of, those involved in life course research. You must demonstrate how interdisciplinary research studies can advance the field.

• Provide a brief literature review that discusses the significance of issues, needs, and gaps in life course research. You must demonstrate how an interdisciplinary multi-site research network can address the identified needs, including the needs of underserved populations, such as low-income, racial/ethnic minorities, immigrants, individuals who have limited access to services, and/or other underserved populations.

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

This section of the narrative must include:

- A numbered list of the specific goals and objectives that address the major network activities listed in the Purpose section of this notice to be accomplished during the funding period. The specific objectives should be succinctly stated. You should be innovative with respect to specific objectives, but direct attention to the scope of expected activities listed.
- The process for developing an integrated research network and present a plan of proposed activities that shows progressive implementation during the 5-year period of performance.
- A description of the activities or steps that will be used to achieve each of the project goals. Please use a timeline that includes each activity and identifies responsible staff.
- A description of how proposed activities will build upon ongoing efforts, and not duplicative of existing efforts. As appropriate, identification of meaningful support and collaboration with key stakeholders and partners in planning, designing, and implementing all activities. A logic model for designing and managing the project in this section of the narrative. A logic model is a onepage diagram that presents the conceptual framework for a proposed project and explains the links among program elements. While there are many versions of logic models, for the purposes of this notice, the logic model should summarize the connections between the:

- Goals of the project;
- Theoretical approach;
- Inputs (e.g., organizational profile, collaborative partners, other resources);
- Target population(s);
- o Activities;
- Outputs (i.e., products); and
- Outcomes (i.e., the results of the project, typically describing a change in people or systems).

More information on logic models may be found in <u>Section VIII</u> of this NOFO.

Provide documentation (letters of agreement) of participation of Collaborating Research Entities (CREs) sites that will collaborate to fulfill the goals and objectives of the research network, with descriptions of each CRE's characteristics, including patient population characteristics, average patient numbers, types of treatment or services currently delivered, number, characteristics and structure of staff. **Include letters of agreement from CRE sites in Attachment 2.** At least one CRE should demonstrate success in recruiting from underserved population(s) such as low-income, racial/ethnic minorities, immigrants, individuals who have limited access to services, and/or other underserved populations as defined by your organization.

#### Responsibility of the Network Coordinating Center (NCC) overseeing the CREs:

Address how the Network will manage CRE or sites. The Network provides the CREs with guidance to ensure:

- staff and training needed for the CREs to implement a study protocol and participate in 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 data acquisition system to collect intake, treatment and outcome data for all study participants, according to protocol-specific requirements; and additional support such as quality control to ensure the successful completion of the scientific goals of a research project and other Network activities. You should include budgets for CRE travel support to Network meetings in your applications.

#### Responsibility of Each CRE Site:

Each CRE should, as appropriate, in conducting studies and participating in Network activities:

- Describe his/her plan to establish and sustain the CREs;
- Participate in Network subcommittees and agree to attend 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 Network;
- Agree to participate in observational studies and clinical trials, including subject enrollment, data collection, patient record maintenance, adherence to good clinical practice, compliance with protocol requirements, randomization methods for assignment of patients to experimental or control groups or randomization of care delivered to different conditions;
- Participate in Network activities that enhance the research training and mentorship of junior/new investigators; and,
- Participate in the translation of critical Network findings to practice settings and educational training that will result in advancing and strengthening the evidence base on life course research and other related 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 of the narrative must provide detailed descriptions of the methodology for accomplishing the work of the Network and each of the specific objectives. You must provide sufficient technical detail to demonstrate the necessary steps to accomplish each objective, and to convey to reviewers adequate information to assess the methodology.

You must also indicate the specific methods to be used to evaluate progress in each area of activity. You must list and discuss anticipated obstacles that may be encountered and indicate how each obstacle will be overcome.

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

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

In addition, plans to disseminate findings must be described. These include:

 Peer-reviewed publications: It is expected that the Network will produce several peer-reviewed publications per multi-site study per year, and several peer-reviewed publications per year; you must clearly indicate the number of multi-site studies and peer-reviewed publications proposed per year of the grant;

- Network website: Maintain a Network website to disseminate research findings, generate interest in the Network, and expand Network membership;
- Research acceleration: Accelerate the synthesis, analysis and translation of existing and future knowledge so that it can be applied to practice and effective health policy at the state and national levels;
- Dissemination: Coordinate the dissemination of findings to health professionals, policymakers, family members and the greater public; and
- Stakeholder engagement: Other dissemination to the research and practice communities, as well as families and communities, including but not limited to: informational products and educational opportunities, including webinars, website material, plenary sessions, abstracts, conference presentations, annual Network meetings, and consumer materials for key stakeholders such as providers, communities, states, and families that will promote the transfer of findings to improve care.

You should also indicate the specific methods to be used to evaluate progress in each area of activity. You must list and discuss anticipated obstacles that may be encountered and describe plans to overcome these obstacles.

#### B. Evaluation:

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

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. You must describe any potential obstacles for implementing the program performance evaluation and how those obstacles will be addressed.

For each described objective, an evaluation measure must be included. The evaluation measure should be specific, measurable, achievable, realistic and time-bound with a timeline for evaluation and should be presented consistent with the plan and schedule of implementation of the goals and objectives.

 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

In this section of the narrative, you must 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. You must provide a draft organizational chart describing the leadership structure of the Network demonstrating collaboration between the PI, Co-Investigators, and other CREs.

In addition, an implementation schedule should be provided 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 Network program, you should 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 Network.

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

#### NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.

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

Evaluation and Technical Support Capacity	(7) Program Assurances
Protection of Human Subjects	(7) Program Assurances
Targeted/Planned Enrollment	(7) Program Assurances

#### iii. Budget

See Section 4.1.iv of HRSA's <u>SF-424 R&R Application Guide</u>. 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, if applicable, the additional budget instructions provided below to ensure that, if HRSA selects the application for funding, you will have a well-organized plan and by carefully following the approved plan can avoid audit issues during the implementation phase.

Travel

The following travel is required to be budgeted for the Network:

The budget should reflect the travel expenses associated with participating in meetings that address MCH research efforts and other proposed trainings or workshops. You must budget for in-person attendance at the HRSA MCH Research Network meeting of all funded Research Networks (one meeting per year) in the Washington, DC area for up to two people (the PI and one other attendee) for 2 days. Meeting attendance is an award requirement.

**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 LCI-RN program requires the maximum of 5 budget periods. A budget period represents 12 months of project effort.

You should use the "Other Sponsored Program/Activities" indirect cost rate because the LCI-RN is an infrastructure platform to support and coordinate applied and translational national research in life-course theory. Your organizational "Research" indirect rate does not apply to this program, as this program is intended to develop the infrastructure to support a platform for research activities.

The PI of the Research Network is expected to attend the HRSA MCH Research Network In-Person Recipient Meeting of all funded Research Networks held in the Washington, D.C. metropolitan area. Budget plans should include travel to this inperson recipient meeting. For planning, it is recommended that the budgets include travel costs for up to two Network staff associated with this 2-day recipient meeting.

NOTE: Travel outside of the U.S. is not supported for the LCI-RN.

The Consolidated Appropriations Act, 2018 (P.L. 115-141), Division H, § 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 will apply in FY 2019, as required by law.

#### iv. Budget Justification Narrative

See Section 4.1.v of HRSA's <u>SF-424 R&R Application Guide</u>. In addition, the LCI-RN program requires the following:

#### Staffing Plan and Personnel Requirements

Please refer to instructions in Section 4.1.vi of HRSA's SF-424 R&R Application Guide. Include 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 each biographical sketch be no more than two pages in length per person and must follow the HRSA font/margin requirements. Biographical sketches should document education, skills, and experience that are relevant, necessary, and demonstrate capability to fulfill the assigned roles for the proposed project.

#### v. Program-Specific Forms

Program-specific forms are not required for application.

#### vi. Attachments

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

#### Attachment 1: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying key positions. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch. Given the 80-page limit, it is recommended that biographical sketches be no more than two pages in length per person.

#### Attachment 2: Letters of Agreement/Letters of Support

Provide any documents that describe working relationships between your agency and other agencies and programs cited in the proposal. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the collaborators and any deliverables. Include only letters of support 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 Key Publications by Research Team

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 Network. The chart should provide the following information for key personnel: Institution, Responsibilities/Activities.

#### Attachment 5: Logic Model

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

Attachments 7-15: Other Relevant Documents, As Necessary Include here any other documents that are relevant to the application. All documents are included in the page limit.

# 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) (<u>https://www.sam.gov</u>)
- Grants.gov (<u>http://www.grants.gov/</u>)

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

ALERT from SAM.gov: If you are registering a <u>new</u> entity in <u>SAM.gov</u>, you must now provide an original, signed <u>notarized letter</u> stating that you are the authorized Entity Administrator before your registration will be activated by SAM.gov. Please read <u>these FAQs</u> to learn more about this process change. Applicants registering as a new entity in SAM.gov should plan for additional time associated with submission and review of the notarized letter. This change is effective March 23, 2018. Entities already registered in SAM.gov are advised to log into SAM.gov and review their registration information, particularly their financial information.

# 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 *June 12, 2018 at 11:59 p.m. Eastern Time.* HRSA suggests submitting applications to Grants.gov at least **3 days before the deadline** to allow for any unforeseen circumstances.

See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's <u>SF-424 R&R</u> <u>Application Guide</u> for additional information.

#### 5. Intergovernmental Review

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

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

#### 6. Funding Restrictions

You must request funding for a period of performance of 5 years, at no more than \$1,200,000 per year (inclusive of direct **and** indirect costs). Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

Funds under this notice may not be used for travel outside of the U.S.

The General Provisions in Division H of the Consolidated Appropriations Act, 2018 (P.L. 115-141) apply to this program. Please see Section 4.1 of HRSA's <u>SF-424 R&R</u> <u>Application Guide</u> for additional information. Note that these or other restrictions will apply in FY 2019, as required by law.

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

all other applicable grants requirements, the effectiveness of these policies, procedures and controls is subject to audit.

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

## V. Application Review Information

#### 1. Review Criteria

HRSA has instituted procedures for assessing the technical merit of applications to provide for an objective review of applications and to assist you in understanding the standards against which your application will be judged. HRSA has developed critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. See the review criteria outlined below with specific detail and scoring points.

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 Life Course Research Network Program has seven review criteria:

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	20 points
Criterion 6.	Support Requested	5 points
Criterion 7.	Program Assurances	5 points

TOTAL:

100 points

*Criterion 1: NEED (10 points) -- Corresponds to* Section IV's Background and Significance

#### Need

The extent to which the application describes:

 An approach using interdisciplinary collaborative multi-site research to address the identified needs, including the needs of underserved populations, such as low-income, racial/ethnic minorities, immigrants, individuals who have limited access to services, and/or other underserved populations;

- The current research gaps in the evidence base related to life course theory and research focusing on those with limited research and evidence, and for which prevailing policy and practice environments call for increased attention given their potential to improve health outcomes for MCH populations; and
- The national significance and impact of a LCI-RN and how the coordination of multi-site research can advance the field.

#### Alignment with HRSA/MCHB Goals, HRSA Clinical Priorities, HRSA/MCHB Strategic Issues, MCH Title V Performance priority areas, and Healthy People 2020

- The extent to which studies supported by the Network will address HRSA/MCHB Strategic Research Issues (Appendix A).
- The extent to which studies supported by the Network are likely to strengthen and expand topics identified among the HRSA clinical priorities and that are relevant to life-course and aligned with the MCH Block Grant National Performance Domains, and the populations they serve (<u>Appendix C</u>).
- The extent to which studies supported by the Network will address specific Healthy People 2020 objectives. (See HRSA's <u>SF-424 R&R Application</u> <u>Guide</u>, Section 2.1: Administrative and National Policy Requirements).

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

The extent to which the proposed project responds to the "Purpose" included in the program description. The clarity of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives.

- The extent to which the applicant demonstrates awareness of previous work in the area of this project, including citation of relevant literature and justification of the need for the Network.
- The extent to which the goals and objectives are clear, concise, and appropriate.
- The extent to which the aims of the project 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.

- The extent to which the application describes critical research and methodology that challenges and seeks to shift current research, practice, or service paradigms by utilizing innovative theoretical concepts, approaches or methodologies, instrumentation, or interventions.
- The extent to which a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions is proposed.
- The extent to which application proposes intervention studies and how the proposed studies will address health outcomes across the life course. Applications that do not propose intervention studies will be deemed non-responsive to this section of the NOFO.
- The extent to which the applicant demonstrates its abilities to implement all activities described in the "Purpose" section for this competition.
- The extent to which the applicant describes a plan to ensure successful collaboration with all key partners identified in the proposal.
- The extent to which the proposed logic model is clear.

#### *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) to what extent the program objectives have been met, and 2) to what extent these can be attributed to the project.

- The extent to which the objectives, including intervention research studies, are time-framed and measurable.
- The extent to which the proposed activities are capable of attaining project goals and objectives.
- The extent to which the plan and methodology for establishing and managing the Network described in the proposal are appropriate, feasible, and of high quality.
- The extent to which the implementation of the proposed intervention studies are clearly articulated.
- The degree to which a familiarity and experience with data gathering procedures as they relate to collaborative multi-site research are described.

- The degree to which the methods include an effective publication and a robust dissemination plan.
- The dissemination plan is robust and includes but is not limited to producing publications per multi-site Network study, disseminating information to scientific and professional audiences, website and webinars.
- The degree to which the methods section includes other dissemination to the research and practice communities, as well as families and communities that will promote the transfer of findings to improve care.
- The degree to which measurable evaluation measures are included for each described objective, with a timeline for evaluation consistent with the plan and schedule of implementation.

# *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 the establishment of a Network and the nature and technical quality of the activities proposed.
- The significance of the project in terms of its potential impact in creating a multisite, collaborative, interdisciplinary research network that will advance and strengthen the evidence base related to selected outcomes for MCH populations across the life course.
- The feasibility and effectiveness of plans for dissemination of project results. The potential impact of project results in advancing and strengthening the evidence base related to selected outcomes for MCH populations across the life course.
- The extent to which there is an effective publication and dissemination plan to facilitate the transfer of Network findings to a broad audience including researchers, health and related professionals, policy makers, educators, and families.
- The extent to which the applicant has a feasible plan for meeting the expectation to produce several peer-reviewed publications with a clearly indication of the number of publications proposed.
- The extent to which there is an effective plan for engaging other funded MCH programs, research networks, and cooperative agreements pertinent to LCI-RN.

#### Criterion 5: RESOURCES/CAPABILITIES (20 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 extent to which project personnel and collaborators are qualified by training and/or experience to implement and carry out the project. This includes evaluation of the capabilities of the applicant organization and collaborators, and the quality and availability of facilities, and personnel to fulfill the needs and requirements of the proposed project.

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

- The extent to which 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 extent to which the PI, staff, and collaborators are well-qualified by training and/or expertise to develop the infrastructure of the Network and to accomplish the activities of the Network as described in this NOFO.
- The extent to which the PI and other key personnel demonstrate current and/or past success in publishing the findings of their research.
- The extent to which the applicant has the existing resources/facilities to achieve project objectives and to successfully support the Network described in the proposal.

# *Criterion 6: SUPPORT REQUESTED (5 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.

- The extent to which costs, as outlined in the budget and required resources sections, are reasonable given the scope of work.
- The extent to which budget line items are well described and justified in the budget justification.
- The extent to which time allocated by key personnel is appropriate to achieve project objectives.

#### Criteria 7: PROGRAM ASSURANCES (5 points) -- Corresponds to Feasibility; Evaluation and Technical Support Capacity; Protection of Human Subjects; Targeted/Planned Enrollment

#### Feasibility

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

#### **Proposed Sequence or Timetable**

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

#### **Resolution of Challenges**

- The extent to which potential barriers to project progress are anticipated and addressed.
- The extent to which the application provides assurance that a research platform can be sustained as proposed.
- The extent to which the application demonstrates the feasibility of reaching targeted/planned enrollment levels within the timeline provided.

#### **Evaluation and Technical Support Capacity**

• The extent to which plans are in place to evaluate whether the project objectives are being met according to the timeline provided.

#### **Protection of Human Subjects**

- The extent to which adequate protections are afforded to human subjects, including children and youth, and the extent to which measures are in place to ensure the security of the research data (data security).
- The extent to which the proposal is in compliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR Part 46). See the instructions in HRSA's SF-424 R&R Application Guide, <u>Appendix B</u>: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan.

• The extent to which the applicant discusses 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 extent to which the proposal provides details regarding the Targeted/Planned Enrollment for their proposed studies, including information on anticipated ethnic, racial and gender categories.
- The extent to which appropriate diversity is planned with regard to the target population.
- The extent to which the project provides assurance regarding cultural competence as appropriate.

#### 2. Review and Selection Process

The objective review provides advice to the individuals responsible for making award decisions. The highest ranked applications receive priority consideration for award within available funding. 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 <u>SF-424 R&R Application Guide</u> for more details.

#### 3. Assessment of Risk and Other Pre-Award Activities

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 (<u>45 CFR § 75.205</u>).

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 the applicant's 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 grants 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, the HRSA 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 <u>Federal Awardee Performance and Integrity</u> <u>Information System (FAPIIS)</u>. 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 <u>FAPIIS</u> 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 <u>45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants</u>.

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

#### 4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing awards prior to the start date of September 1, 2018.

# **VI.** Award Administration Information

#### 1. Award Notices

HRSA will issue the Notice of Award prior to the start date of September 1, 2018. See Section 5.4 of HRSA's <u>SF-424 R&R Application Guide</u> for additional information.

#### 2. Administrative and National Policy Requirements

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

#### **Requirements under Subawards and Contracts under Grants:**

The terms and conditions in the Notice of Award (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 and contractors under grants, unless the NOA specifies an exception. See <u>45 CFR § 75.101 Applicability</u> for more details.

#### Human Subjects Protection:

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

#### **Data Rights:**

All publications the cooperative agreement recipient develops or purchases with funds awarded under this notice must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the cooperative agreement recipient owns the copyright for materials that it develops under this cooperative agreement, 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 cooperative agreement 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 other researchers. The specific scope of HRSA rights with respect to a particular grant-supported effort will be addressed in the Notice of Award (NoA). Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government's copyright license and data rights.

#### 3. Reporting

The new Discretionary Grant Information System (DGIS) reporting system will continue to be available through the Electronic Handbooks (EHBs). HRSA enhanced the DGIS and these improvements are available for recipient reporting as of October 1, 2017. HRSA will communicate with recipients and provide instructions on how to access the system for reporting. HRSA will also provide technical assistance via webinars, written guidance, and one-on-one sessions with an expert, if needed.

The updated and final reporting package incorporating all OMB-accepted changes can be reviewed at:

https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-datacollection\_(OMB Number: 0915-0298 Expiration Date: 06/30/2019).

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

**1) Progress Report(s)**. The recipient must submit a progress report to HRSA on an **annual** basis, which should address progress against program outcomes, including any expected outcomes in the first year of the program. Further information will be available in the award notice.

**2) Final Report Narrative.** The recipient must submit a final report narrative to HRSA after the conclusion of the project.

**3) Performance Reports.** HRSA has modified its reporting requirements for Special Projects of Regional and National Significance projects, Community Integrated Service Systems projects, and other grant/cooperative agreement programs to include national performance measures that were developed in

accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act.

#### a) Performance Measures and Program Data

To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are at <a href="https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UA6\_3.HTML">https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UA6\_3.HTML</a> and below.

Form 1, Project Budget Details

Form 2, Project Funding Profile

Form 4, Project Budget and Expenditures

Form 6, Maternal & Child Health Discretionary Grant

Form 7, Discretionary Grant Project

Form 8, (For Research Projects Only) MCH Discretionary Grant Project Abstract for FY

Products, Publications, and Submissions Data Collection Form

**Updated DGIS Performance Measures, Numbering by Domain** (All Performance Measures are revised from the previous OMB package)

Performance Measure	New/Revised Measure	Prior PM Number (if applicable)	Торіс	
Core				
Core 1	New	N/A	Grant Impact	
Capacity Building				
CB 4	Revised	5	Sustainability	
CB 5	Revised	3, 4	Scientific	
			Publications	
CB 6	New	N/A	Products	

#### b) Performance Reporting Timeline

Successful applicants receiving HRSA funds will be required, within 120 days of the period of performance start date start date, to register in HRSA's Electronic Handbooks (EHBs) and electronically complete the program-specific data forms that are required for this award. This requirement entails the provision of budget breakdowns in the financial forms based on the award amount, the project abstract and other grant/cooperative agreement summary data as well as providing objectives for the performance measures.

Performance reporting is conducted for each year of the period of performance. Recipients will be required, within 120 days of the budget period start date, to enter HRSA's EHBs and complete the program-specific forms. This requirement includes providing expenditure data, finalizing the abstract and grant/cooperative agreement summary data as well as finalizing indicators/scores for the performance measures.

#### c) Period of Performance End Performance Reporting

Successful applicants receiving HRSA funding will be required, within 90 days from the end of the period of performance, to electronically complete the program specific data forms that appear for this program. The requirement includes providing expenditure data for the final year of the period of performance, the project abstract and grant/cooperative agreement summary data as well as final indicators/scores for the performance measures.

**4) Integrity and Performance Reporting.** The Notice of Award will contain a provision for integrity and performance reporting in FAPIIS, as required in <u>45 CFR</u> part <u>75 Appendix XII</u>.

### **VII. Agency Contacts**

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

Ms. Ernsley Charles Grants Management Specialist Division of Grants Management Operations, OFAM Health Resources and Services Administration 5600 Fishers Lane, Mailstop 1N146A Rockville, MD 20857 Telephone: (301) 443-8329 Fax: (301) 443-9320 Email: ECharles@hrsa.gov

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

Jessica DiBari, PhD, MHS and Evva Assing-Murray, PhD, MA Program Officers, Division of Research, Office of Epidemiology and Research Attn: Life Course Intervention Research Network (LCI-RN) Maternal and Child Health Bureau, HRSA Health Resources and Services Administration 5600 Fishers Lane, Room 18N-136A Rockville, MD 20857 Telephone: DiBari: (301) 443-4690; Assing-Murray: (301) 594-4113 Email: <u>JDiBari@hrsa.gov</u>; <u>EAssing-Murray@hrsa.gov</u>

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: <u>support@grants.gov</u> Self-Service Knowledge Base: <u>https://grants-</u> <u>portal.psc.gov/Welcome.aspx?pt=Grants</u>

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks. 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**

#### Logic Models

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

OUTPUTS		OUTCOMES	INADACT		
INPUTS	ACTIVITIES	PRODUCT/SYSTEMS	OUTCOMES	IMPACT	
<u>Partners &amp;</u> <u>resources</u>	Activities to create/improve health/service systems and infrastructure	<u>Health/service systems</u> and infrastructure <u>created to support</u> <u>desirable systems</u> <u>behaviors</u>	<u>Health/service</u> systems behaviors that lead to improved health outcomes	Improved health & wellness outcomes for population/ sub- population	
Eligible Grantee: Public or non- profit institutions of higher learning and public or private non-profit agencies engaged in research or in programs relating	<ul> <li>Create an interdisciplinary research network for Life Course intervention research.</li> <li>Form an interdisciplinary Network Steering</li> </ul>	<ul> <li>Interdisciplinary Network Steering Committee/ Advisory Board.</li> <li>Publication of a national research agenda for Life Course intervention research in</li> </ul>	<ul> <li>The field of Life Course intervention Research is further developed and advanced through knowledge creation and</li> </ul>	<ul> <li>Practitioners in the Network are trained and become skilled in the practice of Life Course intervention research.</li> <li>Practitioners in the Network translate knowledge of Life</li> </ul>	

	01	JTPUTS		
INPUTS	ACTIVITIES	PRODUCT/SYSTEMS	OUTCOMES	IMPACT
Partners & resources to maternal and child health	Activities to create/improve health/service systems and infrastructure Committee / Advisory Board	Health/service systems and infrastructure created to support desirable systems behaviors collaboration with HRSA.	Health/service systems behaviors that lead to improved health outcomes information dissemination.	Improved health & wellness outcomes for population/ sub- population Course theory into research studies and
and/or services for children with special health care needs. <u>Stakeholders:</u> Interdisciplinary network of national experts and research entities Federal staff Women, children, and families	<ul> <li>composed of diverse professionals and family members.</li> <li>Engage family members in Network studies.</li> <li>Conceptualize a national research agenda for Life Course intervention research.</li> <li>Design and implement multi- site intervention research studies that apply Life Course theory and methodologies and addresses the health needs of MCH and other vulnerable populations.</li> <li>Develop and implement a dissemination plan for communicating research findings to diverse stakeholders.</li> <li>Engage key audiences (e.g., researchers, clinicians, Title V populations, families,</li> </ul>	<ul> <li>Completion of multi-site research studies.</li> <li>Several publications in peer- reviewed journals clearly identifying number of publications per multisite study per year, and per grant period.</li> <li>Publication of non-peer-reviewed articles, such as reports, infographics, etc. that reach beyond the scientific community.</li> <li>Resources developed and utilized in clinical practice or intervention-based research in communities.</li> <li>Develop and implement strategies to sustain the Network infrastructure and to expand the scientific knowledge generated from this grant.</li> <li>Website representing the work of the Research Network developed and published.</li> </ul>	<ul> <li>A national framework that provides guidelines for the implementation of Life Course intervention research studies is established and adopted by researchers and practitioners.</li> <li>Various MCH stakeholders actively contribute and are committed to developing and translating Life Course intervention research into practice. Strategies for sustaining the Network outside of HRSA are successful.</li> <li>A Several multi- site research studies aimed at improving and advancing the field of Life Course intervention research is designed and implemented.</li> <li>Increasing pipeline of new Life Course intervention</li> </ul>	programs/practice for diverse MCH populations. Practitioners in the Network develop plans to disseminate the Life Course intervention framework to their practices / organizations. Professional organizations become aware of Life Course intervention research and draft plans to adapt its framework into practice.

	OL	JTPUTS		
INPUTS	ACTIVITIES	PRODUCT/SYSTEMS	OUTCOMES	IMPACT
<u>Partners &amp;</u> <u>resources</u>	<u>Activities to</u> <u>create/improve</u> <u>health/service</u> <u>systems and</u> infrastructure	<u>Health/service systems</u> <u>and infrastructure</u> <u>created to support</u> <u>desirable systems</u> <u>behaviors</u>	<u>Health/service</u> systems behaviors that lead to improved health outcomes	Improved health & wellness outcomes for population/ sub- population
	<ul> <li>policymakers) to advance the translation of Life Course research into practice.</li> <li>Develop and evaluate resources such as guidelines, tools, or toolkits for use in clinical practice or intervention- based research in communities.</li> <li>Develop and implement strategies to sustain the Network infrastructure and to expand the scientific knowledge generated from this grant;</li> <li>Train and mentor Junior/New Investigators in Life Course intervention research.</li> <li>Develop and maintain a public website for engaging multiple stakeholders.</li> </ul>		researchers/ investigators are trained/mentored across the project years.	
Measures of success with timeline	<ul> <li>Established an interdisciplinary Network Steering Committee/ Advisory Board</li> </ul>	<ul> <li>Annual in-person</li> <li>Network Steering</li> <li>Committee / Advisory</li> <li>Board meeting</li> <li>convened</li> </ul>	<ul> <li># of researchers, practitioners, and other stakeholders who adopt the Life Course</li> </ul>	<ul> <li>100% of practitioners in the Network are trained and become skilled in the practice of Life course intervention</li> </ul>

	Ol	JTPUTS			
INPUTS	ACTIVITIES PRODUCT/SYSTEMS		OUTCOMES	IMPACT	
Partners & resources (Within the 5-	Activities to create/improve health/service systems and infrastructure • Developed a	Health/service systems and infrastructure created to support desirable systems behaviors • Track at baseline and	Health/service systems behaviors that lead to improved health outcomes intervention	Improved health & wellness outcomes for population/ sub- population research, which they	
year study period)	national research agenda • Developed a dissemination plan • Developed website • Strategies for sustaining the Network identified • Research study proposals completed	<ul> <li>annually:</li> <li># of manuscripts developed and submitted for publication in peer- reviewed, scientific publications</li> <li># of multi-site research studies developed and implemented during the period of performance</li> <li># of new investigators trained/mentored</li> <li>Dissemination of research findings to scientific and professional audiences:</li> <li># Conference presentations</li> <li># Invited lectures</li> <li># of attendees at presentations/lectures</li> <li># of white/gray papers</li> <li># of times information shared with MCH program audiences (e.g., State Title V, Family Voices)</li> <li>Dissemination to the public/other stakeholders. Examples include but are not limited to:</li> <li># Website hits</li> <li># Media contacts</li> <li># Talks to diverse audiences about projects</li> </ul>	framework in research, policy, and practice # research studies completed Increasing # of manuscripts developed and submitted to peer- reviewed journals after network's study completion # of times published research findings are cited in the peer- reviewed literature after study completion # of studies translated into practice or applied research From baseline, documented increase in number of young/new investigators being trained or mentored through Research Network From baseline, # of completed strategies to sustain the Network increases over time # of publications that contributed to	<ul> <li>will implement in their practices to address the health needs of MCH and other vulnerable populations</li> <li>50% of practitioners in the Network develop plans to disseminate/implement Life Course intervention framework/strategies to their practices/organizations</li> <li>Increased # of professional organizations that become aware of Life Course intervention research and draft plans to adapt its framework into their practice</li> </ul>	

	OUTPUTS			INADACT
INPUTS	ACTIVITIES	PRODUCT/SYSTEMS	OUTCOMES	IMPACT
<u>Partners &amp;</u> <u>resources</u>	<u>Activities to</u> <u>create/improve</u> <u>health/service</u> <u>systems and</u> <u>infrastructure</u>	Health/service systems and infrastructure created to support desirable systems behaviors	Health/service systems behaviors that lead to improved health outcomes	Improved health & wellness outcomes for population/ sub- population
		<ul> <li># Project brochures distributed in person or downloaded from website</li> <li># Newsletter disseminations (number subscribers, number of times per year)</li> <li># of strategies proposed to ensure Network sustainability completed.</li> <li># of family members/ representatives who actively participate on Network Steering Committee or Advisory Board</li> <li># of family members/ representatives who actively participate in the design of Network studies</li> </ul>	clinical guidelines/policies	

\* A research advance is a finding, new method, or a new application of an existing method that pushes the MCH field forward in some way, which are highlighted in peer-reviewed publications. Progress in research may be slow and take several years to come to fruition. By tracking measures of success regularly, we will document incremental steps along this pathway leading to long-term outcomes. It is not possible to quantify or suggest how many advances we expect researchers to produce upfront. However, you can review the literature and document the advance and ultimately the number of advances you have at the end of the program.

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

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: http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf.

### Technical Assistance

HRSA has scheduled the following pre-submission technical assistance webinar:

Day and Date: Thursday, May 3, 2018 Time: 3 p.m. – 4 p.m. ET Call-In Number: 888-790-3364 Participant Passcode: 7415078 Weblink: <u>https://hrsa.connectsolutions.com/ta\_hrsa\_18\_103/</u>

Replay

End date: July 3, 2018, 11:59 p.m. ET Number: 1-888-566-0478 Passcode: 4690

In an attempt to most effectively utilize our TA webinar time, if you have questions about the NOFO, please send them via email to Jessica DiBari at <u>JDiBari@hrsa.gov</u> and Evva Assing-Murray at <u>EAssing-Murray@hrsa.gov</u>. We will compile and address these questions during the TA call.

### **Relevant Websites**

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

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

Human Subjects Assurances <u>http://www.hhs.gov/ohrp</u> <u>http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html</u>

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

National Academy of Medicine <u>https://nam.edu/</u>

Making Websites Accessible: Section 508 of the Rehabilitation Act <a href="http://www.section508.gov/">http://www.section508.gov/</a>

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

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

National Center for Medical Home Implementation <a href="http://www.medicalhomeinfo.org/">http://www.medicalhomeinfo.org/</a>

### Logic Models

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

### Tips for Writing a Strong Application

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

### Appendix A: Maternal and Child Health Bureau (MCHB) Strategic Research Issues

Strategic Research Issue I. Public health service systems and infrastructures at the community, state and/or national levels, as they apply to different maternal and child health (MCH) populations based on demographic,\* epidemiological, and/or other factors.\*\*

(Correlates to HRSA/MCHB Goal: Improve the Health Infrastructure and Systems of Care.)

\* Demographic factors may include age and developmental status, gender, sex, race/ethnicity, geography, socio-economic status, etc. \*\* Other factors may include legislation, policies, etc. that may influence availability and access to specific services.

**IMPORTANT:** To assist the reader in better understanding what is meant by MCHB Strategic Research Issue I, the following are examples of possible areas of study addressing this issue. These are only examples for illustrative purposes and do not constitute preferences for funding consideration. The Bureau strongly encourages research studies that align with MCHB Strategic Research Issues. Bold words indicate key words defined later in subsequent pages of this appendix.

- Effectiveness of Screening Programs for Women: Study the individual, system, and community factors associated with screening and assessment programs that lead to referral and utilization of intervention for risk factors such as substance abuse and other conditions (e.g., obesity, diabetes) that may affect health outcomes for women and/or their children.
- Integrated systems of care specifically identified in Title V legislation for Children with Special Health Care Needs (CSHCN): Determine the impact of Care Coordination Services provided in the medical home and other settings on child and family outcomes for CSHCN.
- Study public-private partnership models for provision of services, such as public health provision of "wrap around" or "enabling" services, and their overall relative efficacy when compared with models comprised of private practice or public clinics only.
- Investigate the processes involved in the **transition of adolescents** with special health care needs to adult health care, particularly the role of state health systems in facilitating or hindering transitions.

- Investigate the effects of the organization and delivery of comprehensive, continuous services on the health status and services utilization of children/adolescents, including those with special health care needs and those vulnerable for poor psychosocial outcomes (e.g., children/youth in foster care, involved with the juvenile justice system, or who are homeless).
- Assess the impact of integration of the newborn screening program (NBS) on other MCH programs and enhanced data sharing at the state level and evaluate if screened children have access to **medical homes**.
- Assess emerging research in the prevention of dental caries in pregnant women and its effects on their children through the use of oral rinse and varnish, chlorhexidine, xylitol, and/or iodine.

Strategic Research Issue II. MCH services and systems of care efforts to eliminate health disparities and barriers to health care access for MCH populations. These health disparities and barriers to health care access may include racial/ethnic, cultural, linguistic, gender, developmental, geographic, immigrant, underserved, economic considerations, etc.

(Correlates to MCHB Goal: Eliminate Health Barriers and Disparities.)

**IMPORTANT:** To assist the reader in better understanding what is meant by MCHB Strategic Research Issue II, the following are examples of possible areas of study addressing this issue. These are only examples for illustrative purposes and do not constitute preferences for funding consideration. The Bureau strongly encourages research studies that align with MCHB Strategic Research Issues.

- Determine the effectiveness, impact, and cost benefits of **cultural and linguistic competence** in public health care and service systems.
- Study the causes for disparities in access to and utilization of early and adequate prenatal care in different regions of the country, differentiating by rural, urban and frontier areas, and the effects of such disparities.
- Investigate the effects of interdisciplinary and collaborative practice of health professions (including but not limited to nursing, oral health, pharmacy, mental health and pediatrics) on reducing barriers to health care access.
- Assess the impact of community-based genetic counseling and education programs in medically underserved communities to evaluate whether increased genetic counseling and education programs will make a difference in access by underserved communities to genetic resources and services.

- Study interventions to reduce racial/ethnic disparities in pre-term/low birth weight and other infant health outcomes.
- Study the contribution of contextual effects on disparities in MCH outcomes.

Strategic Research Issue III. Services and systems to assure quality of care for MCH populations.

(Correlates to MCHB Goal: Assure Quality of Care.)

**IMPORTANT:** To assist the reader in better understanding what is meant by MCHB Strategic Research Issue III, the following are examples of possible areas of study addressing this issue. These are only examples presented here for illustrative purposes and do not constitute preferences for funding consideration. The Bureau strongly encourages research studies that specifically address issues that align with MCHB Strategic Research Issues.

- Explore mechanisms of information transfer of evidence-based MCH strategies that lead to enhanced quality of provider practices and consumer behavior.
- Determine the effectiveness and impact of the current system of care (both public and private) to assure that women and infants receive risk-appropriate perinatal care.
- Study the extent to which children and adolescents needing **emergency medical services** actually receive them and the quality of care received from hospital emergency departments.
- Study the impact of specific characteristics of the medical home, such as the use of written "care plans," on improvements in the quality of care for CSHCN.
- Study how duration, organization and content of visits for clinical preventive services affect the quality of anticipatory guidance/health counseling provided to children, adolescents and women.
- Investigate the factors that promote quality of health care service delivery, with attention to understanding the effectiveness and impact of interdisciplinary training of MCH professionals.
- Investigate factors that decrease fragmentation of MCH service delivery.

Strategic Research Issue IV. Promoting the healthy development of MCH populations.

(Correlates with MCHB Goal: Promote an Environment that Supports Maternal and Child Health.)

**IMPORTANT:** To assist the reader in better understanding what is meant by MCHB Strategic Research Issue IV, the following are examples of possible areas of study addressing this issue. <u>These are only examples presented here for illustrative purposes and do not constitute preferences for funding consideration</u>. The Bureau strongly encourages research studies that incorporate the HRSA clinical priorities, MCHB Strategic Research Issues, and Healthy People 2020.

- Study the effectiveness of health promotion and prevention strategies for infant, child, adolescent and adult populations (e.g., **Bright Futures Guidelines**) that use coordinated strategies and a variety of venues involving the clinical setting, the community and the home environment.
- Conduct **longitudinal studies of health and normative development** in special populations of children such as minority children; children with special health needs; and children of low socioeconomic status, rural, migrant and homeless backgrounds.
- Study the effectiveness of health promotion and prevention strategies to promote healthy weight and prevent **obesity** in children and adolescence.
- Study child, parental (including fathers) and family strengths, i.e., coping and resilience associated with pregnancy, childbearing and parenting; significant injuries; chronic and catastrophic disease conditions; and natural and man-made catastrophic events.
- Study the effects of family/professional partnerships and integrated community systems on the health (including mental and oral health) and development of children.
- Study the factors associated with health care utilization that positively influence health care utilization and preventive health behaviors of women at various stages of and throughout their life span.
- Study the effectiveness of community outreach workers in increasing **breastfeeding** duration rates in underserved populations.

### **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
- D Preconception/Interconception Health & Well-Woman Care
- D 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
- D 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
- D 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 28<sup>th</sup> week of gestation)
- Derinatal (28<sup>th</sup> week of gestation to 4 weeks after birth)
- □ Infancy (1-12 months)
- □ Toddlerhood (13-35 months)
- □ Early Childhood (3-5 years)
- Middle Childhood (6-11 years)
- □ Adolescence (12-18 years)
- Young Adulthood (19-25 years)

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

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

### **Appendix D: Application Completeness Checklist**

Funding Opportunity Number:\_\_\_\_\_

Application Due Date in Grants.gov: \_\_\_\_\_

Are you applying to the correct funding opportunity?       Image: Constraint of the second of the seco	Requirement	Yes	No	Comments
funding opportunity?       Image: Constraint of the eligibility criteria?         Did you read the R&R Application Guide?       HRSA's SF-424 R&R Application Guide?         Do you have a DUNS number?       Dun and Bradstreet number:         Did your Authorized Organization Representative register in SAM and Grants.gov?       This process can take up to 1 month to complete.         Grants.gov?       This process can take up to 1 month to complete.       System for Award Manageme (SAM:) http://www.sam.gov/         In the NEED Section, did you fully address Needs and Alignment?       Attp://www.grants.gov/       Http://www.grants.gov/         In the RESPONSE Section, did you fully address:       Goals and Hypotheses?       Significance of Methodology/Research Strategy?         In the IMPACT Section, did you fully address:       Scientific Innovation and Importance?       Importance?         In the IMPACT Section, did you fully address:       Scientific Innovation and Importance?       Impact and Dissemination?         In the SUPPORT REQUESTED       The directions offered in the SE-424				
Do you meet the eligibility criteria?       HRSA's SF-424 R&R Application         Did you read the R&R Application       Guide:         https://www.hrsa.gov/grants/apply/       application guide/sf424rrguidev2.pdf         Do you have a DUNS number?       Dun and Bradstreet number:         Did your Authorized Organization       This process can take up to 1         Representative register in SAM and       This process can take up to 1         Grants.gov?       Grants.gov:         In the NEED Section, did you fully       Grants.gov:         address Needs and Alignment?       Http://www.grants.gov/         In the RESPONSE Section, did you fully       framework         address:       Goals and Hypotheses?         Significance of       Methodology/Research         Mork Plan Approach?       In the EVALUATIVE MEASURES         Section, did you fully       address:         Scientific Innovation and Importance?       Importance?         Importance?       Importance?         Importance?       Importance?         Importance?       The directions offered in the SF-424				
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				those offered by Grants.gov. Please
				follow the instructions included in the
R&R Application Guide and, <i>if</i>				
Did you follow the budget applicable, the additional budget	Did you follow the budget			
instructions in the <b>NOFO</b> and <b>R&amp;R</b> instructions in the <b>NOFO</b> .				
Application Guide?				
Your institution's indirect cost rate is				Your institution's indirect cost rate is
negotiated by the institution with the				

Requirement	Yes	No	Comments
Do you know your institution's			U.S. Department of Health and Human
indirect cost rate?			Services (HHS). Check with your
			sponsored programs office for further
			information about the indirect cost rate.
In the PROGRAM ASSURANCES			
Section, did you fully address:			
<ul> <li>Feasibility?</li> </ul>			
<ul> <li>Evaluation and Technical</li> </ul>			
Support Capacity?			
<ul> <li>Protection of Human</li> </ul>			
Subjects?			
<ul> <li>Targeted/Planned</li> </ul>			
Enrollment?			
Is your Project Summary/Abstract			
one page in length <u>and</u> single-			
spaced?			
Did you clearly label your			
attachments?			
Are your <b>page borders</b> no more			Bio sketches can have .5" margins.
than 1 inch wide?			
Did you include <b>Bio sketches</b> ?			
Did you use 12-point <b>font</b> ?			Face page Standard OMD enproved
Are your <b>pages</b> , including attachments and bio sketches, within			Face page, Standard OMB-approved
the 80-page limit?			forms, Indirect Cost Rate Agreement, proof of non-profit status (if
			applicable), and budget pages <u>do not</u>
			<u>count</u> toward the 80-page limit.
Is the RESEARCH STRATEGY			
Section within the 12-page limit?			
Is the <b>budget</b> within the funded limit			
per year?			
Did you experience system glitches			Submit exemption request in writing to:
or a qualified emergency and need to			DGPWaivers@hrsa.gov
request an exemption/waiver?			

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

# Where do I find application materials for the Life Course Intervention Research Network Program?

All application materials are available through Grants.gov

### How can I download the complete application package for the Life Course Intervention Research Network NOFO?

You can download the application from Grants.gov.

### What is Grants.gov?

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

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

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

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

• New applications will now fill out detailed budgets for each of the years in the period of performance. For example, grants with 3-year periods of performance will submit detailed budgets for each of the 3 years.

### What types of institutions can apply?

Only domestic public or non-profit institutions of higher learning and public or private non-profit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs are eligible to apply (42 CFR § 51a.3(b)).

### We are a foreign organization interested in applying for the Life Course Intervention Research Network Program. Are foreign entities eligible to apply?

The Life Course Intervention Research Network Program is a domestic grant program and open only to U.S. entities that meet the eligibility criteria as outlined in the NOFO.

### We are interested in applying for the Life Course Intervention Research Network Program. We are wondering if our ideas would be a good fit for the program.

Applications must demonstrate alignment with: one or more MCHB strategic issues; one or more Healthy People 2020 objectives; one or more HRSA Clinical Priorities that are relevant to life-course and the work of the Network; and one or more Title V performance priority areas. The NOFO has appendices that describe the MCHB strategic issues and the Title V performance priority areas. Information on Healthy People 2020 can be found at the <u>HealthyPeople.gov</u> website. You should highlight how your proposal aligns with the HRSA clinical priorities, MCHB Strategic Research issues, Healthy people 2020, and the MCH Title V performance priority areas. All funding decisions are based on scientific merit as determined by an external review committee, and on availability of funds.

# How do we align our project research questions with the national performance priority areas and outcome measures? Do we need to, first, establish our state's performance measures and community needs?

The MCHB Strategic Priorities, Healthy People 2020, and MCH Title V Performance Priority Areas are used as frameworks for demonstrating the extent to which the proposed project clearly describes the unmet health needs of a maternal and child population and the extent to which the proposed project demonstrates alignment with HRSA Goals and Healthy People 2020.

# 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, "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 also contains information on how to negotiate the indirect cost rate.

### 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. Your sponsored programs office will be able to provide further information about the indirect cost rate.

### We are a university that would like to partner with the recipient of the Title V Maternal and Child Health Block Grant, which is our state's department of health. Is the intended recipient of these awards the block grant administrator?

The recipient of the award is typically the PI's institution, which should meet eligibility criteria as given in the NOFO.

### 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:

- The capabilities of the applicant organization, and quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed research project; and
- The extent to which time allocated by key personnel is realistic and appropriate to achieve project objectives.

Given this, you must demonstrate in the proposal how the time devoted by the PI meets these review criteria and how the proposed PI's allocated time would potentially be sufficient for the success of the project.

# Is it possible for postdoctoral fellows to apply as PI if they are affiliated with a university?

The NOFO does not contain language that excludes postdoctoral fellows from serving as PI. Ultimately, the determination of who may or may not serve as PI depends on the rules of the institution.

### Can someone who is currently a PI on another agency grant be a PI of the Life Course Intervention Research Network?

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

### 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.

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

Please include a five page biographical sketch for the PD/PI and any key personnel proposed in the application. Bio sketches should include only pertinent relevant to the proposal including name, position title, education/training beginning with baccalaureate or other initial professional education, with dates, institutions, and locations, brief personal statement, positions and honors, contribution to the field relevant to the proposal, select publications and research funding history.

### The NOFO references "several" when describing some research activities such as studies or peer-reviewed publications. How do we know whether we are meeting the threshold requirement for the NOFO.

HRSA tries not to be overly prescriptive but allows applicants to be innovative. Applicants are expected to propose the number of activities and publications that they can successfully implement.

### Are there page limits for the submitted application?

Yes, the NOFO specifies strict page limitations for the overall submission and for specific sections of the application. You are required to comply with these page limitations, or the application will not be considered for funding.

### What counts towards the page limits?

- The total size of all uploaded files may not exceed the equivalent of 80 pages when printed by HRSA as indicated in the NOFO. The page limit applies to the:
  - o Abstract
  - Project and budget narratives
  - o Attachments
  - Letters of commitment and support required in application guide and the NOFO
  - Biographical sketches

- The page limit does not apply to the following:
  - Standard OMB-approved forms that are included in the application package
  - o Indirect Cost Agreement
  - Proof of Non-Profit Status

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

- The NOFO requires the following page limitations:
  - A 12-page limit for the research strategy section of the narrative.
- The research strategy includes: Significance, Innovation, and Approach.
- Preliminary studies can be included in the Approach section of the Research Strategy if applicable and would be included in the 12-page limit as described above.
- The other parts of the program narrative, which includes Sections A to B and D to G, do not have page limits. However, the entire application is limited to 80 pages total, excluding the SF 424 R&R form pages and proof of nonprofit status. It is important that you consult the NOFO you are responding to for any changes to these guidelines.
- If an application exceeds required page limitations, it will not be considered for funding.

### Does the Specific Aims section have a page limitation?

The Specific Aims section does not have a page limitation. However, this section typically runs three to five pages.

### Are there font/margin requirements?

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

### 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.

# Will there be another Life Course Intervention Research Network Program competition next year?

The Life Course Intervention Research Network Program will re-compete in 2023, subject to the availability of funds.

### Where can I find information on previous awards for the MCH Research Program?

Information on current and past funded research projects can be found on our website. Please feel free to search our funded projects at <u>http://mchb.hrsa.gov/research/.</u>

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

Please contact:

- For programmatic questions, the Project Officer listed in the NOFO via email.
- For budget questions, the Grants Management Specialist listed in the NOFO via email.