U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Maternal and Child Health Bureau
Office of Epidemiology and Research

R40 Maternal and Child Health Field-Initiated Innovative Research Studies (FIRST) Program

Funding Opportunity Number: HRSA-18-071
Funding Opportunity Type(s): New, Resubmission
Catalog of Federal Domestic Assistance (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2018

Application Due Date: January 8, 2018

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!
Deadline extensions are not granted for lack of registration.
Registration in all systems, including SAM.gov and Grants.gov,
may take up to 1 month to complete.

Issuance Date: November 6, 2017

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), Office of Epidemiology and Research is accepting applications for the fiscal year (FY) 2018 R40 Maternal and Child Health (MCH) Field-Initiated Innovative Research Studies (FIRST) Program. The purpose of this grant program is to advance the health and wellbeing of maternal and child health (MCH) populations, including children with special health care needs and the Title V Block Grant populations, through 3-year grants for innovative applied and translational intervention research studies. The program is specifically designed to promote innovation in the field by supporting the exploration of new ideas and the development of new interventions. Research should advance the current body of knowledge, and when implemented in states and communities, should result in health and health services improvements.

Funding Opportunity Title:	R40 Maternal and Child Health Field-Initiated Innovative Research Studies (FIRST) Program
Funding Opportunity Number:	HRSA-18-071
Due Date for Applications:	January 8, 2018
Anticipated Total Annual Available FY18 Funding:	$900,000
Estimated Number and Type of Award(s):	Up to 3 grants
Estimated Award Amount:	Up to $300,000 per year
Cost Sharing/Match Required:	No
Project Period/Period of Performance:	July 1, 2018 through June 30, 2021 (3 years)
Eligible Applicants:	Only 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)). In addition, non-U.S. entities are not eligible to apply. See Section III-1 of this notice of funding opportunity (NOFO), formerly known as the funding opportunity announcement (FOA), for complete eligibility information.

Application Guide

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

Technical Assistance

The following pre-submission technical assistance conference call has been scheduled:

Webinar

Day and Date: Monday, November 20, 2017
Time: 3 p.m. – 4 p.m. ET
Call-in Number: 1-800-369-1901
Participant Passcode: 5287373
Weblink: https://hrsa.connectsolutions.com/ta_hrsa_18_071/

Replay

End date: Monday, November 20, 2018, 11:59pm (ET)
Number: 1-866-430-4721
Passcode: 4113

Table of Contents

I. Program Funding Opportunity Description

1. Purpose

This notice solicits applications for the R40 Maternal and Child Health (MCH) Field-Initiated Innovative Research Studies (FIRST) Program. The purpose of the MCH FIRST Program grant is to advance the health and wellbeing of MCH populations by supporting innovative, applied, and translational intervention[1] research studies on critical issues affecting MCH populations.

The research findings of the R40 MCH FIRST Program should be generalizable to the broader U.S. population, and of regional and national significance.

Findings from the research supported by the R40 MCH FIRST program are expected to:

- Strengthen and expand topics addressed by the MCH Block Grant National Performance Domains. (see Appendix C). For more background materials on the MCH Block Grant, see: http://mchb.hrsa.gov/programs/titlevgrants/index.html. Researchers are encouraged to use the life course perspective as a frame of reference for study proposals;
- Address MCHB Strategic Research Issues (see Appendix A) such as improving public health systems and infrastructure, reducing health inequalities, increasing quality of and access to care, and/or promoting the health of MCH populations;
- Address the U.S. Department of Health and Human Services' (HHS) clinical priorities, namely, mental health, childhood obesity, and opioid abuse. Proposals must indicate how study findings will further develop the evidence base for the above clinical priority topics; and
- Address emerging research topics of regional and national significance that highlight new data, knowledge, evidence, and strategies for addressing the burden of diseases.

HRSA expects each R40 MCH FIRST award recipient to complete the following major activities:

- Conduct innovative applied or translational intervention research using rigorous scientific methodology;
- Recruit, track, and report study participants from diverse backgrounds to include diversity with regards to ethnicity, race, gender/sex, geographic location, and socioeconomic status;
- Develop and submit a dissemination plan for the distribution of research findings and products to scientific, professional, and lay audiences. Dissemination activities include, but are not limited to, manuscripts, conference presentations, newsletter articles, webcasts, fact sheets, infographics, policy briefs, websites, and social media posts, as appropriate;

[1] For the purpose of this NOFO, an "intervention" is defined to include behavioral, social, or structural / health systems approaches, as well as combination applied clinico-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.

- Submit and publish scientific findings through the development and publication of at least three peer-reviewed manuscripts; and
- Continue to further the science by leveraging additional funding from other sources.

2. Background

The R40 MCH Field-initiated Research Program (FIRST) program is authorized by Title V, § 501(a)(2) of the Social Security Act (42 U.S.C. § 701(a)(2)), as amended, and is a component of the Special Projects of Regional and National Significance.

Built on over 60 years of experience, the MCH FIRST program is administered by the MCH Research Program, in MCHB's Office of Epidemiology and Research. The MCH Research Program has supported groundbreaking investigations that have significantly influenced clinical practice, organization and delivery of health care services, preventive care, and early intervention for the MCH population, including children with special health care needs.

The MCH FIRST program supports intervention research that is specifically focused on improving the quality, efficiency, and accessibility of health care service delivery as related to health promotion and disease prevention among Title V Block Grant MCH populations through innovative intervention research. For example, a prior MCH FIRST study demonstrated that dieting and unhealthful weight-control behaviors predict outcomes related to obesity and eating disorders 5 years later.[2] The study called for a shift away from dieting and drastic weight-control measures toward the long-term implementation of healthful eating and physical activity behaviors that is needed to prevent obesity and eating disorders in adolescents.[2]

More information about the MCH FIRST Program, funded projects, and current activities can be found at https://www.mchb.hrsa.gov/research.

[2] Neumark-Sztainer, D, Wall, M, Guo, J, et al. Obesity, Disordered Eating, and Eating Disorders in a Longitudinal Study of Adolescents: How Do Dieters Fare 5 Years Later? Journal of Academy of Nutrition and Dietetics. 2006; 160(4): 559-568.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New, Resubmission[3]

HRSA will provide funding in the form of a grant.

2. Summary of Funding

Approximately $900,000 is expected to be available annually to fund three (3) recipients. You may apply for a ceiling amount of up to $300,000 total cost (including both direct and indirect, facilities, and administrative costs) per year. The actual amount available will not be determined until enactment of the final FY 2018 appropriation. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, applications can be processed, and funds awarded in a timely manner. The project period is July 1, 2018 through June 30, 2021 (3 years). Funding beyond the first year is dependent on the availability of appropriated funds for R40 MCH FIRST 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 45 CFR part 75.

III. Eligibility Information

1. Eligible Applicants

Only 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)). Faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply, if they otherwise meet these eligibility criteria. Non-U.S. entities are not eligible to apply.

Applicants are required to submit proof of non-profit status.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

[3] A resubmission is a subsequent application from the same investigator for a revised proposal following an earlier, unsuccessful application and review.

3. Other

Applications that exceed the $300,000 ceiling amount will be considered non-responsive and will not be considered for funding under this notice. This ceiling includes both direct and indirect expenses.

Any application that fails to satisfy the deadline requirements referenced in *Section IV.4* will be considered non-responsive and will not be considered for funding under this notice.

NOTE: Multiple applications from an organization **are** allowable. Multiple applications from an organization with the same DUNS number are allowable if the applications propose separate and distinct intervention projects. For example, different investigators (or research teams) from the same institution can apply for the same NOFO.

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.

Please make sure you submit your application to the correct NOFO number: HRSA-18-071, the R40 MCH FIRST Program competition. Applications submitted to the wrong competition will be deemed nonresponsive and will not be considered for funding under this notice

Due to funding limitations and in order to diversify the HRSA R40 portfolio, the following are additional application responsiveness criteria. All applications that do not comply with these criteria will be deemed nonresponsive and will not be considered for funding under this notice.

- An individual cannot be named as the Project Director (PD) or Principal Investigator (PI) for multiple applications for the R40 MCH FIRST or another R40 competition. For example, an individual cannot be named as PI on an R40 MCH FIRST and R40 MCH Secondary Data Analysis Research (SDAR) Program application simultaneously (i.e., an individual can only be named PI once for one NOFO or grant).
- Applications that overlap in project period with a currently funded R40 MCH Research project by the same PI will not be considered for funding (i.e., a PI cannot have two (2) R40 MCH FIRST awards in effect simultaneously). A 1-year no-cost extension of a current MCH Research project counts as part of the total project period during which an overlap in project period with a newly awarded application is not allowable;
- A current PI of an MCH FIRST award can serve for no more than 10 percent time on a new proposal;
- Longitudinal follow-up studies will not be considered for funding under this notice until 3 years have elapsed. That is, a recipient who currently has or in the past has had an R40 award cannot apply for an award to follow longitudinally the population used in their previous R40 award for a period of 3 years. Not excluded

are: applications that include a longitudinal design within the proposed 3-year project period; and applications that involve collecting follow-up data on a population targeted in an award funded by another agency as part of this competition;
- Projects that focus primarily on secondary data analysis will not be considered for funding under this award as there is a separate competition, the R40 MCH SDAR competition;
- Projects addressing autism spectrum disorder will not be considered for this award competition (a separate competition for Autism Field-Initiated Innovative Research Studies Program may be held, if funds are available); and
- Projects which include the collection of biological specimens will not be considered for the award competition as this program funds translational intervention research on underserved MCH populations.

IV. Application and Submission Information

1. Address to Request Application Package

HRSA ***requires*** you to apply electronically through Grants.gov. You must use the SF-424 Research and Related (R&R) application package associated with this NOFO following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

Effective December 31, 2017 - You **must** use the Grants.gov Workspace to complete the workspace forms and submit your application workspace package. After this date, you will no longer be able to use PDF Application Packages.

HRSA recommends that you supply an email address to Grants.gov on the grant opportunity synopsis page when accessing the notice of funding opportunity (NOFO) [also known as "Instructions" on Grants.gov] or application package. This allows Grants.gov to email organizations that supply an email address in the event the NOFO is changed and/or republished 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 Find Grant Opportunities page for all information relevant to desired opportunities.*

2. Content and Form of Application Submission

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

See Section 8.5 of the *SF-424 R&R Application Guide* for the Application Completeness Checklist.

Application Page Limit
The total size of all uploaded files may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments including biographical sketches (bio sketches), and letters of commitment and support required in HRSA's *SF-424 R&R Application Guide* and this NOFO. Standard OMB-approved forms that are included in the application package do not count in the page limitation. Biographical sketches **do** count in the page limitation. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) will not be counted 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 Appendix E for more information on what does and does not apply to the 80-page limit.

In addition to the overall 80-page limit, please 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 Appendix D).

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification
1) 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.
2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
3) Where the prospective recipient is unable to attest to the statements in this certification, an explanation shall be included in Attachment 6: Other Relevant Documents.

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

Temporary Reassignment of State and Local Personnel during a Public Health Emergency
Section 201 of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), Public Law 113-5 amends section 319 of the Public Health Service (PHS) Act to provide the Secretary of the Department of Health and Human Services

(HHS) with discretion to authorize the temporary reassignment of state, tribal, and local personnel during a declared federal public health emergency upon request by a state or tribal organization. The temporary reassignment provision is applicable to state, tribal, and local public health department or agency personnel whose positions are funded, in full or part, under PHS programs and allows such personnel to immediately respond to the public health emergency in the affected jurisdiction. Funds provided under the award may be used to support personnel who are temporarily reassigned in accordance with section 319(e). This authority terminates September 30, 2018. Please reference detailed information available on the Assistant Secretary for Preparedness and Response (ASPR) website via http://www.phe.gov/Preparedness/legal/pahpa/section201/Pages/default.aspx.

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

i. *Project Abstract*
See Section 4.1.ix of HRSA's *SF-424 R&R Application Guide*. In addition, clearly indicate the NOFO number/title. Briefly state the principal needs and problems addressed by the project, including the project's relationship to MCHB Strategic Research Issues (Appendix A). Also briefly describe the research design and methods within the abstract and include data collection methods and participant information (i.e., age range and demographic background of target population). A complete and informative abstract is critical to the review of your application.

From Appendix B, select: (a) a maximum of 10 significant content terms that describe your project, and as many (b) targeted populations and (c) age ranges as apply. Include the selected key terms for (a) content, (b) populations, and (c) age ranges targeted 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:

- ***A. INTRODUCTION (for resubmission only)***
  NOTE: FOR RESUBMISSIONS, MARK THE APPLICATION AS "RESUBMISSION" FOR ITEM #8 "TYPE OF APPLICATION" ON THE FIRST PAGE OF THE SF-424 R&R.

  For a resubmission of a previously reviewed proposal, begin the Introduction by specifying that it is a resubmission; state the application/tracking number of the prior submission, its title, and HRSA notice number of the prior submission. **Example: This is a resubmission of application #, 'Determinants of Racial Disparities in**

Infant Mortality Rates,' that was submitted for HRSA-15-062. There is no limit to the amount of time lapsed from the initial submission of an application to resubmission. The following criteria pertain to a resubmission:

- The PD/PI must make significant changes to the application;
- An Introduction must be included that summarizes the substantial additions, deletions, and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Summary Statement. The Introduction **should not exceed three pages; and**
- The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or changing the typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. The Preliminary Studies/Progress Report section should incorporate work completed since the prior version of the application was submitted.

B. SPECIFIC AIMS -- Corresponds to Section V's Review Criteria 1 Need and 2 Response

1) **Needs and Alignment** -- Corresponds to Section V's Review Criterion 1 Need

- This section outlines the unmet needs of the targeted population that the current project will address, and should help reviewers understand how the targeted population will benefit from the proposed project.
- Briefly describe the target population(s) (including age ranges and other demographic information) and unmet health needs.
- As appropriate, include sociocultural determinants of health and health disparities impacting the population that the current project will address.

Alignment with HRSA/MCHB Goals, HHS Priorities, and Healthy People 2020

- Identify relevance to MCHB Strategic Research Issues (Appendix A). You are responsible for explaining the project's relevance to an MCHB Strategic Research Issue.
- Discuss how the research findings will strengthen and expand the MCH Block Grant National Performance Domains (Appendix C) and the populations they serve.
- Discuss how the research findings will address strengthen and expand topics identified among the HHS clinical priorities such as mental health, childhood obesity, and opioid abuse.
- Identify the relationship to specific Healthy People 2020 objectives.

2) ***Goals and Hypotheses*** *-- Corresponds to Section V's Review Criterion 2 Response*

Goals and Objectives

- State clearly and succinctly the specific objectives of the particular research proposed, for example, create a novel intervention, test a novel intervention at scale, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, and/or develop and test a new health technological intervention.
- Clearly and concisely summarize the expected outcome(s) and how these will address the unmet needs of the targeted population.

Hypotheses and Specification of Variables

- Clearly and succinctly, present the specific questions that the intervention study will answer. These should include not only predictions as to findings (hypotheses) but also justifications for the predictions.
- Present a summary table of the variables, classified as independent, intervening, mediating, moderating, and dependent, etc., specifying the nature of the variables, the measures to be employed as indicators for these variables, and the units and levels of measurement of the indicators.
- If possible, construct and present a graphical analytical model or graphical representation of the set of relationships held to be operative among the variables for the intervention study.
- Ensure congruence among the associations depicted by the graphic model (if included), the table of variables, the statement of hypotheses, and the plan for data analysis.

C. METHODOLOGY -- Corresponds to Section V's Review Criteria 2 Response, 3 Evaluative Measures, and 4 Impact

- Organize the Methodology/Research Strategy section in the specified order using the instructions provided below. Start each section with the appropriate section heading – Significance, Work Plan/Approach, Scientific Innovation and Importance. Cite published experimental details in the Methodology/Research Strategy section and provide the full reference in the Bibliography and References Cited section.
- The **Methodology/Research Strategy section (Significance, Work Plan/Approach, Scientific Innovation and Importance) is limited to 12 pages in length.** Applications that exceed this page limit in the Methodology/Research Strategy section will be deemed nonresponsive, and will not be considered for funding under this notice.

1) Significance -- Corresponds to Section V's Review Criterion 2 Response

- Describe the background literature, with focus on its pertinence to and rationale for the current research problem.
- Explain the critical problem or barrier to progress in the field that the proposed intervention project addresses.
- Indicate the relevance of the problem to MCH or children with special health care needs programs and identify the envisioned application of findings to the clinical management of mothers and children and/or the ways that

maternal and child health services are organized and delivered.

2) Work Plan/Approach -- Corresponds to Section V's Review Criterion 3 Evaluative Measures

- Describe the overall study design, strategy, methodology, and analyses you will use to accomplish the specific aims of the project.
- Describe the procedures for data collection and instrumentation as appropriate.
- Describe the study population. Include demographic information on the participant population (i.e., targeted ages, expected racial/ethnic background and socioeconomic status, rural/urban, etc.).
- Identify at least one HHS clinical priority topic and a MCH Block Grant National Performance Domain as its key independent variable(s) or as main outcome variable(s).
- Describe eligibility inclusion/exclusion criteria.
- Address issues regarding sampling design and randomization as appropriate.
- Include expected enrollment number and power analyses as appropriate.
- Include a description of strategies for participant recruitment.
- Include how you will collect, analyze, and interpret the data, as well as any resource sharing plans, as appropriate.
- Letters of Agreement from study sites supporting recruitment must be included in Attachment 1, if applicable.

Preliminary Studies: Include information on preliminary studies as part of the Section (2) Work Plan/Approach section. Use this section to provide an account of the PD/PI's preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the population subgroups of interest This information will also help to establish the experience and competence of the investigator to pursue the proposed project. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.

3) Scientific Innovation and Importance -- Corresponds to Section V's Review Criterion 4 Impact

- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe the impact that the results of the proposed research will exert on the research field(s) involved.

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, policies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, policies, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, policies, or interventions.
- Describe how the concepts, methods, technologies, treatments, services, policies, or preventive interventions that drive this field will be changed if the proposed aims are achieved.

D. IMPACT AND DISSEMINATION -- Corresponds to Section V's Review Criterion 4 Impact

Public Health Impact

- Describe the public health impact that study results are likely to have.
- Describe the impact that the expected outcomes are likely to have on care delivery strategies involved and/or the health and well-being of targeted MCH populations and/or strengthening and expanding the evidence base for the HHS clinical priorities.
- Describe the extent to which study results will be generalizable and replicable.
- Describe the extent to which study results will be of regional and national significance.

Publication and Dissemination Plan

- Describe plans for dissemination of project results.
- Include information on how you will accomplish delivering the required minimum of three peer-reviewed publications resulting from the MCH research award.
- Past MCH FIRST Program recipients should list publications from their previous MCH research award.
- In addition to peer-reviewed publications, you must demonstrate a plan to advance the transfer of findings into practice by disseminating findings, reports, and/or project outputs to key target audiences, including researchers, providers, State Title V and other program(s) serving MCH populations, policymakers, families and the general public. Awardees will have implemented their plan to advance the transfer of findings into practice by the end of the project period. In terms of communication channels, awardees may distribute research findings and information on project activities and findings through targeted email messages, newsletter articles, conference presentations, webcasts, fact sheets, infographics, policy briefs,

and website and social media posts, as appropriate.

E. RESOURCES/CAPABILITIES -- Corresponds to Section V's Review Criterion 5 Resources/Capabilities

This information is used to assess the capability of the organizational and personnel resources available to perform the effort proposed. NOTE: The SF-424 R&R Table of Contents Page refers to Environment as "Facilities & Other Resources." This section on "Environment" can be included as an attachment in the Other Project Information Form, box 10, or included as part of the research narrative.

Organizational Facilities and Other Resources

- Identify the facilities you will use (laboratory, clinical setting, computer lab, office, and/or other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work.
- Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed study will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.
- For Early Stage Investigators, describe institutional investment in the success of the investigator; examples of such investment include provision of resources such as laboratory space sufficient to project needs, collegial support such as the availability of organized peer groups, logistical support such as administrative management and oversight, and financial support such as protected time for research with salary support.
- If there are multiple performance sites, describe the resources available at each site.

Qualifications of Research Team's Key Personnel

The qualifications of the research team's key personnel are assessed as part of Section V's Review Criterion 5 Resources/Capabilities. To assess the qualifications of the research team's key personnel, the following items are used: (a) Preliminary Studies in Section C. Methodology/Research Strategy Work Plan/Approach; (b) Staffing Plan in Budget Narrative; and (c) Biographical Sketches of key personnel.

Biographical sketches should follow the format described below. When applicable, biographical sketches should include training, language fluency and experience working with the culturally and linguistically diverse populations served by their programs.

NOTE: The Biographical Sketch may not exceed five pages for each person. Follow the formats and instructions below.

Professional Information: At the top of page 1, include Name, Position Title, Education/Training including: institution and location, degree, month/year degree attained, field of study. Then complete the sections as described below:

- **Personal Statement**
  Briefly describe why you are well-suited for your role(s) in the project described in this application. The relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

- **Positions and Honors**
  List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

- **Contribution to Science**
  Briefly describe up to five of your most significant contributions to science. For each contribution, indicate: the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one-half page including figures and citations.

- **Research Support**
  List both selected ongoing and completed research projects for the past 3 years (federal or non-federally supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

Do not confuse "Research Support" with "Other Support." Although they sound similar, these parts of the application are very different. As part of the biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, "Other Support" information is required for all applications that are selected to receive grant awards. HRSA staff will request complete and up-to-date "other support" information from you after peer review. This information will be used to check that the proposed research has not already been federally funded.

***F. FEASIBILITY -- Corresponds to Section V's Review Criterion* 7 Program Assurances**

This section addresses questions around project feasibility. Provide assurance that the research team will conduct the study as designed. Once funded, it is critical that the awardee implements and completes the study as proposed and approved.

Proposed Sequence or Timetable

- Provide a sequence or timetable for the project that includes the steps that will be taken to achieve each of the activities proposed during the entire project period. Use a timeline that includes each activity and identifies responsible staff.

- **Resolution of Challenges -- *Corresponds to Section V's Review Criterion 7 Program Assurances***
  - Discuss any challenges that you might likely encounter in designing and implementing the research activities described in the Work Plan/Approach, and approaches that will be used to resolve such challenges. Examples include recruitment of study sites and study participants, staff training and standardization of research protocols across multiple sites, putting culturally/linguistically competent project staff in place quickly, recruiting participants from specific populations, etc.
  - Discuss alternative strategies should any of these potential challenges arise.
  - Discuss the feasibility of reaching targeted/planned enrollment levels.
  - Describe any strategy to establish the feasibility, and to address the management of any high-risk aspects of the proposed work.
  - If appropriate, point to any procedures, situations, or materials that may be hazardous to personnel, and precautions you would exercise.

G. EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criterion 7 Program Assurances

- Describe a plan for performance evaluation (evaluating project progress towards its specific aims) that will contribute to continuous quality improvement of project efforts. The project performance evaluation should reflect the Specific Aims described in Section B above, as well as the specific timeline goals set in the Proposed Sequence or Timetable under Section F Feasibility above (e.g., all staff identified and trained by month 4, data collection begun by month 6, etc.). The purpose is to monitor ongoing processes and the progress towards the aims and objectives of the project.

H. PROTECTION OF HUMAN SUBJECTS – Corresponds to Section V's Review Criterion 7 Program Assurances

- If human subjects are involved, the project should be in compliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR Part 46) (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). Please refer to instructions provided in HRSA's SF-424 R&R Application Guide, Appendix: Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy for specific instructions on preparing the human subjects section of the application.
- This section is required if you answer "yes" to the question "Are human subjects involved?" on the R&R Other Project Information form. If the answer is "No" to the question but the proposed research involves data from human subjects, you must provide a justification in this section for the claim that no human subjects are involved.
- Discuss plans to seek Institutional Review Board (IRB) approval or exemption. IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent the page limit of the Methodology/Research Strategy section.

I. TARGETED/PLANNED ENROLLMENT – Corresponds to Section V's Review Criterion 7 Program Assurances

- Provide details about the Targeted/Planned Enrollment for the study. Information should include targeted/planned enrollment totals by:
    - Ethnic Category (Hispanic Heritage): "Hispanic or Latino" or "Not Hispanic or Latino"
        - Gender distribution within each Ethnic Category (Hispanic Heritage)
        - Total planned enrollment by Ethnic Category (Hispanic Heritage)

- Racial Categories
  - American Indian/Alaska Native
  - Asian
  - Native Hawaiian or Other Pacific Islander
  - Black or African American
  - White
  - More than One Race
  - Gender distribution within each racial category
  - Total planned enrollment by racial category
- Geographic Location
  - Urban
  - Rural
- Socio-economic Status

- The “Ethnic Category (Hispanic Heritage): Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.” Also, list any proposed racial/ethnic subpopulations, if applicable.
- The “Total Planned Enrollment” means the number of subjects that you expect to enroll during the entire period of the study and are needed to evaluate the research question. The “Total Planned Enrollment” will be reported in two ways in the table: by self-reported “Ethnic Category (Hispanic Heritage)”, and by self-reported “Racial Categories.”
- Describe how the project will assure cultural competence. Describe how the analytic plan will reflect an understanding and valuing of the culture of the study population.

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	Points
A. Introduction (Previous application information)	Not Applicable--For Resubmissions only	N/A
B. Specific Aims: 1) Needs and Alignment	(1) Need	10
B. Specific Aims: 2) Goals and Hypotheses	(2) Response	20
C. Methodology/Research Strategy: 1) Significance	(2) Response	
C. Methodology/Research Strategy: 2) Work Plan/Approach	(3) Evaluative Measures	20
C. Methodology/Research Strategy: 3) Scientific Innovation and Importance	(4) Impact	20
D. Impact and Dissemination	(4) Impact	
E. Resources and Capabilities:	(5) Resources/Capabilities	10
Budget and Budget Justification (below)	(6) Support Requested	10
F. Feasibility	(7) Program Assurances	10
G. Evaluation and Technical Support Capacity	(7) Program Assurances	
H. Protection of Human Subjects	(7) Program Assurances	
I. Targeted/Planned Enrollment	(7) Program Assurances	
Total Points		**100**

iii. Budget
See Section 4.1.iv of HRSA's *SF-424 R&R Application Guide*. Please note: the directions offered in the *SF-424 R&R Application Guide* may differ from those offered by Grants.gov. Please follow the instructions included in the *R&R Application Guide* and the additional budget instructions provided below. A budget that follows the *R&R Application Guide* will ensure that, if the application is selected for funding, you will have a well-organized plan and by carefully following the approved plan can avoid audit issues during the implementation phase.

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

The Consolidated Appropriations Act, 2017 (P.L. 115-31), 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." Please see Section 4.1.iv Budget – Salary Limitation of HRSA's *SF-424 R&R Application Guide* for additional information. Note that these or other salary limitations may apply in FY 2018, as required by law.

iv. Budget Justification Narrative

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

In addition, the R40 MCH FIRST program requires the following:

Within Personnel Costs, include the staffing plan by providing position descriptions (roles, responsibilities, and qualifications of proposed project staff) in the "Budget Justification" section that you will add to SF-424 R&R Budget Period – Section F – K Form, Box K. This staffing plan should describe the complementary and integrated expertise of the investigators and show that the leadership approach, governance and organizational structure are appropriate for the project. The staffing plan should reflect the commitment of the research team in conducting and completing the study. (NOTE: A current PI of an MCH Research grant can serve for no more than 10 percent time on a new proposal in a capacity other than as PD/PI.) Copies of biographical sketches for all senior/key personnel and other significant contributors must also be submitted as an attached file to each SF-424 R&R Senior/Key Person Profile.

v. Program-Specific Forms

Program-specific forms are not required for application.

vi. Attachments

Please 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. **Each attachment must be clearly labeled**.

Attachment 1: 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, including letters of agreement for use of datasets and/or administrative records for secondary analysis. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the subcontractors and any deliverables. Include only letters of support that specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.). Letters of agreement and letters of support must be dated.

Attachment 2: Key Publications or Condensed Citations with Abstracts.

A list of citations for key publications by the key personnel that are relevant to the proposal can be included. **Do not include 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 3: Surveys, Questionnaires, Data Collection Instruments, Clinical Protocols.

Surveys, questionnaires, other data collection instruments, clinical protocols and informed consent documents may be submitted as an attachment as necessary, keeping in mind that these count in the 80-page limitation.

Attachment 4: Explanation on Delinquent Federal Debt, if applicable.

Attachment 5: Proof of Non-profit Status. (Note: the non-profit status determination letter is not included in the page limit).

Attachments 6-15: Other Relevant Documents

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management

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

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

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

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

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

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

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 *January 8, 2018 at 11:59 p.m. Eastern Time.*

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

5. Intergovernmental Review

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

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

6. Funding Restrictions

Funds under this notice (HRSA-18-071) may not be used for travel outside of the U.S.

Applicants may request funding for a project period of 1 year, at no more than $300,000 total cost (direct plus indirect expenses).

The General Provisions in Division H of the Consolidated Appropriations Act, 2017 (P.L. 115-31) apply to this program. Please see Section 4.1 of HRSA's *SF-424 R&R Application Guide* for additional information. Note that these or other restrictions will apply in FY 2018, 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 addition. Post-award requirements for program income can be found at 45 CFR § 75.307.

V. Application Review Information

1. Review Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist you in understanding the standards against which your application will be judged. Critical indicators have been developed 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. Review criteria are 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 R40 MCH FIRST Program has seven (7) 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	10 points
Criterion 6.	Support Requested	10 points
Criterion 7.	Program Assurances	10 points
TOTAL:		100 points

Criterion 1: NEED (10 points) -- Corresponds to Program Narrative Section B Specific Aims: 1) Needs and Alignment

B. Specific Aims: 1) Needs and Alignment

Needs Assessment

- The extent to which the proposed project clearly describes the unmet health needs of the targeted population and, if appropriate, the sociocultural determinants of health and health disparities impacting the targeted population.
- The extent to which the target population characteristics (including age ranges of children/youth) are clearly stated in the abstract and described in the application.

Alignment with HRSA/MCHB Goals, HHS Clinical Priorities, and Healthy People 2020

- The extent to which findings from the research supported by the MCH Research Program are likely to strengthen and expand topics addressed by the MCH Block Grant National Performance Domains, and the populations they serve (Appendix C).
- The extent to which findings from the research supported by the MCH Research Program are likely to strengthen and expand topics identified among the HHS clinical priorities and that are aligned with the MCH Block Grant National Performance Domains, and the populations they serve (Appendix C).
- The extent to which the research project identifies its relationship to specific Healthy People 2020 objectives. (See HRSA's *SF-424 R&R Application Guide*, *Section 2.2: Administrative and National Policy Requirements).*

Criterion 2: RESPONSE (20 points) -- Corresponds to Program Narrative Sections B. Specific Aims: 2) Goals and Hypotheses; and C. Methodology/Research Strategy: 1) Significance

B. Specific Aims: 2) Goals and Hypotheses

Goals and Objectives (5 points)

- The extent to which the application clearly and succinctly lists the project's goals and specific objectives.
- The extent to which the goals and objectives are clear, concise and appropriate.
- The extent to which the application clearly and succinctly summarizes expected outcomes, with attention to how these outcomes will address the unmet needs of the targeted population.

Hypotheses and Specification of Variables (5 points)

- The extent to which the proposal clearly and succinctly presents the specific questions the study will answer, including not only hypotheses, but also justifications for the hypotheses.
- The extent to which the application clearly states hypotheses and clearly defines variables.
- The extent to which the application clearly states and links to need the logic of the study.
- The extent to which the overall scientific approach presents clear and logically derived hypotheses and goals.
- The extent to which the application presents a thoughtful and logical overall scientific approach.
- The extent to which there is congruence among the associations depicted by the graphic analytical model (if included), the table of variables, the statement of hypotheses, and the plan for data analysis.

C. Methodology/Research Strategy: 1) Significance

Background Literature and Statement of Problem (5 points)

- The extent to which the investigators demonstrate awareness of previous and current work in the area of the project.
- The extent to which the application cites literature pertinent to the research problem and provides a rationale for the research.
- The extent to which the application presents logically-derived from the literature hypotheses that clearly states and relates to the defined problem.

Relevance (5 points)

- The extent to which the project addresses a critical problem or barrier to progress in the field.
- The extent to which the proposed project describes a significant issue relevant to the health of maternal and child populations to include HHS clinical priorities.

Criterion 3: EVALUATIVE MEASURES (20 points) -- Corresponds to Program Narrative Section C. Methodology/Research Strategy: 2) Work Plan/Approach

C. Methodology/Research Strategy: 2) Work Plan/Approach

Study Design (5 points)

- The appropriateness of the research plan and methodologies described.
- The extent to which the overall strategy, methodology, and analyses are well-reasoned and appropriate to accomplish the specific aims of the project.
- The appropriateness of the study design to answer the research questions.
- The degree to which the application includes proper controls
- The extent to which the description of the design is explicit enough to permit replication.
- The extent to which all significant threats to internal and external validity of the design have been adequately acknowledged and addressed.
- The extent to which the application clearly describes the method of randomization, if used.
- The degree to which the project activities are replicable and generalizable.
- As appropriate, the extent to which the project assures cultural competence in the planning and implementation of the research project.
- The extent to which the application clearly states the proposed database(s) i in the abstract and described in the application, including rationale for using that/those particular database(s) to answer the proposed research questions.

Data Collection (5 points)

- If new data are to be collected, the extent to which instruments have been selected or developed and are adequate and appropriate.
- The extent to which adequate attention is given to reliability and validity (psychometric properties).
- The extent to which any self-reported data can provide convincing validity for intended measurements, e.g., self-reported blood pressure, parent-reported anthropometric data.

Population Description, Sampling, and Recruitment (5 points)

- The degree to which the application describes the study population (i.e., targeted age or age ranges, expected racial/ethnic background and socioeconomic status, urban/rural, etc.).
- The degree to which the sampling design is appropriate.
- The degree to which the sample size is adequate and justified in terms of statistical power.
- The extent to which expected differences between groups are defined in terms of statistical as well as clinical significance.
- The extent to which there is a basis for anticipating the quality of sample estimates and the degree to which the quality is adequate for the purpose of the study.
- The extent to which the proposed inclusion of members of selected study populations are justified in terms of the scientific goals and research strategy proposed.
- The extent to which the eligibility criteria for entering the study are well defined.
- The extent to which the recruitment plan is clearly described.
- The extent to which letters of agreement from study sites supporting recruitment are in place.
- The extent to which the project is feasible in terms of participant recruitment.
- The extent to which the targeted enrollment is feasible to complete within the project period, given recruitment methods.

Plan for Data Analysis (5 points)

- The degree to which plans for data analysis are presented in detail.
- The extent to which the plans describe the process of data analysis and the rationale for the sequence of steps to be taken.
- The appropriateness of the plans to the nature of the data, design and samples.
- The appropriateness of the statistical methods.
- The extent to which sufficient time is allocated for data analysis and reporting.

CRITERION 4: IMPACT (20 points) -- Corresponds to Program Narrative Sections C. Methodology/Research Strategy: 3) Scientific Innovation and Importance; and D. Impact and Dissemination

C. Methodology/Research Strategy: 3) Scientific Innovation and Importance

(8 points)

- The extent to which the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields relevant to MCH populations.
- The extent to which scientific knowledge, technical capability, and/or clinical practice will be improved, if the aims of the project are achieved.
- The extent to which successful completion of the aims will change the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field.
- The extent to which the application challenges and seeks to shift current research or clinical practice paradigms by utilizing innovative theoretical concepts, approaches or methodologies, instrumentation, or interventions.
- The extent to which the concepts, approaches or methodologies, instrumentation, or interventions are novel to one field of research or novel in a broad sense.
- 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 the overall scientific approach proposes an innovative solution, intervention or strategy.
- The extent to which project results are likely to exert a sustained influence on the research field(s) involved.

D. Impact and Dissemination

Public Health Impact (6 points)

- The extent to which the expected outcomes are likely to have an impact on health care delivery strategies involved.
- The extent to which the expected outcomes are likely to help improve the health and well-being of targeted MCH populations.
- The extent to which the problem addressed by the proposed research is unique to a community or region or is one of national proportion.
- The extent to which the findings will be generalizable and of regional and national significance.
- The extent to which the proposed study specifically addresses challenges with expected broad public health impact.

- The extent to which the number of mothers or children affected by the problem or who will benefit from the research is significant.
- The extent to which project results may be regional and national in scope.

Publication and Dissemination Plan (6 points)

- The extent to which there is a feasible and appropriate publication and dissemination plan described.
- The degree to which the applicant has a sound plan for how they will meet the expectation to produce the expected minimum number of peer-reviewed publications (i.e., three publications expected for each R40 MCH FIRST Program project).
- The degree to which the PI and other key personnel demonstrate current and/or past success in publishing the findings of their research. In particular, if investigators are past MCH FIRST Program recipients, the degree to which they demonstrate publication success from their previous award(s).
- The extent to which the proposal clearly demonstrates a plan to advance the transfer of findings into practice by disseminating findings, reports, and/or award project outputs to key target audiences, including researchers, providers, State Title V and children with special health care needs programs and other program(s) serving MCH populations, policymakers, families and the general public.

CRITERION 5: RESOURCES/CAPABILITIES (10 points)

E. Resources/Capabilities (5 points)

Organizational Facilities and Resources

- 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.
- The extent to which the scientific environment in which the work will be done contributes to the probability of project success.
- The adequacy of the institutional support, equipment, and other physical resources available to the PI and co-investigators for the proposed project.
- The extent to which the project will benefit from unique features of the scientific environment, subject populations, or collaborative arrangements.

Qualifications of Research Team -- Corresponds to (a) Preliminary Studies in C. Methodology/Research Strategy Work Plan/Approach; (b) Staffing Plan in Budget Narrative; and (c) Biographical Sketches in Program Narrative Section E

(5 points).

- The extent to which the Key/Senior Support Personnel Profiles and Biographical Sketches indicate that the Principal Investigator (PI), collaborators, staff, and other researchers are well qualified by training and/or expertise to conduct the research.
- If Early Stage Investigators or New Investigators, the appropriateness of their experience and training. If established, the degree to which they have demonstrated an ongoing record of accomplishments that have advanced their field(s).
- The extent to which the proposal describes relevant preliminary studies performed by key personnel, indicating the capacity to conduct the work as described.

CRITERION 6: SUPPORT REQUESTED (10 points) -- Corresponds to Budget and Budget Justification

- The reasonableness of the proposed budget in relation to the objectives, the complexity of the research 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 realistic and appropriate to achieve project objectives.
- The extent to which the application describes other current and pending support.

CRITERION 7: PROGRAM ASSURANCES (10 points) -- Corresponds to F. Feasibility; G. Evaluation and Technical Support Capacity; H. Protection of Human Subjects; and I. Targeted/Planned Enrollment

F. Feasibility (3 points)

Proposed Sequence or Timetable

- The extent to which the timeline provided is clear, and feasible to conduct within the project time frame.

Resolution of Challenges

- The extent to which the application anticipates and addresses potential barriers to project progress.

- The degree to which the applicant provides assurance that they can conduct and complete the research as proposed. (The expectation is that funded projects will demonstrate ongoing progress and completion as proposed and approved).
- The degree to which the applicant demonstrates the feasibility of reaching targeted/planned enrollment levels within the timeline provided.

G. Evaluation and Technical Support Capacity (3 points)

- The extent to which plans are in place to evaluate whether the applicant will meet the project objectives according to the timeline provided.

H. Protection of Human Subjects(1 point)

- 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 complies with the HHS regulations for protection of human subjects (45 CFR Part 46). See the instructions in HRSA's SF-424 R&R Application Guide, Appendix: Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy.
- 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.

I. Targeted/Planned Enrollment (3 points)

- The extent to which the proposal provides details regarding the Targeted/Planned Enrollment for the study, including demographic information on members of the selected study populations
- The extent to which the applicant plans appropriate diversity 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 independent review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. In addition to the ranking based on merit criteria, HRSA approving officials may also apply other factors in award selection, (e.g., geographical distribution), if specified below in this NOFO. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

Please see Section 5.3 of HRSA's *SF-424 R&R Application Guide* 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 (45 CFR § 75.205).

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

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

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

A determination that an applicant is not qualified will be reported by HRSA to FAPIIS (45 CFR § 75.212).

4. Anticipated Announcement and Award Dates

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

VI. Award Administration Information

1. Award Notices

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

2. Administrative and National Policy Requirements

See Section 2.2 of HRSA's *SF-424 R&R Application Guide*.

Human Subjects Protection:
Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR part 46), available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

3. Reporting

The Discretionary Grant Information System (DGIS) reporting system will continue to be available through the Electronic Handbooks (EHB). HRSA is enhancing the DGIS and will have these improvements available for recipient reporting on October 1, 2017. MCHB will provide technical assistance via webinars, written guidance, and one-on-one sessions with an expert, if needed.

Recipients with active awards should be able to access DGIS between October 1, 2017 and February 28, 2018 to report their performance objectives for the remaining years of the grant/cooperative agreement. Once all recipients have reported their performance objectives, they will then return to the normal reporting schedule for reporting final 2017 performance data.

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

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

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

1) **Progress Report**(s). The recipient must submit a progress report to HRSA on an **annual** basis. Further information will be provided in the award notice.

2) **Final Report Narrative.** The recipient must submit a final report narrative along with a formal presentation 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 administered by MCHB 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). GPRA 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

   After HRSA issues the notice of award (NOA), the MCHB project officer will inform recipients of the administrative forms and performances measures they must report.

   b) Performance Reporting Timeline

   Successful applicants receiving HRSA funds will be required, within 120 days of the NOA, to register in HRSA's 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 project period. Recipients will be required, within 120 days of the NOA, 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) Project Period End Performance Reporting

Successful applicants receiving HRSA funding will be required, within 90 days from the end of the project period, 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 project period, 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 45 CFR part 75 Appendix XII.

VII. Agency Contacts

You may request additional information 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:

Evva Assing-Murray, Ph.D., M.A.
Program Officer, Division of Research, Office of Epidemiology and Research
Attn: R40 MCH FIRST Program
Maternal and Child Health Bureau, HRSA
Health Resources and Services Administration
5600 Fishers Lane, Room 18N-136A
Rockville, MD 20857
Telephone: (301) 594-4113
Fax: (301) 480-0508
Email: EAssing-Murray@hrsa.gov

You may need assistance when working online to submit your application forms electronically. Always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, 7 days a week, excluding federal holidays at:

Grants.gov Contact Center
Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)
Email: support@grants.gov
Self-Service Knowledge Base: https://grants-portal.psc.gov/Welcome.aspx?pt=Grants

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

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

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

Technical Assistance

The following pre-submission technical assistance conference call has been scheduled:

Webinar

Day and Date: Monday, November 20, 2017
Time: 3 p.m. – 4 p.m. ET
Call-In Number: 1-800-369-1901
Participant Passcode: 5287373
Weblink: https://hrsa.connectsolutions.com/ta_hrsa_18_071/

Replay

End date: Monday November 20, 2018, 11:59pm (ET)
Number: 1-866-430-4721
Passcode: 4113

Relevant Websites

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

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

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

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

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

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

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

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

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

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

IX. 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 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. **These are only examples presented here for illustrative purposes and do not constitute preferences for funding consideration**. The Bureau strongly encourages research studies that align with MCHB Strategic Research Issues.

- 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.

DEFINITIONS

Care Coordination Services – those services that promote the effective and efficient organization and utilization of resources to assure access to necessary comprehensive services for children with special health care needs and their families **(Title V sec. 501 (b)(3)**)

Care Plan – a comprehensive care plan combines a medical summary, an emergency care plan, and an action care plan. It provides information that can be shared across providers; a ready reference in an emergency; and an action plan that prioritizes concerns, identifies specific tasks to address concerns, assigns responsibility for tasks, evaluates outcomes, and is done in collaboration with the child/youth and family **(Division of Services for Children with Special Health Needs, MCHB, HRSA)**

Children with Special Health Care Needs (CSHCN) – those who have, or are at increased risk for, a chronic physical, developmental, behavioral or emotional condition and who also require health and related services of a type or amount beyond that required by children generally **(The American Academy of Pediatrics)**

Cultural Competence – a set of behaviors, attitudes, policies, practices and structures that come together in a system, agency or among professionals and enable that system and agency or those professionals to work effectively in cross-cultural situations **(National Center for Cultural Competence, 2002)**

MCH Population – includes all of the nation's women, infants, children, adolescents, and their families, including fathers and children with special health care needs **(MCHB Strategic Plan: FYs 2003-2007)**

Medical Home – a medical home can be a physician's office, a hospital outpatient clinic, a community health center or school-based clinic, as long as it provides the services that constitute comprehensive care – continuous access to medical care; referral to pediatric medical subspecialties and surgical specialists; and interaction with child care, early childhood education programs and schools to ensure that the special needs of the child and family are addressed **(The American Academy of Pediatrics)**

Linguistic Competence – the capacity of an organization and its personnel to communicate effectively with persons of limited English proficiency, those with low literacy skills or who are not literate, and individuals with disabilities **(National Center for Cultural Competence, 2002)**

Quality of Care – 1) safe - avoiding injuries to patients from the care that is intended to help them; 2) effective - providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit; 3) patient-centered -providing care that is respectful of and responsive to individual preferences, needs and values and ensuring that patient values guide all clinical decisions; 4) timely - reducing waits and sometimes harmful delays for both those who receive and those who give care; 5) efficient -avoiding waste, including waste of equipment, supplies, ideas and energy; and 6) equitable -providing care that does not

vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status **(National Committee for Quality Assurance)**

Appendix B: Key Terms for Project Abstracts

(a) Content Terms (maximum of 10)

Health Care Systems & Delivery

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

Primary Care & Medical Home

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

Insurance & Health Care Costs

- Cost Effectiveness
- Health Care Costs
- Insurance Coverage

Prenatal/Perinatal Health & Pregnancy Outcomes

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

Nutrition & Obesity

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

Parenting & Child Development

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

School Settings, Outcomes, & Services

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

Screening & Health Promotion

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

Illness, Injury, & Death

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

Mental/Behavioral Health & Well-being

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

Special Health Care Needs & Disabilities

- Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder
- Asthma
- Chronic Illness
- Developmental Disabilities
- Special Health Care Needs
- Youth with Special Health Care Needs Transition to Adulthood

Life Course & Social Determinants

- Neighborhood
- Life Course
- Social Determinants of Health

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

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

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

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

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

No.	Performance Domain	MCH Population Domain
1	Well-Woman Visits and 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: Grant Application Completeness Checklist

Funding Opportunity Number:_____

Application Due Date in Grants.gov: _____

Requirement	Yes	No	Comments
Are you applying to the **correct funding opportunity**?			
Do you meet the **eligibility criteria**?			
Did you read the **R&R Application Guide?**			HRSA's SF-424 R&R Application Guide: https://www.hrsa.gov/grants/apply/application guide/sf424rrguidev2.pdf
Do you have a **DUNS number**?			Dun and Bradstreet number: http://www.dnb.com/duns-number.html
Did your Authorized Organization Representative register in **SAM and Grants.gov?**			• This process can take up to 1 month to complete. • System for Award Management (SAM:) https://www.sam.gov/ • Grants.gov: http://www.grants.gov/
In the **NEED Section**, did you fully address Needs and Alignment?			
In the **RESPONSE Section,** did you fully address: • Goals and Hypotheses? • Significance of Methodology/Research Strategy?			
In the **EVALUATIVE MEASURES Section,** did you fully address your Work Plan Approach?			
In the **IMPACT Section**, did you fully address: • Scientific Innovation and Importance? • Impact and Dissemination?			
In the **RESOURCES CAPABILITIES Section,** did you fully address Organizational Information/ Environment?			
In the **SUPPORT REQUESTED Section**, did you accurately complete the Budget and Budget Justification? Did you follow the budget instructions in the **NOFO and R&R Application Guide**?			The directions offered in the **SF-424 R&R Application Guide** differ from those offered by Grants.gov. Please follow the instructions included in the R&R Application Guide and, *if applicable*, the additional budget instructions in the **NOFO**. Your institution's indirect cost rate is negotiated by the institution with the

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

Appendix E: Frequently Asked Questions (FAQs)

Where do I find application materials for the R40 MCH Field-Initiated Innovative Research Studies (FIRST) Program?

All application materials are available through Grants.gov

How can I download the complete application package for the R40 NOFO?

You can download the application from Grants.gov.

What is Grants.gov?

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

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 Grants.gov. In order to submit your application (new or continuation), your university and your Authorized Organization Representative MUST be registered in Grants.gov. 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 Grants.gov.

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

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

Can I get a copy of the NOFO from last year's competition?
The past year NOFO is not published to avoid confusion among potential applicants.

What types of institutions can apply?

Only 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 R40 MCH FIRST Program. Are foreign entities eligible to apply?

The R40 is a domestic grant program and open only to U.S. entities that meet the eligibility criteria as outlined in the NOFO.

The NOFO notes that the grant supports "applied research." What do you mean by "applied research"?

In general, we define applied research as bringing basic research models and theories to application in practice—e.g., efficacy trials of new interventions, implementation studies, etc.

We are interested in applying for the R40 MCH FIRST 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; 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 HealthyPeople.gov website. You should highlight how your proposal aligns with MCHB Strategic issues, Healthy people 2020, and the 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 National 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/MCHB 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 (HHS). 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 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.

The NOFO states that "Longitudinal follow-up studies will not be considered for funding under this notice." Does this mean that studies that include follow-up within the 3-year project period do NOT meet the application responsiveness criteria?

A PI who currently has or in the past has had an R40 is excluded from applying for a grant to follow longitudinally the population used in their just-ending or previous R40 grant. ***Not excluded are:*** *Applications which include a longitudinal design within the proposed 3-year project period; and applications which involve collecting follow-up data on a population targeted in a grant funded by another agency.*

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 for the R40 MCH Research Program if they are affiliated with a university?

The NOFO does not contain language that excludes postdoctoral fellows from serving as PI on the R40 grants. 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 on an R40 grant?

The above application responsiveness criterion refers only to PIs of R40 grants within MCHB. 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.

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 under the R40, as long as other application responsiveness criteria are met.

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.

Are there page limits for the submitted application?

Yes, the R40 MCH FIRST Program 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:*
  - *Abstract*
  - *Project and budget narratives*
  - *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*
  - *Indirect Cost Agreement*
  - *Proof of Non-Profit Status*

Are there any page limitations to the narrative?

- *The current R40 MCH Field-Initiated Research Program NOFO requires the following page limitations:*
  - ***R40 MCH FIRST Grant:** 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 to R40 MCH FIRST Program applications?

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 R40 MCH FIRST Program competition next year?

In general, the MCH R40 Maternal and Child Health Research Program is competed annually, subject to the availability of funds.

Can I submit a proposal on autism spectrum disorder (ASD) for the R40 MCH FIRST Program competition?

The NOFO states: "Projects addressing autism spectrum disorder (ASD) will not be considered for the R40 MCH FIRST competition." A separate competition for autism research may be held, subject to the availability of funds. Please sign up for our listserv in order to receive an announcement when NOFOs are released: http://mchb.hrsa.gov/research/.

When will your next Autism NOFO be released?

Any R40 Autism Research competition is subject to the availability of funds. Please join our listserv at http://mchb.hrsa.gov/research in order to receive an alert whenever one of our NOFOs is released.

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

Information on current and past funded R40 MCH Field-Initiated Research projects can be found on our website. Please feel free to search our funded projects at http://mchb.hrsa.gov/research/.

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.*