U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration

Maternal and Child Health Bureau
Office of Epidemiology and Research

R40 Maternal and Child Health Research Program

Announcement Type: New, Resubmission
Funding Opportunity Numbers:
HRSA-16-032 (R40 MCH Research (MCHR))
HRSA-16-029 (R40 MCH Secondary Data Analysis Studies (SDAS))

Catalog of Federal Domestic Assistance (CFDA) No. 93.110

FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2016

Application Due Date: November 6, 2015

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 one month to complete.

Release Date: September 1, 2015

Issuance Date: September 1, 2015

Robin Harwood, PhD (MCHR) and Romuladus Azuine, DrPH, MPH, RN (SDAS)
Program Officers, Division of Research
E-mail: rharwood@hrsa.gov; razuine@hrsa.gov
Telephone: (301) 443-3888 (Harwood); (301) 443-2410 (Azuine)
Fax: (301) 480-0508

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau/ Office of Epidemiology and Research is accepting applications for fiscal year (FY) 2016 R40 Maternal and Child Health Research program. The purpose of this grant program is to advance the health and wellbeing of maternal and child populations through applied and translational research on critical issues affecting maternal and child health through the implementation of two unique programs: (1) the R40 MCH Research Program (MCHR) and (2) the R40 MCH Secondary Data Analysis Study (SDAS).

Funding Opportunity Title:	R40 Maternal and Child Health Research Program
Funding Opportunity Number:	**HRSA-16-032** (R40 MCH Research (MCHR)) **HRSA-16-029** (R40 MCH Secondary Data Analysis Studies (SDAS))
Due Date for Applications:	November 6, 2015
Anticipated Total Annual Available Funding:	**HRSA-16-032**: R40 MCHR: $1,500,000 **HRSA-16-029**: R40 MCH SDAS: $1,000,000
Estimated Number and Type of Award(s):	**HRSA-16-032:** R40 MCHR: Approximately five (5) awards **HRSA-16-029**: R40 MCH SDAS: Approximately ten (10) awards
Estimated Award Amount:	**HRSA-16-032**: R40 MCH Research: Subject to the availability of appropriations, the ceiling amount of an individual award is $300,000 total cost per year. **HRSA-16-029:** R40 SDAS: Subject to the availability of appropriations, the ceiling amount of an individual award is $100,000 total cost.
Cost Sharing/Match Required:	No
Project Period:	**HRSA-16-032:** R40 MCHR: Approved projects will be awarded project periods of up to three (3) years, April 1, 2016 – March 31, 2019. **HRSA-16-029:** R40 MCH SDAS: Approved projects will be awarded a project period of one (1) year, April 1, 2016 – March 31, 2017.
Eligible Applicants:	As cited in 42 CFR Part 51a.3(b), only public or nonprofit institutions of higher learning and public or private nonprofit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs are eligible. [See Section III-1 of this funding opportunity announcement (FOA) for complete eligibility information.]

Application Guide

All applicants 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/sf424rrguide.pdf, except where instructed in this FOA to do otherwise. A short video for applicants explaining the *Application Guide* is available at http://www.hrsa.gov/grants/apply/applicationguide/.

Technical Assistance

A technical assistance call will be held on Thursday, September 17, 2015 from 1:00 p.m. to 2:30 p.m. Eastern Time. The MCHB Project Officer will provide an overview of the FOA and be able to answer questions. The call-in information is as follows: Dial-in number: 1-877-680-3086 and Passcode: 3560816#. In addition, the link to register for the call is: https://hrsa.connectsolutions.com/ta-webinar/event/registration.html and upon registration, you will receive a confirmation.

Table of Contents

I. Program Funding Opportunity Description

1. Purpose

This announcement solicits applications for two (2) separate competitions, R40 MCH Research (MCHR) and R40 MCH Secondary Data Analysis Studies (SDAS).

R40 MCH Research (MCHR) Program (HRSA-16-032)

The R40 MCH Research Program supports translational and applied research on critical issues affecting maternal and child health, including services for children with special health care needs. Research should advance the current knowledge pool, and when implemented in states and communities should result in health and health services improvements. Findings from the research supported by the MCH Research Program are expected to strengthen and expand topics addressed by the new MCH Block Grant National Performance Priority Areas, and the populations they serve (see Appendix C). For more background materials on the Block Grant Transformation, see: http://mchb.hrsa.gov/programs/titlevgrants/index.html.

The R40 MCHR will support research that addresses MCHB Strategic Research Issues such as how to improve public health systems and infrastructure, reduce health disparities, increase quality of care, and/or promote the health of MCH populations. Addressing at least one of the four MCHB Strategic Research Issues (see Appendix A) is part of Review Criterion 1, Need, and is worth up to 10 points. By supporting research on HRSA/MCHB program populations[1], the R40 MCHR program is strategically tied to HRSA/MCHB investments and programs. The "life course perspective" is currently being integrated into MCHB's strategic directions, and can serve as a helpful frame of reference for study proposals designed to address the critical MCH questions defined by the Bureau.

Research projects should demonstrate rigorous scientific methodology. R40 MCHR recipients will complete the following major activities:

- Recipients will conduct applied research on critical MCH issues;
- Recipients will disseminate findings through development of at least three peer-reviewed publications and other dissemination activities including conference presentations, newsletter articles, webcasts, fact sheets, infographics, policy briefs and website and social media posts, as appropriate;
- Recipients will demonstrate 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 HRSA/MCHB populations, policymakers, families and the general public. Supported research will achieve the aims of the program by generating new knowledge on critical MCH issues that will advance the evidence base and promote the transfer of findings to improve practice.

[1] HRSA/MCHB program populations: Maternal and Child populations served by HRSA and/or MCHB programs.

R40 MCH Secondary Data Analysis Studies (SDAS) Program (HRSA-16-029)

The R40 MCH SDAS program supports applied research relating to maternal and child health services that exclusively utilizes secondary analysis of existing national databases and/or administrative records. These projects should have the potential to improve health services and delivery of care for maternal and child health populations.

Findings from the research supported by the MCH Research Program are expected to strengthen and expand topics addressed by the new MCH Block Grant National Performance Priority Areas, and the populations they serve (see Appendix C). For more background materials on the Block Grant Transformation, see: http://mchb.hrsa.gov/programs/titlevgrants/index.html.

The R40 MCH SDAS will support research that addresses MCHB Strategic Research Issues such as how to improve public health systems and infrastructure, reduce health disparities, increase quality of care, and/or promote the health of MCH populations. Addressing at least one of the four MCHB Strategic Research Issues (see Appendix A) is part of Review Criterion 1, Need, and is worth up to 10 points. By supporting research on HRSA/MCHB program populations, the R40 MCH SDAS program is strategically tied to HRSA/MCHB investments and programs.

R40 MCH SDAS recipients will complete the following major activities:

- Recipients will conduct secondary data analyses using existing national databases and administrative records, using various analytic methods;
- Recipients will disseminate findings through development of at least two peer-reviewed manuscripts and other dissemination activities including conference presentations, newsletter articles, webcasts, fact sheets, policy briefs, website and social media posts, as appropriate;
- Recipients will demonstrate a plan to advance the transfer of 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 programs serving HRSA/MCHB populations, policymakers, families and the general public.

2. Background

The R40 MCH Research Program is authorized by Title V, § 501(a)(2); 42 U.S.C. 701(a)(2) of the Social Security Act, as amended, and is a component of the Special Projects of Regional and National Significance (SPRANS). The program is administered by the Division of Research, Office of Epidemiology and Research, Maternal and Child Health Bureau (MCHB), Health Resources and Services Administration (HRSA). The MCH Research Program, built on over 50 years of experience, has supported investigations which have significantly influenced clinical management, organization and delivery of health care services, preventive care, and early intervention for maternal and child populations through support of field-initiated research focused exclusively on improving health and related care and promoting health and well-being among MCH populations. By supporting research on HRSA/MCHB program populations, it is strategically tied to HRSA/MCHB investments and programs.

The R40 MCHR and R40 MCH SDAS programs advance the field through research on maternal and child health and services that demonstrate a substantial contribution to advancement of the current knowledge pool, and when used in states and communities will result in health and health services improvements. These programs advance health equity through research that addresses health and related issues for all MCH populations, including vulnerable and underserved HRSA/MCHB program populations. The research findings of the R40 program should be generalizable and of regional or national significance.

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

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New, Resubmission

Funding will be provided in the form of a grant.

2. Summary of Funding

HRSA-16-032: R40 Maternal and Child Health Research Program
This program will provide funding during federal fiscal years 2016 – 2018. Approximately $1,500,000 is expected to be available annually to fund five (5) recipients. Applicants may apply for a ceiling amount of up to $300,000 per year. The actual amount available will not be determined until enactment of the final FY 2016 federal budget. This program announcement 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 can be awarded in a timely manner. The project period is three (3) years. Funding beyond the first year is dependent on the availability of appropriated funds for the Maternal and Child Health Research Program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

HRSA-16-029: R40 MCH Secondary Data Analysis Studies (SDAS)
This program will provide funding during federal fiscal year 2016. Approximately $1,000,000 is expected to be available annually to fund ten (10) recipients. Applicants may apply for a ceiling amount of up to $100,000 per year. The actual amount available will not be determined until enactment of the final FY 2016 federal budget. This program announcement 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 can be awarded in a timely manner. The project period is one (1) year.

Effective December 26, 2014, all administrative and audit requirements and the cost principles that govern federal monies associated with this award will be subject to the Uniform Guidance 2 CFR 200 as codified by HHS at 45 CFR 75, which supersedes the previous administrative and audit requirements and cost principles that govern federal monies.

III. Eligibility Information

1. Eligible Applicants

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

2. Cost Sharing/Matching

Cost sharing/matching is not required for the two (2) announcements in this FOA.

3. Other

For the **R40 MCHR program (HRSA 16-032)**, applications that exceed the $300,000 total cost per year ceiling amount will be considered non-responsive and will not be considered for funding under this announcement. This ceiling includes both direct and indirect expenses.

For the **R40 MCH SDAS Program (HRSA-16-029)**, applications that exceed the $100,000 total cost ceiling amount will be considered non-responsive and will not be considered for funding under this announcement. This ceiling includes both direct and indirect expenses.

Any application that fails to satisfy the deadline requirements referenced in *Section IV.3* will be considered non-responsive and will not be considered for funding under this announcement.

NOTE: Multiple applications from an organization **are** allowable.

The following are additional eligibility requirements:

An individual cannot be named as the Principal Investigator (PI) in multiple applications for the R40 MCHR or the R40 MCH SDAS competitions. An individual cannot be named as PI on an R40 MCHR and R40 MCH SDAS applications simultaneously (i.e., an individual can only be named PI once for this entire FOA). All applications that do not comply with these requirements will be deemed non-responsive, and will not be considered for funding under this announcement.

Due to funding limitations and in order to diversify the R40 portfolio, the following additional eligibility requirements apply to the **R40 MCHR** and **R40 MCH SDAS Programs**:

- Applications that overlap in project period with a currently funded MCH Research project by the same Principal Investigator (PI) will not be considered for funding (i.e., a Principal Investigator cannot have two (2) R40 MCH Research awards in effect simultaneously). A one-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 an award application is not allowable.
- A current PI of an MCH Research award can serve for no more than 10% time on a new proposal.

- Longitudinal follow-up studies will not be considered for funding under this announcement; i.e., 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. Not excluded are: applications which include a longitudinal design within the proposed three-year project period; applications which involve analyzing pre-existing longitudinal data through the R40 MCH SDAS (HRSA-16-029) mechanism; and applications which involve collecting follow-up data on a population targeted in an award funded by another agency.
- Analysis of secondary data previously collected by the applicant PI will not be considered for funding using the R40 MCH SDAS Program (HRSA-16-029). SDAS applications must propose the use of existing national data sets or administrative records.
- Secondary data analysis projects will not be considered for funding under the multiyear R40 MCH Research (HRSA-16-032) award competition.
- Analysis of multiple datasets that require linkage or integration (e.g., combining administrative records from Medicaid, the child welfare system, and hospitals) will not be considered for funding under the multiyear R40 MCHR (HRSA-16-032) award competition.
- Projects addressing autism spectrum disorder (ASD) will not be considered for either the multiyear R40 MCHR (HRSA-16-032) or the R40 MCH SDAS (HRSA-16-029) competitions.
- Projects which include the collection of biological specimens will not be considered for either the R40 MCHR (HRSA-16-032) or the R40 MCH SDAS (HRSA-16-029) competitions.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates), an application is submitted more than once prior to the application due date, HRSA will only accept the applicant's **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 announcement number--HRSA-16-032 for the R40 MCHR multiyear competition, and HRSA-16-029 for the R40 MCH SDAS competition. Applications submitted to the wrong competition will be deemed nonresponsive.

IV. Application and Submission Information

1. Address to Request Application Package

HRSA ***requires*** applicants for this FOA to apply electronically through Grants.gov. Applicants must download the SF-424 Research and Related (R&R) application package associated with this FOA following the directions provided at Grants.gov.

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 Application Guide in addition to the program specific information below. All applicants are responsible for reading and complying with the instructions included in HRSA's *SF-424 R&R Application Guide* except where instructed in the FOA to do otherwise.

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, and letters of commitment and support required in the *Application Guide* and this FOA. Standard OMB-approved forms that are included in the application package are NOT included in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) will not be counted in the page limit. **We strongly urge applicants to take appropriate measures to ensure the application does not exceed the specified page limit.**

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

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 FOA number/title. Briefly state the principal needs and problems which are addressed by the project, including the project's relationship to MCHB Strategic Research Issues (Appendix A). Also describe the research design and methods within the abstract and include data collection methods and participant information (i.e., age and demographic background of target population). In addition, SDAS applications must include the name of the database(s) you will be analyzing in the abstract. 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 (a) content terms, (b) populations, and (c) age ranges targeted at the end of your abstract.

ii. ***Project Narrative (Unless indicated otherwise, all narrative sections below apply to both HRSA-16-032 and HRSA-16-029)***

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.

Use the following section headers for the Narrative:

A. INTRODUCTION **(for resubmission only)**:

Only a single amendment to the original application (called a resubmission application) will be accepted.

NOTE: FOR RESUBMISSIONS, MARK THE APPLICATION AS "RESUBMISSION" ON 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 announcement 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 time limit for a resubmission application. The following requirements 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.**
- 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 Criteria: #1 Need

Needs Assessment

- 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 (including age ranges of children/youth) and its 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 and Healthy People 2020

- Identify relevance to MCHB Strategic Research Issues (Appendix A). The applicant is responsible for explaining the project's relevance to an MCHB Strategic Research Issue.
- Discuss how the research findings will strengthen and expand topics addressed by the new MCH Block Grant National Performance Priority Areas (Appendix C) and the populations they serve.
- Identify relationship to specific Healthy People 2020 objectives.

2) Goals and Hypotheses --Corresponds to Section V's Review Criteria: #2 Response

Goals and Objectives

- State clearly and succinctly the specific objectives of the particular research proposed, for example, to test a stated hypothesis, create a novel intervention, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.
- 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 are to be answered by the study. These should include not only predictions as to findings (hypotheses) but also justifications for the predictions.
- A summary table of the variables, classified as independent, intervening, mediating, and dependent, etc. should be presented, 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 model or graphical representation of the set of relationships held to be operative among the variables.
- **Make sure that there is 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/RESEARCH STRATEGY -- 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 for R40 MCHR (HRSA-16-032). For SDAS (HRSA-16-029) applications, this section is limited to six (6) pages in length. Applications that exceed these page limits in the Methodology/ Research

Strategy section will be deemed nonresponsive, and will not be considered for funding under this announcement.

1) Significance --Corresponds to Section V's Review Criteria #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 project addresses.
- Indicate the relevance of the problem to maternal and child health 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 Criteria #3 Evaluative Measures

- Describe the overall study design, strategy, methodology, and analyses to be used 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.).
- 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 the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- For SDAS applications, include information regarding the database(s) you propose to use.
- Letters of Agreement from study sites supporting recruitment must be included in Attachment 1.

Preliminary Studies: Include information on Preliminary Studies as part of the 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 proposed racial/ethnic group members. 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 Criteria #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.
- Describe the extent to which study results will be generalizable and replicable.
- Describe the extent to which study results will be regional or national in significance.

Publication and Dissemination Plan

- Describe plans for dissemination of project results.
- The following are required products that R40 recipients must deliver as part of the award requirements: **R40 MCHR (HRSA-16-032)** research recipients will produce at least three (3) peer-reviewed publications per study and **R40 MCH SDAS (HRSA-16-029)** research recipients will produce at least two (2) peer-reviewed publications resulting from their MCH Research project. The dissemination plan must include information on how you will accomplish this minimum number of publications.
- Past MCH Research Program recipients should demonstrate publications from their previous MCH research award. (NOTE: Peer-reviewed publications are the cardinal measure of success of the MCH Research Program).
- In addition to peer-reviewed publications, applicants must demonstrate 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 HRSA/MCHB populations, policymakers, families and the general public. Award 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, recipients 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. ORGANIZATIONAL INFORMATION/ENVIRONMENT -- Corresponds to Section V's Review Criterion #5 Resources/Capabilities

This information is used to assess the capability of the organizational 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.

- Identify the facilities to be used (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 would be: resources for classes, travel, training; collegial support such as career enrichment programs, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; 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.

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

Proposed Sequence or Timetable

- Provide a sequence or timetable for the project that includes the activities or 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

- Discuss any challenges that are likely to be encountered 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. This section addresses questions around project feasibility. Due to the competitive nature of the MCH Research Program award competitions and limited availability of funding, it is important that the applicant address the feasibility of conducting and completing the study as proposed. Provide assurance that the research team will conduct the study as designed. Once funded, it is critical that the study is implemented and completed as proposed and approved.

- Discuss alternative strategies should any of these potential challenges arise.
- Discuss the feasibility of reaching targeted/planned enrollment levels.
- Describe any strategy to establish feasibility, and 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 to be exercised.

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 B: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, for specific instructions on preparing the human subjects section of the application.

This section is required for applicants answering "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 human specimens and/or data from subjects, applicants 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. IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.

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

- 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 are expected to be enrolled 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. For **R40 MCHR (HRSA-16-032)**, describe how the project will assure cultural competence in terms of including individuals from the study population in the planning and implementation of the research project and in adapting the research methodology to reflect an understanding of and valuing the culture of the study population. For **R40 MCH SDAS (HRSA-16-029)**, describe how the analytic plan will reflect an understanding and valuing of the culture of the study population.

NARRATIVE GUIDANCE In order to ensure that the Review Criteria are fully addressed, this table provides a bridge between the narrative language and where each section falls within the review criteria.	
Narrative Section	Review Criteria
B. Specific Aims: 1) Needs and Alignment	(1) Need
B. Specific Aims: 2) Goals and Hypotheses	(2) Response
C. Methodology/Research Strategy: 1) Significance	(2) Response
C. Methodology/Research Strategy: 2) Work Plan/Approach	(3) Evaluative Measures
C. Methodology/Research Strategy: 3) Scientific Innovation and Importance	(4) Impact
D. Impact and Dissemination	(4) Impact
E. Organizational Information/Environment; Staffing Plan in Budget Narrative; Biographical Sketches	(5) Resources/Capabilities
Budget and Budget Justification	(6) Support Requested
F. Feasibility	(7) Program Assurances
G. Evaluation and Technical Support Capacity	(7) Program Assurances
H. Protection of Human Subjects	(7) Program Assurances
I. Targeted/Planned Enrollment	(7) Program Assurances

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* 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 provided below.

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 and Further Continuing Appropriations Act, 2015, Division G, § 203, (P.L. 113-235) 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 will apply in FY 2016, 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 Research 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 will be uploaded in 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% time on a new proposal in a capacity other than as Principal Investigator.) 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. Refer to Section 4.1.vi of HRSA'S *SF-424 R&R Application Guide* on the required format for biographical sketches.

v. *Program-Specific Forms*

1) Performance Standards for Special Projects of Regional or National Significance (SPRANS) and Other MCHB Discretionary Projects

The Health Resources and Services Administration (HRSA) has modified its reporting requirements for SPRANS projects, Community Integrated Service Systems (CISS) projects, and other award programs administered by the Maternal and Child Health Bureau (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). This Act requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act, the MCHB's authorizing legislation. Performance measures for other MCHB-funded award programs have been approved by the Office of Management and Budget and are primarily based on existing or administrative data that projects should easily be able to access or collect. An electronic system for reporting these data elements has been developed and is now available.

2) Performance Measures for the R40 MCH Research Program and Submission of Administrative Data

To prepare successful applicants for their reporting requirements the listing of MCHB administrative forms and performance measures for this program can be found at: https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/R40_2.HTML.

NOTE: The performance measures and data collection information is for your PLANNING USE ONLY. These forms are not to be included as part of this application. However, this information would be due to HRSA within 120 days after the Notice of Award.

vi. *Attachments*

Include here any other documents that are relevant to the application. Please provide the following items in the order specified below to complete the content of the application.

Attachment 1: Letters of Agreement/Letters of Support
Provide any documents that describe working relationships between the applicant agency and other agencies and programs cited in the proposal. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the subcontractors and any deliverables. Include only letters of support which specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.). Letters of agreement and letters of support must be dated.

Attachment 2: Key Publications or Condensed Citations with Abstracts.
Do not include unpublished theses, or abstracts/manuscripts **submitted** (but not yet accepted) for publication.

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.

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

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

Attachments 6-15: Other Relevant Documents

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**.

3. Dun and Bradstreet Universal Numbering System Number and System for Award Management (formerly, Central Contractor Registration)

Applicant organizations must obtain a valid DUNS number and provide that number in their application. Applicant 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 it has 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 an applicant/awardee organization has 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://fedgov.dnb.com/webform/pages/CCRSearch.jsp)
- 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*.

Applicants that fail to allow ample time to complete registration with SAM or Grants.gov 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 FOA is *November 6, 2015 at 11:59 P.M. Eastern Time*.

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

5. Intergovernmental Review

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

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

6. Funding Restrictions

Funds under these announcements (HRSA-16-032 and HRSA-16-029) may not be used for the following purposes: foreign travel.

HRSA-16-032: R40 MCH Research Program
Applicants may request funding for a project period of up to three (3) years, at no more than $300,000 total cost (direct plus indirect expenses) per year.

Awards for the first year are subject to the availability of appropriations. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

HRSA-16-029: R40 MCH Secondary Data Analysis Studies
Applicants may request funding for a project period of one (1) year, at no more than $100,000 total cost (direct plus indirect expenses).

The General Provisions in Division G of the Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235) 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 2016, as required by law.

All program income generated as a result of awarded funds must be used for approved project-related activities.

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 the applicant in understanding the standards against which each application will be judged. Critical indicators have been developed for each review criterion to assist the applicant 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 the application. The entire proposal will be considered during objective review.

NOTE: The terms *research project* and *study* are used interchangeably.

Review Criteria are used to review and rank applications. The R40 MCH RESEARCH PROGRAM (MCHR) and R40 SECONDARY DATA ANALYSIS STUDIES (SDAS) PROGRAM have seven (7) review criteria:

Criterion 1.	Need	10 points
Criterion 2.	Response	20 points
Criterion 3.	Evaluative Measures	30 points
Criterion 4.	Impact	10 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: Needs and Alignment

B. Specific Aims: 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 (including age ranges of children/youth) is clearly stated in the abstract and described in the application.

Alignment with HRSA/MCHB Goals and Healthy People 2020

- The extent to which the research project addresses an MCHB Strategic Research Issue, which also supports the goals of HRSA (Appendix A).
- The extent to which findings from the research supported by the MCH Research Program are likely to strengthen and expand topics addressed by the new MCH Block Grant National Performance Priority Areas, 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: Goals and Hypotheses; and C Methodology/Research Strategy: Significance

B. Specific Aims: Goals and Hypotheses

Goals and Objectives

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

Hypotheses and Specification of Variables

- The extent to which the proposal clearly and succinctly presents the specific questions to be answered by the study, including not only hypotheses, but also justifications for the hypotheses.
- The extent to which hypotheses are clearly stated and variables clearly defined.
- The extent to which the logic of the study is clearly stated and linked to need.
- The extent to which the overall scientific approach presents clear and logically derived hypotheses and goals.

- The extent to which the overall scientific approach is thoughtful and logical.
- The extent to which there is 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/Research Strategy: Significance

Background Literature and Statement of Problem

- The extent to which the investigators demonstrate awareness of previous and current work in the area of the project.
- The extent to which the cited literature is pertinent to the research problem and provides a rationale for the research.
- The extent to which the hypotheses are logically derived from the literature, clearly stated, and are related to the defined problem.

Relevance

- 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.

Criterion 3: EVALUATIVE MEASURES (30 points) -- Corresponds to Program Narrative Section C Methodology/Research Strategy: Work Plan/Approach

C. Methodology/Research Strategy: Work Plan/Approach

Study Design

- The appropriateness of the research plan and methodologies described.
- The extent to which the research plan is coherent as a whole.
- The extent to which the scientific activities described in the proposal are capable of addressing the problem and attaining the project objectives--the effectiveness of the methods proposed to accomplish the goals of the research project.
- 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 proper controls are included.
- 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 method of randomization, if used, is clearly described.

- 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.
- For SDAS applications, the extent to which the proposed database(s) is/are clearly stated 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

- 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).
- If secondary analysis of existing data is proposed, the extent to which the data are available to the investigator and are appropriate for this study. The extent to which the secondary data provide convincing external validity for intended measurements in the analysis, e.g., self-reported blood pressure, parent-reported anthropometric data. (NOTE: The SDAS award program does not support analysis of data previously collected by the applicant PI).

Population Description, Sampling, and Recruitment

- The degree to which the study population is described (i.e., targeted age, 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 minorities and members of both sexes/genders, as well as the inclusion of children 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

- 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 (10 points) -- Corresponds to Program Narrative Sections C Methodology/Research Strategy: Scientific Innovation and Importance; and D Impact and Dissemination

C. Methodology/Research Strategy: Scientific Innovation and Importance

- The degree to which the proposed project will have a sustained and powerful influence on the research field.
- 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 preventative interventions that drive this field.
- The extent to which the expected outcomes are likely to have an impact on the relevant fields of research.
- The extent to which the application challenges and seeks to shift current research or clinical practice paradigms by utilizing novel 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

- The extent to which the expected outcomes are likely to have an impact on 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 or national significance.
- The extent to which the proposed study specifically addresses issues 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 or national in scope.

Publication and Dissemination Plan

- The extent to which there is an effective publication and dissemination plan.
- 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., 3 publications expected for each R40 MCH Research (HRSA-16-032) study and 2 publications expected for each R40 SDAS (HRSA-16-029) study).
- 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 Research Program recipients, the degree to which they demonstrate publication success from their previous award(s).
- R40 MCHR (HRSA-16-032): 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 HRSA/MCHB populations, policymakers, families and the general public.
- R40 MCH SDAS (HRSA-16-029): The extent to which the proposal clearly demonstrates a plan to advance the transfer of 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 programs serving HRSA/MCHB populations, policymakers, families and the general public.

CRITERION 5: RESOURCES/CAPABILITIES (10 points)

Research Team -- Corresponds to Preliminary Studies in Methodology/Research Strategy Work Plan/Approach; Staffing Plan in Budget Narrative; Biographical Sketches

- The extent to which project personnel are qualified by training and/or experience to implement and carry out the research project.
- 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.

E. Organizational Information/Environment

- 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.

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 other current and pending support is described. (Note: A current PI of an MCH Research award can serve for no more than 10% time on a new proposal).

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

Proposed Sequence or Timetable

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

Resolution of Challenges

- The extent to which potential barriers to project progress are anticipated and addressed.
- The degree to which the applicant provides assurance that the research can be conducted and completed as proposed. (It is expected 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

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

H. Protection of Human Subjects

- The extent to which adequate protections are afforded to human subjects, including children and youth.
- The extent to which the proposal is in compliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR Part 46). See the instructions in HRSA's SF-424 R&R Application Guide, Appendix B: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan.
- If the project involves primary data collection, the extent to which the project includes plans for: 1) protection of human subjects from research risks; and 2) inclusion of minorities and members of both sexes/genders.
- 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).
- The extent to which the applicant discusses the security of data from the research, including plans and processes for the protection of personal and confidential information of research participants and assurance that effective procedures will be put in place to secure and protect identifiable and/or confidential information collected for the purposes of the research project.

I. Targeted/Planned Enrollment

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

2. Review and Selection Process

Please see Section 5.3 of HRSA's *SF-424 R&R Application Guide*.

This program does not have any funding priorities, preferences or special considerations.

Please Note: The Health Resources and Services Administration 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). The decision not to make an award or to make an award at a particular funding level, is discretionary and is not subject to appeal to any OPDIV or HHS official or board.

3. Anticipated Announcement and Award Dates

It is anticipated that awards will be announced prior to the start date of April 1, 2016.

VI. Award Administration Information

1. Award Notices

The Notice of Award will be sent prior to the start date of April 1, 2016. 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 of HRSA's *SF-424 R&R Application Guide*.

Human Subjects Protection:
Federal regulations (45 CFR 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, recipients 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 46), available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

3. Reporting

The successful applicant under this FOA 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). **(Not Applicable to R40 MCH SDAS (HRSA-16-029))** The awardee must submit a progress report to HRSA on an **annual** basis. Further information will be provided in the award notice.

2) **Final Comprehensive Report.** A final comprehensive report is due within 90 days after the project period ends. The final report describes the degree to which the recipient achieved the goals and objectives outlined in the proposal. More information will provided following award. The final report must be submitted online by awardees in the Electronic Handbooks (EHBs) system.

3) **Dissemination.** Recipient for this competition will be required to notify their HRSA project officer as soon as they are aware their research is being or has been published. Recipient must report back to HRSA regarding the execution of their dissemination plans as part of the non-competing continuation (NCC) application and the final comprehensive report. Prompt and timely presentation and publication in the scientific literature of findings resulting from research and analyses undertaken is required. As per HHS grants policy guidelines (See "Publications" section on page II-73 at http://www.hrsa.gov/grants/hhsgrantspolicy.pdf), the awardee agrees to acknowledge HRSA support in the publications and oral presentations resulting from research and/or activities conducted under this program. Peer-reviewed publications are the cardinal measure of success of the MCH Research Program. The number of publications resulting from each funded project contributes to the total number of publications by which the MCH Research Program is evaluated annually.

4) **Performance Report(s).** The Health Resources and Services Administration (HRSA) has modified its reporting requirements for SPRANS projects, CISS projects, and other award programs administered by the Maternal and Child Health Bureau (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). This Act requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act, the MCHB's authorizing legislation. Performance measures for other MCHB-funded award programs have been approved by the Office of Management and Budget and are primarily based on existing or administrative data that projects should easily be able to access or collect.

a) Performance Measures and Program Data

To prepare successful applicants for their reporting requirements, the listing of MCHB administrative forms and performance measures for this program can be found at: https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/R40_2.HTML.

b) Performance Reporting

Successful applicants receiving award funds will be required, within 120 days of the Notice of Award (NoA), to register in HRSA's EHBs and electronically complete the program specific data forms that appear for this program at: https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/R40_2.HTML. This requirement entails the provision of budget breakdowns in the financial forms based on the award amount, the project abstract and other award 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 award summary data as well as finalizing indicators/scores for the performance measures.

c) Project Period End Performance Reporting

Successful applicants receiving 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 at: https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/R40_2.HTML. The requirement includes providing expenditure data for the final year of the project period, the project abstract and award summary data as well as final indicators/scores for the performance measures.

VII. Agency Contacts

Applicants may obtain additional information regarding business, administrative, or fiscal issues related to this FOA by contacting:

Janene P. Dyson
Grants Management Specialist
HRSA Division of Grants Management Operations, OFAM
Parklawn Building, Room 10W05B
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-8325
Fax: (301) 594-4073
E-mail: JDyson@hrsa.gov

Additional information related to the overall program issues and/or technical assistance regarding this funding announcement may be obtained by contacting:

Robin Harwood, PhD (R40 MCHR – HRSA-16-032)
Romuladus Azuine, DrPH (R40 SDAS – HRSA-16-029)
Program Officers, Division of Research
Attn: R40 MCH Research Program
Maternal and Child Health Bureau, HRSA
Parklawn Building, Room 10-77
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-3888 (Harwood), (301) 443-2410 (Azuine)
Fax: (301) 480-0508
E-mail: rharwood@hrsa.gov; razuine@hrsa.gov

Applicants may need assistance when working online to submit their application forms electronically. Applicants should 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, seven days a week, excluding federal holidays at:

Grants.gov Contact Center
Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)
E-mail: support@grants.gov
iPortal: 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 (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday-Friday, 8:00 a.m. to 8:00 p.m. ET:

HRSA Contact Center
Telephone: (877) 464-4772
TTY: (877) 897-9910
Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

VIII. Other Information

Technical Assistance

A technical assistance call will be held on Thursday, September 17, 2015 from 1:00 p.m. to 2:30 p.m. Eastern Time. The MCHB Project Officer will provide an overview of the FOA and be able to answer questions. The call-in information is as follows: Dial-in number: 1-877-680-3086 and Passcode: 3560816#. In addition, the link to register for the call is: https://hrsa.connectsolutions.com/ta-webinar/event/registration.html and upon registration, you will receive a confirmation.

Helpful 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

Institute of Medicine
http://www.iom.edu

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

MCH Training Web Site
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/

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 [(1)] 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, race/ethnicity, geography, 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 specifically address issues related to MCHB investments and programs.

- **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) [(2)]:** Determine the impact of **Care Coordination Services**[(3)] 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 compared with private practice or public clinic 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** [(4)].

- 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 specifically address issues related to MCHB investments and programs.

- Determine the effectiveness, impact, and cost benefits of **cultural and linguistic competence** [(5)] 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 [6] 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 for illustrative purposes and do not constitute preferences for funding consideration**. The Bureau strongly encourages research studies that specifically address issues related to MCHB investments and programs.

- 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," [7] 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 for illustrative purposes and do not constitute preferences for funding consideration**. The Bureau strongly encourages research studies that specifically address issues related to MCHB investments and programs.

- 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 (SES), 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

[1]. **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)**

[2]. **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)**

[3]. **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)**)

[4]. **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)**

[5]. **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)**

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)**

[6]. **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-NCQA)**

[7]. **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)**

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
- SIDS/SUID
- 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

- ADD/ADHD
- Asthma
- Autism
- Chronic Illness
- Developmental Disabilities
- Special Health Care Needs
- YSHCN 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 Priority Areas

No.	National Performance Priority Areas	MCH Population Domains
1	Well-Woman Visits and Preconception/ Interconception Health	Women/Maternal Health
2	Low-Risk Cesarean Delivery	Women/Maternal Health
3	Perinatal Regionalization	Perinatal and Infant Health
4	Breastfeeding	Perinatal and Infant Health
5	Safe Sleep	Perinatal and Infant Health
6	Developmental Screening	Child Health
7	Injury	Child Health and/or Adolescent Health
8	Physical Activity	Child Health and/or Adolescent Health
9	Bullying	Adolescent Health
10	Adolescent well-visit	Adolescent Health
11	Medical Home	Children with Special Health Care Needs
12	Transition	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