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 (MCHR)

Announcement Type: New, Revision
Announcement Numbers:
HRSA-15-062 (R40 MCH Research (MCHR))
HRSA-15-077 (R40 MCH Secondary Data Analysis Studies (SDAS))

Catalog of Federal Domestic Assistance (CFDA) No. 93.110

FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2015

Application Due Date: December 5, 2014

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: October 3, 2014

Issuance Date*:* October 6, 2014

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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) 2015 R40 Maternal and Child Health Research program. The purpose of this grant program is to support applied research and analyses studies relating to maternal and child health services, that have the potential to improve health services and delivery of care for maternal and child health populations.

Funding Opportunity Title:	R40 Maternal and Child Health Research Program (MCHR)
Funding Opportunity Number:	**HRSA-15-062** (R40 MCH Research (MCHR)) **HRSA-15-077** (R40 MCH Secondary Data Analysis Studies (SDAS))
Due Date for Applications:	December 5, 2014
Anticipated Total Annual Available Funding:	**HRSA-15-062:** R40 MCHR: $1,600,000 **HRSA-15-077:** R40 MCH SDAS: $1,000,000
Estimated Number and Type of Award(s):	**HRSA-15-062:** R40 MCHR: Approximately six (6) grants **HRSA-15-077**: R40 MCH SDAS: Approximately ten (10) grants
Estimated Award Amount:	**HRSA-15-062**: R40 MCH Research: Subject to the availability of appropriations, the ceiling amount of an individual award is $300,000 total cost per year. **HRSA-15-077:** 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-15-062:** R40 MCHR: Approved projects will be awarded project periods of up to three (3) years, 4/1/2015 – 3/31/2018. **HRSA-15-077:** R40 MCH SDAS: Approved projects will be awarded a project period of one (1) year, 4/1/2015 – 3/31/2016.
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.]

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 funding opportunity announcement to do otherwise. A short video for applicants explaining the new *Application Guide* is available at http://www.hrsa.gov/grants/apply/applicationguide/.

Table of Contents

I. Funding Opportunity Description

1. Purpose

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

R40 MCH Research (MCHR) Program (HRSA-15-062)

The R40 MCH Research Program supports applied research relating to maternal and child health services, including services for children with special health care needs. Research should demonstrate a substantial contribution to advancement of the current knowledge pool, and when used 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 Affordable Care Act (ACA) implementation. This includes research that drives policy and service delivery of preventive and early intervention services for application in health care delivery programs or develops new knowledge on the impact of insurance coverage on health promotion.

Research proposals should address critical MCH questions such as public health systems and infrastructure, health disparities, quality of care, and promoting the health of MCH populations, which also support the goals of the Health Resources and Services Administration. 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.

Applicants are encouraged to propose translational research studies that specifically address issues related to MCHB investments and programs. Addressing one of the four MCHB Strategic Research Issues (see Appendix A) is part of Review Criterion 1, Need, worth up to 10 points.

R40 MCH Secondary Data Analysis Studies (SDAS) Program (HRSA-15-077)

The R40 MCH SDAS program supports applied research relating to maternal and child health services that utilizes exclusively the 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 Affordable Care Act (ACA) implementation. This includes research that drives policy and service delivery of preventive and early intervention services for application in health care delivery programs or develops new knowledge on the impact of insurance coverage on health promotion.

2. Background

The Maternal and Child Health 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 the maternal and child health population. 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 Award

Funding will be provided in the form of a grant.

2. Summary of Funding

HRSA-15-062: R40 Maternal and Child Health Research (MCHR) Program
The MCH Research Program will provide funding during Federal fiscal years 2015 – 2017. Approximately $1,600,000 is expected to be available annually to fund approximately six (6) awardees. The actual amount available will not be determined until enactment of the final FY 2015 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. Applicants may apply for a ceiling amount of up to $300,000 total cost per year. The project period is three (3) years. Funding beyond the first year is dependent on the availability of appropriated funds for the MCH Research Program in subsequent fiscal years, satisfactory awardee performance, and a decision that continued funding is in the best interest of the Federal Government.

HRSA-15-077: R40 MCH Secondary Data Analysis Studies (SDAS)
The MCH Research Program will provide funding during Federal fiscal year 2015. Approximately $1,000,000 is expected to be available to fund approximately ten (10) awardees. The actual amount available will not be determined until enactment of the final FY 2015 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. Applicants may apply for a ceiling amount of up to $100,000 total cost. The project period is one (1) year.

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 eligibile 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 15-062), 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.

For the R40 MCH SDAS Program (HRSA-15-077), 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. These ceilings include 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 grants 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 a grant application is not allowable.
- A current PI of an MCH Research grant 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 grantee who currently has or in the past has had an R40 grant

cannot apply for a grant to follow longitudinally the population used in their previous R40 grant. 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-15-077) mechanism; and applications which involve collecting follow-up data on a population targeted in a grant 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-15-077). SDAS applications should propose the use of existing national data sets or State or local administrative records.
- Secondary data analysis projects will not be considered for funding under the multi-year R40 MCH Research (HRSA-15-062) grant 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-15-062) grant competition.
- Projects addressing autism will not be considered for either the multiyear R40 MCHR (HRSA-15-062) or the R40 MCH SDAS (HRSA-15-077) competitions.
- Projects addressing oral health will not be considered for the multiyear R40 MCHR (HRSA-15-062) competition.
- Projects which include the collection of biological specimens will not be considered for either the R40 MCHR (HRSA-15-062) or the R40 MCH SDAS (HRSA-15-077) competitions.

IV. Application and Submission Information

1. Address to Request Application Package

HRSA *requires* applicants for this funding opportunity announcement to apply electronically through Grants.gov. Applicants must download the SF-424 Research and Related (R&R) application package associated with this funding opportunity 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 funding opportunity announcement to do otherwise.

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 you to print your application to ensure it 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). For SDAS applications, 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 the list of key terms found in Appendix B, select a maximum of eight significant key terms that describe your project. You can also select an additional 9th key term that is not found in Appendix B. Include the selected significant key terms at the end of your abstract.

ii. *Project Narrative (All narrative sections below apply to both HRSA-15-062 and HRSA-15-077).*
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-14-007.** 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 change of 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. <u>**Specific Aims (Corresponds to Section V's Review Criteria: 1 Need, 2 Response and 3 Evaluative Measures):**</u>

List 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. State concisely the goals of the proposed research and summarize the expected outcome(s).

Identify relevance to MCHB Strategic Research Issues (Appendix A) and relationship to specific Healthy People 2020 objectives. Discuss how the research findings will strengthen and expand Affordable Care Act (ACA) implementation through policy and service delivery of preventive and early intervention services for application in health care delivery programs or develops new knowledge on the impact of insurance coverage on health promotion.

Needs Assessment (Corresponds to Section V's Review Criteria: 1 Need, 2 Response)

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 and its unmet health needs.

- As appropriate, include sociocultural determinants of health and health disparities impacting the population that the current project will address.

- Identify relevance to MCHB Strategic Research Issues (Appendix A) and relationship to specific Healthy People 2020 objectives. The applicant is responsible for explaining the project's relevance to an MCHB Strategic Research Issue.

- Discuss how the research will strengthen and expand Affordable Care Act (ACA) implementation.

Hypotheses and Specification of Variables (Corresponds to Section V's Review Criterion: 3 Evaluative Measures)

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 between the associations depicted by the graphic model, the table of variables, the statement of hypotheses, and the plan for data analysis.**

C. <u>Methodology/Research Strategy:</u>
Organize the Methodology/Research Strategy section in the specified order using the instructions provided below. Start each section with the appropriate section heading – Significance, Innovation, Work Plan/Approach. 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, Innovation, Work Plan/Approach) is limited to <u>12 pages in length</u> for R40 MCHR (HRSA-15-062). For SDAS (HRSA-15-077) applications, this section is limited to <u>6 pages in length</u>. 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.

a) *Significance (Corresponds to Section V's Review Criterion: 2 Response)*

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- 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.
- Describe the public health impact that study results are likely to have.
- Describe the extent to which study results will be national in significance.
- 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.

b) *Innovation (Corresponds to Section V's Review Criteri: 2 Response, 3 Evaluative Measures)*

- 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.

c) Work Plan/Approach (Corresponds to Section V's Review Criterion(a): 3 Evaluative Measures)

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.

- Include expected enrollment number and power analyses as appropriate.

- Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.

- Include a description of strategies for participant recruitment.

- Include demographic information on the participant population (i.e., targeted ages, expected racial/ethnic background and socioeconomic status, rural/urban, etc).

- For SDAS applications, include information regarding the database(s) you propose to use.

As applicable, also include the following information on Preliminary Studies as part of the Work Plan/Approach section of the Research Strategy.

Preliminary Studies: Include information on Preliminary Studies as part of the 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.

D. Resolution of Challenges (Corresponds to Section V's Review Criterion: 3 Evaluative Measures)

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, 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 grant competitions and limited availability of funding, it is important that the applicant address the feasibility of conducting and completing the study as proposed. Once funded, it is critical that the study is implemented and completed as proposed and approved.

- Discuss potential problems and alternative strategies.

- If the project is in the early stages of development, 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.

E. **Proposed Sequence or Timetable (Corresponds to Section V's Review Criterion: 3 Evaluative Measures)**

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. Provide assurance that the research team will conduct the study as designed.

F. **Evaluation and Technical Support Capacity (Corresponds to Section V's Review Criterion: 3 Evaluative Measures)**

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 in Section E 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.

G. **Dissemination Plan (Corresponds to Section V's Review Criterion(a): 4 Impact)**

Describe plans for dissemination of project results. State whether the project results are regional or national in scope and if they are replicable. It is expected that **R40 MCHR (HRSA-15-062)** research grantees will produce at least three (3) peer-reviewed publications per study and that **R40 MCH SDAS (HRSA-15-077)** research grantees will produce at least two (2) peer-reviewed publications resulting from their MCH Research project. The dissemination plan should include information on how you will accomplish this minimum number of publications. Past MCH Research Program grantees should demonstrate publications from their previous MCH research grant. (NOTE: Peer-reviewed publications are the cardinal measure of success of the MCH Research Program).

In addition to peer-reviewed publications, applicants must also include a plan to disseminate findings, reports, products, and/or grant project outputs to key target audiences, including researchers, providers, State Title V programs and programs that serve children with special health care needs, families potentially impacted by study findings, and the general public. In terms of communication channels, grantees may distribute research findings and information on other project activities through: targeted email messages, newsletter articles, conference presentations, webcasts, fact sheets, infographics, policy briefs and website and social media posts, as appropriate.

H. **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, e.g., 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.

I. Financing (Corresponds to Section V's Review Criterion: 6 Support Requested)
State whether this proposal has been submitted or will be submitted to any other Federal agency or private foundation for consideration and review.

J. Protection of Human Subjects (Corresponds to Section V's Review Criterion: 3 Evaluative Measures)
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.

K. Targeted/Planned Enrollment (Corresponds to Section V's Review Criterion: 3 Evaluative Measures)
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
  - 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-15-062)**, 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-15-077)**, describe how the analytic plan will reflect an understanding of and valuing the culture of the study population.

| ADDITIONAL 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**
Specific Aims (Needs Assessment, Specification of Variables	(1) Need, (2) Response and (3) Evaluative Measures
Methodology/Research Strategy (Significance, Innovation, Work Plan/Approach)	(2) Response and (3) Evaluative Measures
Resolution of Challenges	(3) Evaluative Measures
Evaluation and Technical Support Capacity	(3) Evaluative Measures
Dissemination Plan	(4) Impact
Organizational Information/Environment	(5) Resources/Capabilities
Financing	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.
Protection of Human Subjects	(3) Evaluative Measures
Targeted/Planned Enrollment	(3) Evaluative Measures

iii. *Budget*

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 grant-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.

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

The Consolidated Appropriations Act, 2014, Division H, § 203, (P.L. 113-76) 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 2015, 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, CISS projects, and other grant 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 grant 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 of 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*
Please provide the following items in the order specified below to complete the content of the application. Unless otherwise noted, attachments count toward the application page limit. Indirect cost rate agreements and proof of non-profit status, if applicable, will not count toward the page limit. **Each attachment must be clearly labeled**.

Attachment 1: Letters of Agreement/Letters of Support
   Provide any documents that describe working relationships between 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 deliverable. 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, and 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, if applicable.

Attachments 5-15: Other Relevant Documents
   Include here any other documents that are relevant to the application.

3. Submission Dates and Times

Application Due Date
The due date for applications under this funding opportunity announcement is *December 5, 2014 at 11:59 P.M. Eastern Time*.

4. Intergovernmental Review

The R40 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.

5. Funding Restrictions

Funds under these announcements (HRSA-15-062 and HRSA-15-077) may not be used for the following purposes: foreign travel.

HRSA-15-062: 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 government.

HRSA-15-077: 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 H, Title V of the Consolidated Appropriations Act, 2014 (P.L. 113-76), apply to the MCH Research 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 2015, as required by law.

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

V. Application Review Information

1. **Review Criteria (*All review criteria below apply to both HRSA-15-062 and HRSA-15-077*).**

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 and R40 Secondary Data Analysis Studies Programs have six *(6)* review criteria:

Criterion 1.	Need	10 points
Criterion 2.	Response	20 points
Criterion 3.	Evaluative Measures	40 points
Criterion 4.	Impact	10 points
Criterion 5.	Resources/Capabilities	10 points
Criterion 6.	Support Requested	10 points

TOTAL: 100 points

Criterion 1: NEED (10 points) *(Corresponds to Program Narrative Section B Specific Aims: Needs Assessment & Specification of Variables)*
The extent to which the application clearly and succinctly describes an important strategic MCH research problem/issue and associated contributing factors, as described in the MCHB Strategic Research Issues (Appendix A). The Bureau strongly encourages research studies that specifically address issues related to MCHB investments and programs.
- The extent to which the goals of the proposed research project are clearly and concisely summarized.
- The extent to which the specific questions to be answered by the study are clearly stated.

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 research project addresses an MCHB Strategic Research Issue (Appendix A).
- The extent to which the target population is clearly stated in the abstract and described in the application.

- 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).*
- The extent to which the research project addresses how it will strengthen and expand Affordable Care Act (ACA) implementation through policy and service delivery of preventive and early intervention services for application in health care delivery programs or develops new knowledge on the impact of insurance coverage on health promotion.

Specification of Variables
- 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.

Criterion 2: RESPONSE (20 points) *(Corresponds to Program Narrative Section: B Specific Aims: Needs Assessment; and C Research Strategy: Significance, & Innovation)*
The extent to which the proposed project describes a significant issue relevant to the health of maternal and child populations, presents clear and logically derived hypotheses and goals, and proposes an innovative solution, intervention or strategy.

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.
- The extent to which the goals and objectives are clear, concise and appropriate.
- The extent to which there is congruence among the associations depicted by the graphic model, the table of variables, the statement of hypotheses, and the plan for data analysis.

Significance
- The extent to which the project addresses a critical problem or barrier to progress in the 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 the expected outcomes are likely to have an impact on the research field(s) and/or care delivery strategies involved.
- The degree to which the proposed project will have a sustained and powerful influence on the research field.
- 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 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 and/or the likelihood for the project to exert a sustained influence on the research field(s) involved.

Innovation
- 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 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.

Criterion 3: EVALUATIVE MEASURES (40 points) *(Corresponds to Program Narrative Section: B Specific Aims; C Research Strategy: Work Plan/Approach; D Resolution of Challenges; E Proposed Sequence or Timetable; F Evaluation and Technical Support Capacity; J Protection of Human Subject; & K Targeted/Planned Enrollment Table)*

The extent to which the scientific activities described in the application are capable of addressing the problem and attaining the project objectives. The effectiveness of the methods proposed to conduct 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.

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 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.

Scientific and Technical Merit:
- The extent to which the overall scientific approach is thoughtful, logical, and original.
- The appropriateness of the research plan and methodologies described.
- The extent to which the research plan is coherent as a whole.

Tests and Measurements:
- The extent to which data gathering procedures are described.
- 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 validity for intended measurements, e.g., self-reported blood pressure, parent-reported anthropometric data. (NOTE: The SDAS grant program does not support analysis of data previously collected by the applicant PI).

Study Design:
- 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 the 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 and criteria for entering the study are well defined.
- 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.

Population Description and Sampling Plan:
- 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.

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.

Resolution of Challenges and Evaluation Capacity
- The proposed performance and continuous improvement plan must be able to assess to what extent the project objectives are being met according to the timeline provided.
- Are potential problems, alternative strategies, and benchmarks for success presented?
- If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
- The extent to which the proposed project is feasible in terms of participant recruitment, as well as in terms of conducting and completing the study as proposed within the given time frame.

- 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).

Protection of Human Subjects:
- The extent to which adequate protections are afforded to human subjects.
- 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.
- 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).

CRITERION 4: IMPACT (10 points) *(Corresponds to Program Narrative Section: G Dissemination Plan)*
The Bureau strongly encourages research studies that specifically address issues with expected broad public health impact.

- 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., three (3) publications expected for each **R40 MCH Research (HRSA-15-062)** study and two (2) publications expected for each **R40 SDAS (HRSA-15-077)** study).
- If the investigators are past MCH Research Program grantees, the extent to which they have demonstrated publication success from their previous grant(s).
- The extent of plans for dissemination of project results.

CRITERION 5: RESOURCES/CAPABILITIES (10 points) *(Corresponds to Program Narrative Section: Preliminary Studies in C Evaluative Measures: Work Plan/Approach; H Organizational Information/Environment; Staffing Plan in Budget Narrative; and Biographical Sketches)*
The extent to which project personnel are qualified by training and/or experience to implement and carry out the research project. 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 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 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.
- The extent to which all key personnel have indicated other current and pending support in their biographical sketches. (Note: A current PI of an MCH Research grant can serve for no more than 10% time on a new proposal).
- 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 grantees, the degree to which they demonstrate publication success from their previous grant(s).

CRITERION 6: SUPPORT REQUESTED (10 points) *(Corresponds to Program Narrative Section: I Financing; and Budget Forms and Budget Justification)*
The reasonableness of the proposed budget in relation to the objectives, the complexity of the research activities, and the anticipated results.

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

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.

3. Anticipated Announcement and Award Dates

It is anticipated that awards will be announced prior to the start date of April 1, 2015.

VI. Award Administration Information

1. Award Notices

The Notice of Award will be sent prior to the start date of April 1, 2015. 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, grantees 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 funding opportunity announcement 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-15-077))**   The awardee must submit a progress report to HRSA on an **annual** basis. Further information will be provided in the award notice.

2. **Mid-Project Progress Report(s).** For **R40 MCH Research (HRSA-15-062)**, submit a **Mid-Project Progress Report**. For **R40 MCH SDAS (HRSA-15-077)**, submit a **Mid-Year Progress Report**. Further information will be provided in the NoA.

3. **Comprehensive Final Report.** A comprehensive final report is due within 90 days after the project period ends. The final report collects program-specific goals and progress on strategies; core performance measurement data; impact of the overall project; the degree to which the grantee achieved the mission, goal and strategies outlined in the program; grantee objectives and accomplishments; barriers encountered; and responses to summary questions regarding the grantee's overall experiences over the entire project period. The final report must be submitted on-line by awardees in the Electronic Handbooks system at https://grants.hrsa.gov/webexternal/home.asp.

4. **Dissemination.** Grantees 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. Grantees 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 contribute to the total number of publications by which the MCH Research Program is evaluated annually.

5. **Performance Report(s).** The Health Resources and Services Administration (HRSA) has modified its reporting requirements for SPRANS projects, CISS projects, and other grant 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 grant 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 grant funds will be required, within 120 days of the Notice of Award (NoA), to register in HRSA's Electronic Handbooks (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 grant award amount, the project abstract and other grant summary data as well as providing objectives for the performance measures.

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

   c) **Project Period End Performance Reporting**

   Successful applicants receiving grant 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 grant 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 funding opportunity announcement by contacting:

    Janene P. Dyson
    Grants Management Specialist
    Maternal, Child & Health Systems Branch
    HRSA, Division of Grants Mgmt. Operations
    Parklawn Building, Room 10W03B
    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, and Hae Young Park, MPH
    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) 443-2207
    Fax: (301) 480-0508
    E-mail: rharwood@hrsa.gov; hpark@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/awardees 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 Call 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

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/

Logic Models:

Additional information on developing logic models can be found at the following website:
http://www.cdc.gov/nccdphp/dnpao/hwi/programdesign/logic_model.htm.

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

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

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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. **They 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** [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 and 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 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. **They 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. **They 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. **They 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

Access to Health Care
Acculturation
ADD/ADHD
Asthma
Autism

Breastfeeding

Capacity & Personnel
Cesarean
Child Care
Chronic Illness
Clinical Practice
Cognitive & Linguistic Development
Coordination of Services
Cost Effectiveness
Cultural Competence

Depression
Developmental Disabilities
Down Syndrome

Early Childhood Education
Early Intervention
Emergency Care

Fathers

Health Care Costs
Health Care Utilization
Health Disparities
Health Education & Family Support
Home Visiting
Hospitalization

Immigrant Populations
Immunization
Infections & Illness

Labor & Delivery
Low Birthweight

Medicaid, SCHIP, & Health Insurance
Medical Home
Mental Health & Wellbeing
Mortality

Neighborhood
Nutrition & Diet

Obesity & Weight Gain
Oral Health

Parent-Child Relationship
Parenting
Perinatal
Physical Activity
Physical Growth
Postpartum
Pregnancy
Preconception Health
Preterm
Primary Care

Rural
Risk Behaviors

Safety
School Health Programs
School Outcomes & Services
Screening
Sexually Transmitted Diseases
SIDS
Sleep
Smoking
Social & Emotional Development
Special Health Care Needs
Stress
Substance Use

Telehealth & Health Information Technology
Trauma & Injury

Violence & Abuse

Well-Child Pediatric Care