U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Maternal and Child Health Bureau
Office of Epidemiology and Research

R40 Maternal and Child Health (MCH)
Secondary Data Analysis Research (SDAR) Program

Funding Opportunity Number: HRSA-18-072
Funding Opportunity Type(s): New, Resubmission
Catalog of Federal Domestic Assistance (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2018

Application Due Date: January 8, 2018

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

Issuance Date: November 6, 2017

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), Office of Epidemiology and Research is accepting applications for fiscal year (FY) 2018 R40 Maternal and Child Health (MCH) Secondary Data Analysis Research (SDAR) Program. The purpose of this program is to advance the health and wellbeing of maternal and child populations through applied and translational research on policy and service delivery issues through 1-year grants for secondary analyses of existing national datasets and/or administrative records.

Funding Opportunity Title:	R40 Maternal and Child Health (MCH) Secondary Data Analysis Research (SDAR) Program
Funding Opportunity Number:	HRSA-18-072
Due Date for Applications:	January 8, 2018
Anticipated Total Annual Available FY18 Funding:	$500,000
Estimated Number and Type of Award(s):	Up to 5 grants
Estimated Award Amount:	Up to $100,000
Cost Sharing/Match Required:	No
Project Period/Period of Performance:	July 1, 2018 through June 30, 2019 (1 year)
Eligible Applicants:	Only public or non-profit institutions of higher learning and public or private non-profit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs are eligible to apply (42 CFR § 51a.3(b)). In addition, non-U.S. entities are not eligible to apply. See Section III-1 of this notice of funding opportunity (NOFO), formerly known as the funding opportunity announcement (FOA), for complete eligibility information.

Application Guide

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

Technical Assistance

The following technical assistance conference call has been scheduled:

Webinar

Day and Date: Monday, November 20, 2017
Time: 1:30 - 2:30 p.m. ET
Call-In Number: 1-888-989-4611
Participant Code: 2833358
Weblink: https://hrsa.connectsolutions.com/ta_hrsa_18_072/

Replay (available 1-hour after the call ends)
Toll free number: 1-866-507-3579
Passcode: 2540

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I. Program Funding Opportunity Description

1. Purpose

This announcement solicits applications for the R40 Maternal and Child Health (MCH) Secondary Data Analysis Research (SDAR) Program. The MCH SDAR program supports applied MCH research that exclusively utilizes the secondary analysis of existing national databases and/or administrative records to improve the health and well-being of MCH populations.

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

- Strengthen and expand topics addressed by the new MCH Block Grant National Performance Domains (see Appendix C for list of MCH Block Grant Performance Domains). For more background materials on the MCH Block Grant, see: http://mchb.hrsa.gov/programs/titlevgrants/index.html. By supporting research on HRSA/MCH program populations, the R40 MCH program aims to inform HRSA/MCHB's other investments and programs, see: https://mchb.hrsa.gov/maternal-child-health-initiatives. For instance, the life course perspective has been integrated into MCHB's strategic research issues (see Appendix A), and can serve as a helpful frame of reference for study proposals designed to address the critical MCH questions defined by HRSA;
- Address MCHB Strategic Research Issues (see Appendix A) such as improving public health systems and infrastructure, reducing health inequalities, increasing quality of and access to care, and/or promoting the health of MCH populations;
- Address the U.S. Department of Health and Human Services' (HHS) clinical priorities, namely mental health, childhood obesity, and opioid abuse. Proposals must indicate how study findings will further develop the evidence base for the aforementioned clinical priorities; and
- Address emerging research topics of regional and national significance that highlight new data, knowledge, evidence, and strategies for addressing the burden of diseases.

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

- Conduct applied or translational research on critical and emerging MCH issues through appropriate secondary analyses of existing national databases and/or administrative records, that are aligned with research goals;
- Develop and submit a dissemination plan for the distribution of research findings and products to scientific, professional, and lay audiences. Dissemination activities include development and publication of at least two peer-reviewed manuscripts, but are not limited to, conference presentations, newsletter articles, webcasts, fact sheets, infographics, policy briefs, websites, and social media posts, as appropriate;
- Report study sample information with regards to diversity (i.e., ethnicity, race, gender/sex, geographic location, and socioeconomic status) to HRSA;
- Extend the reach and impact of research activities by leveraging additional funding from other sources.

2. Background

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

Findings from the research supported by the R40 MCH SDAR program are expected to strengthen and expand activities addressed in the MCH Block Grant National Performance Domains and MCHB Strategic Research Issues (Appendix A) ultimately affecting Title V populations.

The R40 MCH SDAR program is the only federal program that supports research focused on improving the quality, efficiency, and accessibility of health care service delivery as related to health promotion and disease prevention among MCH populations through secondary analysis of extant national databases and/or administrative records. For example, findings from prior supported research has improved knowledge on the relationship between nighttime sleep duration and childhood obesity.[1] This study demonstrated that younger children (ages 0-4) with short durations of nighttime sleep were at greater risk for becoming overweight or obese. However, this association did not exist for older children (ages 5-13). The MCH SDAR program focuses on current as well as emerging MCH policy and service delivery issues.

The MCH Research Program, in MCHB's Office of Epidemiology and Research, administers the R40 MCH SDAR Program. The MCH Research Program has supported groundbreaking studies that have significantly influenced clinical practice, organization and delivery of health care services, preventive care, and early intervention for the MCH population, including children with special health care needs. More information about the MCH SDAR Program, funded projects, and current activities can be found at http://www.mchb.hrsa.gov/research.

[1]Bell, JF, Zimmerman, FJ. Shortened Nighttime Sleep Duration in Early Life and Subsequent Childhood Obesity. *Archives of Pediatrics and Adolescent Medicine*. 2010; 164(9): 840-845. doi: 10.1001/archpediatrics.2010.143.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New, Resubmission[2]

HRSA will provide funding in the form of a grant.

2. Summary of Funding

Approximately $500,000 is expected to be available to fund five (5) recipients for one year. You may apply for a ceiling amount of up to $100,000 total cost (includes both direct and indirect, facilities and administrative costs). The actual amount available will not be determined until enactment of the final FY 2018 appropriation. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, applications can be processed and funds awarded in a timely manner. The project period is July 1, 2018 through June 30, 2019 (1 year).

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

III. Eligibility Information

1. Eligible Applicants

Only public or non-profit institutions of higher learning and public or private non-profit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs are eligible to apply (42 CFR § 51a.3(b)). Faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply, if they otherwise meet these eligibility criteria. Non-U.S. entities are not eligible to apply.

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

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

Applications that exceed the ceiling amount will be considered non-responsive and will not be considered for funding under this notice.

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

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

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

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates) an application is submitted more than once prior to the application due date, HRSA will only accept your **last** validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

Due to funding limitations and in order to diversify the R40 portfolio, the following additional application responsiveness criteria apply to the R40 MCH SDAR Program. All applications that do not comply with these requirements will be deemed non-responsive and will not be considered for funding under this notice.

- An individual cannot be named as the Project Director (PD) or Principal Investigator (PI) for multiple applications for the R40 MCH SDAR competition.
- A current PI of an MCH Research award can serve for no more than 10 percent time on a new proposal;
- Applications to analyze pre-existing longitudinal data are allowed;
- Analysis of secondary data previously collected by the applicant PI will not be considered for funding;
- Applications must propose the use of existing national datasets and/or administrative records;
- All secondary analyses, including those that involve the linkage of multiple datasets, must be submitted to the R40 SDAR competition, and cannot exceed 1 year in length;
- Projects addressing autism spectrum disorder will not be considered for the R40 MCH SDAR competition (a separate competition for Autism Secondary Data Analysis Research Studies (Autism SDAR) Program may be held, if funds are available); and
- Projects that include the collection of biological specimens will not be considered, as this program funds translational research on underserved MCH populations and allows the use of existing databases and administrative data.

IV. Application and Submission Information

1. Address to Request Application Package

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

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

HRSA recommends that you supply an email address to Grants.gov on the grant opportunity synopsis page when accessing the notice of funding opportunity (NOFO) (also known as "Instructions" on Grants.gov) or application package. This allows Grants.gov to email organizations that supply an email address in the event the NOFO is changed and/or republished on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or nonresponsive application. *Please note you are ultimately responsible for reviewing the Find Grant Opportunities page for all information relevant to desired opportunities.*

2. Content and Form of Application Submission

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

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

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

In addition to the overall 80-page limit, please note that the Methodology/Research Strategy of the application narrative is STRICTLY LIMITED TO 6 PAGES. Applications that do not adhere to the stated page limit for this Section of their narrative will be deemed nonresponsive and will not be considered for funding under this notice.

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

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

1) The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
3) Where the prospective recipient is unable to attest to the statements in this certification, an explanation shall be included in Attachments 6-15: Other Relevant Documents.

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

Temporary Reassignment of State and Local Personnel during a Public Health Emergency

Section 201 of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), Public Law 113-5 amends section 319 of the Public Health Service (PHS) Act to provide the Secretary of the Department of Health and Human Services (HHS) with discretion to authorize the temporary reassignment of state, tribal, and local personnel during a declared federal public health emergency upon request by a state or tribal organization. The temporary reassignment provision is applicable to state, tribal, and local public health department or agency personnel whose positions are funded, in full or part, under PHS programs and allows such personnel to immediately respond to the public health emergency in the affected jurisdiction. Funds provided under the award may be used to support personnel who are temporarily reassigned in accordance with section 319(e). This authority terminates September 30, 2018. Please reference detailed information available on the Assistant Secretary for Preparedness and Response (ASPR) website via http://www.phe.gov/Preparedness/legal/pahpa/section201/Pages/default.aspx.

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

i. *Project Abstract*
See Section 4.1.ix of HRSA's *SF-424 R&R Application Guide*. In addition, clearly indicate the NOFO number/title. Briefly state the principal needs and problems addressed by the project, including the project's relationship to MCHB Strategic Research Issues (Appendix A). Also briefly describe the research design and methods within the abstract and include data collection methods and participant information (i.e., age range and demographic background of target population) for the database that you propose to use in your analysis. In addition, your application 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 key terms for (a) content, (b) populations, and (c) age ranges targeted at the end of your abstract.

ii. *Project Narrative*
This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project.

Successful applications will contain the information below. Please use the following section headers for the Narrative:

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

For a resubmission of a previously reviewed proposal, begin the Introduction by specifying that it is a resubmission; state the application/tracking number of the prior submission, its title, and HRSA notice number of the prior submission. **Example: This is a resubmission of application #, 'Determinants of Racial Disparities in Infant Mortality Rates,' that was submitted for HRSA-15-062.** There is no limitation to the amount of time lapsed from initial submission of an application to resubmission; however, 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**; and

- The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or changing the typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. The Preliminary Studies/Progress Report section should incorporate work completed since the prior version of the application was submitted.

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

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

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

Alignment with HRSA/MCHB Goals, HHS Clinical Priorities, 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 the MCH Block Grant National Performance Domains (Appendix C) and the populations they serve.
- Discuss how the research findings will strengthen and expand topics identified among the HHS clinical priorities such as mental health, childhood obesity, and opioid abuse.
- Identify the relationship to specific Healthy People 2020 objectives.

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

Goals and Objectives

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

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

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

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

- Describe the background literature, with focus on its pertinence to and rationale for the current research problem.
- Explain the critical problem or barrier to progress in the field that the proposed 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 Criterion 3 Evaluative Measures

- Describe the overall study design, strategy, methodology, and analyses you will use to accomplish the specific aims of the project.
- Describe the procedures for data collection and instrumentation as appropriate.
- Describe the study sample. Include demographic information on the participant population (i.e., targeted ages, racial/ethnic background and socioeconomic status, geographic location, 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 you will collect, analyze, and interpret the data, as well as any resource sharing plans as appropriate.
- Include information regarding the database(s) you propose to use; written confirmation of the availability of the database for the proposed study should be included in Attachment 1.
- 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 Section (2) Work Plan/Approach section. Use this section to provide an account of the PD/PI's preliminary studies pertinent to this application. This information will also help to establish the experience and competence of the investigator to pursue the proposed project. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.

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

- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe the impact that the results of the proposed research will exert on the research field(s) involved.
- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, policies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, policies, or interventions.

- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, policies, or interventions.
- Describe how the concepts, methods, technologies, treatments, services, policies, or preventive interventions that drive this field will be changed if the proposed aims are achieved.

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

Public Health Impact

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

Publication and Dissemination Plan

- Describe plans for dissemination of project results.
- Include information on how you will accomplish delivering the required minimum of two peer-reviewed publications resulting from the MCH research project
- In addition to peer-reviewed publications, you must demonstrate a plan to advance the transfer of findings into practice by disseminating findings, reports, and/or project outputs to key target audiences, including scientific, professional, and lay audiences. 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. RESOURCES/CAPABILITIES -- Corresponds to Section V's Review Criterion 5 Resources/Capabilities

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

Organizational Facilities and Other Resources

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

Qualifications of Research Team's Key Personnel

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

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

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

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

- **Personal Statement**
  Briefly describe why you are well-suited for your role(s) in the project described in this application. The relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may

mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

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

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

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

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

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

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

Proposed Sequence or Timetable

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

Resolution of Challenges

- 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 staff training, putting culturally/linguistically competent project staff in place quickly, etc.
- Discuss alternative strategies should any of these potential challenges arise.
- Discuss the feasibility of reaching targeted/planned enrollment levels.
- Describe any strategy to establish the feasibility of the proposed work, and to address the management of any high-risk aspects of the proposed work.
- If appropriate, point to any procedures, situations, or materials that may be hazardous to personnel, and precautions 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 analysis begun by month 6, etc.). The purpose is to monitor ongoing processes and the progress towards the aims and objectives of the project.

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

- If human subjects are involved, the project should be in compliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR Part 46) (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). Please refer to instructions provided in HRSA's SF-424 R&R Application Guide, Appendix

Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy for specific instructions on preparing the human subjects section of the application.

- This section is required if you answer "yes" to the question "Are human subjects involved?" on the R&R Other Project Information form. If the answer is "No" to the question but the proposed research involves data from human subjects, you must provide a justification in this section for the claim that no human subjects are involved.
- Discuss plans to seek Institutional Review Board (IRB) approval or exemption. IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent the page limits of the Methodology/Research Strategy section.

I. DATA AVAILABILITY AND DIVERSITY OF DATABASE SAMPLE – Corresponds to Section V's Review Criterion 7 Program Assurances

- Provide details about the diversity of the sample selected for the study/analysis. Information should include study sample totals by:
    - Ethnic Category (Hispanic Heritage): "Hispanic or Latino" or "Not Hispanic or Latino"
    - Gender/sex distribution within each Ethnic Category (Hispanic Heritage)
    - Total distribution 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/sex distribution within each racial category
    - Total participants by racial category
    - Socioeconomic status
    - Geographic Location
        - Urban
        - Rural

- The "Ethnic Category (Hispanic Heritage): Total of All Participants" must be equal to the "Racial Categories: Total of All Participants." Also list any proposed racial/ethnic subpopulations, if applicable.
- The "Total Sample" means the number of subjects in the dataset that will be used to evaluate the research question. They 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 analytic plan will reflect an understanding and valuing of the culture of the study population.

- Provide written confirmation that the proposed data that will be used for the R40 MCH SDAR project are available to the investigator, including information such as name of dataset, year of dataset, and date of data availability, and correspondence from the organization overseeing the dataset.

NARRATIVE GUIDANCE To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.		
Narrative Section	Review Criteria	Points
A. Introduction (for resubmission only)	Not Applicable--For Resubmissions Only	N/A
B. Specific Aims: 1) Needs and Alignment	(1) Need	10
B. Specific Aims: 2) Goals and Hypotheses	(2) Response	20
C. Methodology/Research Strategy: 1) Significance	(2) Response	
C. Methodology/Research Strategy: 2) Work Plan/Approach	(3) Evaluative Measures	20
C. Methodology/Research Strategy: 3) Scientific Innovation and Importance	(4) Impact	20
D. Impact and Dissemination	(4) Impact	
E. Resources and Capabilities	(5) Resources/Capabilities	10
Budget and Budget Justification	(6) Support Requested	10
F. Feasibility	(7) Program Assurances	10
G. Evaluation and Technical Support Capacity	(7) Program Assurances	
H. Protection of Human Subjects	(7) Program Assurances	
I. Data Availability and Diversity of Database Sample	(7) Program Assurances	
Total Points		**100**

iii. *Budget*

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

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

The Consolidated Appropriations Act, 2017 (P.L. 115-31), Division H, § 202 states "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." Please see Section 4.1.iv Budget – Salary Limitation of HRSA's *SF-424 R&R Application Guide* for additional information. Note that these or other salary limitations may apply in FY 2018, as required by law.

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

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

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

v. *Program-Specific Forms*
Program-specific forms are not required for application.

vi. ***Attachments***
Please provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. **Each attachment must be clearly labeled**.

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

Attachment 2: Key Publications or Condensed Citations with Abstracts.
A list of citations for key publications by the key personnel that are relevant to the proposal can be included. Do not include unpublished theses, or abstracts/

manuscripts **submitted** (but not yet accepted) for publication. In consideration of the 80-page limitation, a list of citations only may be included.

Attachment 3: Surveys, Questionnaires, Data Collection Instruments, Clinical Protocols.

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

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

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

Attachments 6-15: Other Relevant Documents

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

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

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

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

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

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

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

If you fail to allow ample time to complete registration with SAM or Grants.gov, you will not be eligible for a deadline extension or waiver of the electronic submission requirement.

4. Submission Dates and Times

Application Due Date
The due date for applications under this NOFO is *January 8, 2018 at 11:59 p.m. Eastern Time*.

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

5. Intergovernmental Review

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

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

6. Funding Restrictions

Funds under this notice (HRSA-18-072) may not be used for travel outside of the U.S.

Applicants may request funding for a project period of 1 year, at no more than $100,000 total cost (direct plus indirect expenses).

The General Provisions in Division H of the Consolidated Appropriations Act, 2017 (P.L. 115-31) apply to this program. Please see Section 4.1 of HRSA's *SF-424 R&R Application Guide* for additional information. Note that these or other restrictions will apply in FY 2018, as required by law.

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

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative(s) applied to the award(s) under the program will be addition. Post-award requirements for program income can be found at 45 CFR § 75.307.

V. Application Review Information

1. Review Criteria

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

These criteria are the basis upon which the reviewers will evaluate and score the merit of the application. The entire proposal will be considered during objective review.

Review criteria are used to review and rank applications. The R40 MCH SDAR Program has seven (7) review criteria:

Criterion 1.	Need	10 points
Criterion 2.	Response	20 points
Criterion 3.	Evaluative Measures	20 points
Criterion 4.	Impact	20 points
Criterion 5.	Resources/Capabilities	10 points
Criterion 6.	Support Requested	10 points
Criterion 7.	Program Assurances	10 points
TOTAL:		100 points

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

B. Specific Aims: 1) Needs and Alignment

Needs Assessment

- The extent to which the target population characteristics (i.e., including age ranges of children/youth) are clearly stated in the abstract and described in the application.
- 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.

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

- The extent to which the research project addresses an MCHB Strategic Research Issue (Appendix A).
- The extent to which findings from the research supported by the MCH Research Program are likely to strengthen and expand topics identified by the HHS clinical

priorities, and align with the MCH Block Grant National Performance Domains, and the populations they serve (Appendix C).

- The extent to which the research project identifies its relationship to specific Healthy People 2020 objectives. (See HRSA's *SF-424 R&R Application Guide*, *Section 2.2: Administrative and National Policy Requirements).*

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

C. Specific Aims: 2) Goals and Hypotheses (10 points)

Goals and Objectives

- The extent to which the application clearly and succinctly lists the project's goals and specific objectives.
- The extent to which the goals and objectives are SMART (specific, measurable, achievable, relevant, and time bound).
- The extent to which the application clearly and succinctly summarizes expected outcomes, with attention to how these outcomes will address the unmet needs of the targeted population.

Hypotheses and Specification of Variables

- The extent to which the proposal clearly and succinctly presents the specific questions the study will answer, including not only hypotheses, but also justifications for the hypotheses.
- The extent to which the application clearly states hypotheses and clearly defines variables.
- The extent to which the 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 a graphic analytic model (if included), the table of variables, the statement of hypotheses, and the plan for data analysis.

C. Methodology/Research Strategy: 1) Significance (10 points)

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 to include HHS clinical priorities.

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

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

Study Design *(5 points)*

- The appropriateness of the research plan and methodologies described.
- The extent to which the overall strategy, methodology, and analyses are well-reasoned and appropriate to accomplish the specific aims of the project.
- The appropriateness of the study design to answer the research questions.
- The degree to which 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 degree to which the project activities are replicable and generalizable.
- As appropriate, the extent to which the project reflects an understanding and value of the culture of the target population in the research project.
- 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 *(5 points)*

- The extent to which instruments were selected or developed and were adequate and appropriate for the data in the selected database.
- The extent to which adequate attention was given to reliability and validity of instruments (psychometric properties).
- The extent to which any self-reported data can provide convincing validity for intended measurements, e.g., self-reported blood pressure, parent-reported anthropometric data.
- The extent to which the data are available to the investigator and are appropriate for this study. **The application must contain written**

confirmation that the proposed data to be used in the analysis are available to the investigator. (NOTE: This award program does not support analysis of data previously collected by the applicant PI).

Population Description and Sampling *(5 points)*

- The degree to which the study population is described (i.e., targeted age or age ranges, sex/gender, racial/ethnic background, socioeconomic status, geographic location, 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 the application describes expected differences between groups in terms of statistical as well as clinical significance.
- The extent to which there is a basis for anticipating the quality of sample estimates and the degree to which the quality is adequate for the purpose of the study.
- The extent to which the proposed inclusion of members of selected study populations are justified in terms of the scientific goals and research strategy proposed.

Plan for Data Analysis *(5 points)*

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

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

C. Methodology/Research Strategy: 3) Scientific Innovation and Importance (10 points)

- The degree to which the proposed project will have a sustained 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 preventive interventions that drive this field.
- The extent to which the application challenges and seeks to shift current research or clinical practice paradigms by utilizing innovative theoretical concepts, approaches or methodologies, instrumentation, or interventions.
- The extent to which the concepts, approaches or methodologies, instrumentation, or interventions are novel to one field of research or novel in a broad sense.
- The extent to which a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions is proposed.
- The extent to which the overall scientific approach proposes an innovative solution, intervention or strategy.
- The extent to which project results are likely to exert a sustained influence on the research field(s) involved.

D. Impact and Dissemination (10 points)

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 and/or strengthening and expanding the evidence base for the HHS priorities.
- The extent to which the problem addressed by the proposed research is unique to a community or region or is one of national proportion.
- The extent to which the findings will be generalizable and of regional and national significance.
- The extent to which the proposed study specifically addresses challenges with expected broad public health impact.
- The extent to which the number of mothers or children affected by the problem or who will benefit from the research is significant.

Publication and Dissemination Plan

- The extent to which there is a feasible and appropriate publication and dissemination plan described.
- The degree to which the applicant has a sound plan for how they will meet the expectation to produce the expected minimum number of peer-reviewed publications (i.e., two publications expected for each R40 SDAR (HRSA-18-072) project).

- The degree to which the PI and other key personnel demonstrate current and/or past success in publishing the findings of their research. In particular, if investigators are past MCH SDAR recipients, the degree to which they demonstrate publication success from their previous award(s).
- The extent to which the proposal clearly demonstrates a plan to advance the transfer of findings into practice by disseminating findings, reports, and/or award project outputs to key target audiences, including researchers, providers, State Title V and children with special health care needs programs and other program(s) serving MCH populations, policymakers, families and the general public.

CRITERION 5: RESOURCES/CAPABILITIES (10 points)

E. Resources/Capabilities

Organizational Facilities and Resources *(5 points)*

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

Qualifications of Research Team -- Corresponds to (a) Preliminary Studies in C. Methodology/Research Strategy Work Plan/Approach; (b) Staffing Plan in Budget Narrative; and (c) Biographical Sketches in Program Narrative Section E. *(5 points)*

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

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

- The reasonableness of the proposed budget in relation to the objectives, the complexity of the research activities, and the anticipated results.
- The extent to which costs as outlined in the budget and required resources sections are reasonable given the scope of work.
- The extent to which budget line items are well described and justified in the budget justification.
- The extent to which time allocated by key personnel is realistic and appropriate to achieve project objectives.
- The extent to which the application describes other current and pending support.

CRITERION 7: PROGRAM ASSURANCES (10 points) -- Corresponds to F. Feasibility; G. Evaluation and Technical Support Capacity; H. Protection of Human Subjects; and I. Data Availability and Diversity of Database Sample

F. Feasibility (3 points)

Proposed Sequence or Timetable

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

Resolution of Challenges

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

G. Evaluation and Technical Support Capacity (3 points)

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

H. Protection of Human Subjects (1 point)

- The extent to which adequate protections are afforded to human subjects, including children and youth, and the extent to which measures are in place to ensure the security of the research data (data security).

- The extent to which the proposal complies with the HHS regulations for protection of human subjects (45 CFR Part 46). See the instructions in HRSA's SF-424 R&R Application Guide, Appendix: Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy.
- The extent to which the applicant discusses plans to seek Institutional Review Board (IRB) approval. IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects.

I. Data Availability and Diversity of Database Sample (3 points)

- The extent to which the proposal provides details assuring the availability and access to the database/administrative record proposed for use in the study.
- The extent to which the proposal provides details on how the applicant proposes to include a sample that reflects diversity regarding ethnicity, race, gender/sex, geographic location, and socioeconomic status.
- The extent to which the application targets appropriate diversity in the database sample.
- The extent to which the project provides assurance regarding considerations for cultural competence in the proposed analysis as appropriate.

2. Review and Selection Process

The independent review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. In addition to the ranking based on merit criteria, HRSA approving officials may also apply other factors in award selection, (e.g., geographical distribution), if specified below in this NOFO. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

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

3. Assessment of Risk and Other Pre-Award Activities

HRSA may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements (45 CFR § 75.205).

Applications receiving a favorable objective review are reviewed for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. You may be asked to submit additional programmatic or administrative information (such as an updated budget or "other

support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that an award will be made. Following review of all applicable information, HRSA's approving and business management officials will determine whether an award can be made, if special conditions are required, and what level of funding is appropriate.

4. Anticipated Announcement and Award Dates

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

VI. Award Administration Information

1. Award Notices

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

2. Administrative and National Policy Requirements

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

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

3. Reporting

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

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

The updated and final reporting package incorporating all OMB accepted changes can be reviewed at (OMB Number: 0915-0298 Expiration Date: 06/30/2019):

https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection

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

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

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

3) **Performance Reports.** HRSA has modified its reporting requirements for Special Projects of Regional and National Significance projects, Community Integrated Service Systems projects, and other grant/cooperative agreement programs administered by MCHB to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). GPRA requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act.

   a) Performance Measures and Program Data

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

   b) Performance Reporting Timeline

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

   Performance reporting is conducted for each year of the project period. Recipients will be required, within 120 days of the NOA, to enter HRSA's EHBs and complete the program-specific forms. This requirement includes providing expenditure data, finalizing the abstract and

grant/cooperative agreement summary data as well as finalizing indicators/scores for the performance measures.

c) Project Period End Performance Reporting

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

VII. Agency Contacts

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

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

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

Deborah Linares, PhD, MA
Program Officer, Division of Research, Office of Epidemiology and Research
Attn: R40 MCH SDAR Research Program
Maternal and Child Health Bureau, HRSA
Health Resources and Services Administration
5600 Fishers Lane, Room 18N-198
Rockville, MD 20857
Telephone: (301) 443-2410
Fax: (301) 480-0508
Email: dlinares@hrsa.gov

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

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

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks. For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday-Friday, 8 a.m. to 8 p.m. ET, excluding federal holidays at:

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

VIII. Other Information

Logic Models

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

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

Technical Assistance

The following technical assistance webinar has been scheduled:

Webinar

Day and Date: Monday, November 20, 2017
Time: 1:30 - 2:30 p.m. ET
Call-In Number: 1-888-989-4611
Participant Code: 2833358
Weblink: https://hrsa.connectsolutions.com/ta_hrsa_18_072/

Replay (available 1-hour after the call ends)
Toll free number: 1-866-507-3579
Passcode: 2540
Weblink: https://hrsa.connectsolutions.com/hrsa_18_072/

Relevant Websites

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

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

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

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

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

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

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

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

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

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

IX. Tips for Writing a Strong Application

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

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

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

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

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

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

- **Effectiveness of Screening Programs for Women:** Study the individual, system, and community factors associated with screening and assessment programs that lead to referral and utilization of intervention for risk factors such as substance abuse and other conditions (e.g., obesity, diabetes) that may affect health outcomes for women and/or their children.

- **Integrated systems of care specifically identified in Title V legislation for Children with Special Health Care Needs (CSHCN):** Determine the impact of **Care Coordination Services** provided in the medical home and other settings on child and family outcomes for CSHCN.

- Study public-private partnership models for provision of services, such as public health provision of “wrap around” or “enabling” services, and their overall relative efficacy when compared with models comprised of private practice or public clinics only.

- Investigate the processes involved in the **transition of adolescents** with special health care needs to adult health care, particularly the role of state health systems in facilitating or hindering transitions.

- Investigate the effects of the organization and delivery of comprehensive, continuous services on the health status and services utilization of children/adolescents, including those with special health care needs and those vulnerable for poor psychosocial outcomes (e.g., children/youth in foster care, involved with the juvenile justice system, or who are homeless).

- Assess the impact of integration of the newborn screening program (NBS) on other MCH programs and enhanced data sharing at the state level and evaluate if screened children have access to **medical homes**.

- Assess emerging research in the prevention of dental caries in pregnant women and its effects on their children through the use of oral rinse and varnish, chlorhexidine, xylitol, and/or iodine.

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

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

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

- Determine the effectiveness, impact, and cost benefits of **cultural and linguistic competence** in public health care and service systems.

- Study the causes for disparities in access to and utilization of early and adequate prenatal care in different regions of the country, differentiating by rural, urban and frontier areas, and the effects of such disparities.

- Investigate the effects of interdisciplinary and collaborative practice of health professions (including but not limited to nursing, oral health, pharmacy, mental health and pediatrics) on reducing barriers to health care access.

- Assess the impact of community-based genetic counseling and education programs in medically underserved communities to evaluate whether increased genetic counseling and education programs will make a difference in access by underserved communities to genetic resources and services.

- Study interventions to reduce racial/ethnic disparities in pre-term/low birth weight and other infant health outcomes.

- Study the contribution of contextual effects on disparities in MCH outcomes.

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

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

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

- Explore mechanisms of information transfer of evidence-based MCH strategies that lead to enhanced quality of provider practices and consumer behavior.

- Determine the effectiveness and impact of the current system of care (both public and private) to assure that women and infants receive risk-appropriate perinatal care.

- Study the extent to which children and adolescents needing **emergency medical services** actually receive them and the quality of care received from hospital emergency departments.

- Study the impact of specific characteristics of the medical home, such as the use of written “care plans,” on improvements in the quality of care for CSHCN.

- Study how duration, organization and content of visits for clinical preventive services affect the quality of anticipatory guidance/health counseling provided to children, adolescents and women.

- Investigate the factors that promote quality of health care service delivery, with attention to understanding the effectiveness and impact of interdisciplinary training of MCH professionals.

- Investigate factors that decrease fragmentation of MCH service delivery.

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

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

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

- Study the effectiveness of health promotion and prevention strategies for infant, child, adolescent and adult populations (e.g., **Bright Futures Guidelines**) that use coordinated strategies and a variety of venues involving the clinical setting, the community and the home environment.

- Conduct **longitudinal studies of health and normative development** in special populations of children such as minority children; children with special health needs; and children of low socioeconomic status, rural, migrant and homeless backgrounds.

- Study the effectiveness of health promotion and prevention strategies to promote healthy weight and prevent **obesity** in children and adolescence.

- **Study child, parental (including fathers) and family strengths**, i.e., coping and resilience associated with pregnancy, childbearing and parenting; significant injuries; chronic and catastrophic disease conditions; and natural and man-made catastrophic events.

- Study the effects of **family/professional partnerships and integrated community systems** on the health (including mental and oral health) and development of children.

- Study the factors associated with health care utilization that positively influence health care utilization and **preventive health behaviors of women at various stages of and throughout their life span**.

- Study the effectiveness of community outreach workers in increasing **breastfeeding** duration rates in underserved populations.

DEFINITIONS

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

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

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

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

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)**

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

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

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

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

Appendix B: Key Terms for Project Abstracts

(a) Content Terms (maximum of 10)

Health Care Systems & Delivery

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

Primary Care & Medical Home

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

Insurance & Health Care Costs

- Cost Effectiveness
- Health Care Costs
- Insurance Coverage

Prenatal/Perinatal Health & Pregnancy Outcomes

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

Nutrition & Obesity

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

Parenting & Child Development

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

School Settings, Outcomes, & Services

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

Screening & Health Promotion

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

Illness, Injury, & Death

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

Mental/Behavioral Health & Well-being

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

Special Health Care Needs & Disabilities

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

Life Course & Social Determinants

- Neighborhood
- Life Course
- Social Determinants of Health

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

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

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

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

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

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

Appendix D: Frequently Asked Questions (FAQs) about the R40 Maternal and Child Health (MCH) Secondary Data Analysis Research Program

Where do I find application materials for the R40 MCH Secondary Data Analysis Research (SDAR) Program?

All application materials are available through Grants.gov.

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

You can download the application from Grants.gov.

What is Grants.gov?

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

Is there anything that we need to do immediately to better prepare for our new grant application?

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

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

1. *Make sure that the Authorized Organization Representative from your university/organization is registered in Grants.gov NOW. This process can take up to 1 month and it is better to complete it and have it out of the way before starting any grant application.*
2. *Read the instructions on Grants.gov carefully and allow time for corrections. Enter information in fields even if it is 0 or the form will remain incomplete. Required fields are highlighted in yellow.*
3. *There are resources available on the Grants.gov web site to help you navigate this new system. Please visit Grants.gov to access these resources.*
4. *Some business practices will change with the introduction of the new SF-424 R&R Form.*

- *With the HRSA SF-424 R&R, you will be reporting faculty and staff time in calendar month equivalents.*
- *Budget details about subcontracts will now be described in a section of the SF-424 R&R Form called sub-awards.*
- *New applications will now fill out detailed budgets for each of the years in the project period. For example, grants with 3-year project periods will submit detailed budgets for each of the 3 years.*

Can I get a copy of the FOA from last year's competition?

The past year FOA is not published to avoid confusion among potential applicants.

What types of institutions can apply?

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

We are a foreign organization interested in applying for the R40 MCH Secondary Data Analysis Research Program. Are foreign entities eligible to apply?

The R40 is a domestic grant program and non-U.S. entities are not eligible to apply as outlined in the NOFO.

How do I know whether to apply to the R40 MCH Secondary Data Analysis Studies (SDAR) grant?

R40 SDAR GRANT: *The purpose of the 1-year SDAR grant is to support the analysis of large, pre-existing national data sets on questions relevant to the field of maternal and child health (e.g., nationally representative databases such as the National Survey of Children's Health, the National Survey of Adoptive Parents, the Early Childhood Longitudinal Study-Birth Cohort, etc.). Alternatively, it might consist of state or local administrative records, which would typically represent universal participation within a program among a particular population (e.g., Medicaid records for the population of children within a state who receive Medicaid, etc.). A proposal to the SDAR program would typically identify such a large, pre-existing dataset, and then identify particular research questions that can be answered through analyzing the data, such as, "What factors will predict which outcomes among X population?"*

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

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

Does the MCH SDAR grant program support a secondary data analysis of substance use/abuse trajectories and patterns of substance/mental health service use among a particular population?

All proposals will be reviewed by an external review committee. To be responsive to the NOFO, applications should propose to use national databases and/or administrative records. The application must show alignment with: one or more MCHB Strategic Research Issues; one or more Healthy People 2020 objectives; and one or MCH Block Grant National Performance Domains*. The NOFO has appendices that describe the MCHB strategic issues and the MCH Block Grant National Performance Domains. Information on Healthy People 2020 can be found at the HealthyPeople.gov site. When you write your application, you would want to highlight how your application shows alignment with each of these. All funding decisions are based on scientific merit as determined by the external review committee, and on availability of funds.*

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

The MCHB Strategic Research Issues, Healthy People 2020, and MCH Block Grant National Performance Domains are used as frameworks for demonstrating the extent to which the proposed project clearly describes the unmet health needs of a maternal and child population and the extent to which the proposed project demonstrates alignment with HRSA/MCHB Goals and Healthy People 2020.

If I were to receive an R40 SDAR grant, what type of data would I receive from HRSA? Would it be data specific to the subject or would it be a large amount of MCH data that I would need to sift through?

You are responsible for identifying the particular data sets that they will use in their proposal. HRSA does not make data available to applicants for the SDAR grant program. You are also responsible for ensuring that you have or will have access to the national database and/or administrative records that you will use for your grant applications.

We are trying to apply for the announced grants, but our organization does not have an Indirect Cost Rate Agreement. What should we do?

According to the HRSA SF-424 R&R, "any non-federal entity that has never received a negotiated indirect cost rate, (except a governmental department or agency unit that receives more than $35 million in direct federal funding) may elect to charge a de minimis rate of 10 percent of modified total direct costs (MTDC) which may be used indefinitely. The HRSA SF-424 R&R also contains information on how to negotiate the indirect cost rate.

How do I know what my institution's indirect cost rate is?

The applicant institution's indirect cost rate is negotiated by the institution with the U.S. Department of Health and Human Services (HHS). Your sponsored programs office will be able to provide further information about the indirect cost rate.

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

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

How do I know if the database I'm thinking of using is appropriate for the SDAR program?

The SDAR program supports research projects that exclusively utilize the analysis of existing national databases and/or administrative records. You should highlight in your proposal how the dataset of choice will yield information that is of regional and national significance, since this is part of the criterion on Public Health Impact that the external review committee will be assessing all proposals on. See Criterion 4 in the NOFO for further information about how your application will be assessed for public health impact.

If the data set we plan to use includes data from only one or several states, will this qualify as a national data set for the R40 MCH SDAR program?

The NOFO states, "Recipients will conduct secondary data analyses using existing national databases and administrative records." However, in cases where no existing national database adequately addresses a given MCH-related research question or specific MCH population, then the best available public data set can be used. In all cases, the NOFO requires that "findings will be generalizable and of regional and national significance." Therefore, you would want to highlight how findings from your proposed project will have regional and national significance. Funding decisions are based on scientific merit as determined by the external review committee, and on availability of funds.

Does the SDAR program allow the use of administrative records?

Yes, administrative records can be used for this grant. The SDAR program supports research projects that exclusively utilize existing national databases and/or administrative records. You should highlight in your proposal how the administrative records of their choice will yield information that is of regional and national significance, since this is part of the criterion on Public Health Impact that the external review committee will be assessing all proposals on. Please review Criterion 4 in the NOFO for additional information.

The NOFO mentions that the applicant must provide information on data availability. What information should I include in my application?

You should provide written confirmation that the proposed dataset for the R40 MCH SDAR project are available to the investigator, including information such as name of dataset, year of dataset, and date of data availability, and correspondence from the organization overseeing the dataset.

Does the R40 MCH SDAR competition allow for multiple Principal Investigators (PIs), also known as Project Directors (PDs)?

HRSA allows one PI/PD to be named on the face page of the SF-424 R&R application, who will serve as the key point of contact. The application can include Co-Investigators as key personnel on the project. An individual cannot be named as the PI/PD on multiple simultaneous applications for the R40 MCH competitions.

Is there a requirement regarding minimum or maximum effort for the PI?

In general, the NOFO does not specify any minimum or maximum time requirement for the PI, but we anticipate that applicant PIs should allocate and devote sufficient time to justify their commitments to the project. Under Review Criteria 5 and 6 of the NOFO, it states that applications will be assessed regarding:

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

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

Is it possible for postdoctoral fellows to apply as PI for the R40 MCH Research Program if they are affiliated with a university?

The NOFO does not contain language that excludes postdoctoral fellows from serving as PI on the R40 grants. Ultimately, the determination of who may or may not serve as PI depends on the rules of the institution.

Can someone who is currently a PI on another agency grant be a PI on an R40 grant?

The above application responsiveness criterion refers only to PIs of R40 grants within MCHB. It does not apply to being a PI on grants from other agencies. However, if selected for funding, the new awardee will need to verify that percent effort across all federally-funded grants does not exceed 100 percent.

We have more than one investigator in our institution planning to apply to this NOFO. Is more than one application per institution allowable?

Yes, more than one application per institution is allowable under the R40, as long as other application responsiveness criteria are met on pages 3-4.

Which format should we follow for the biographical sketch?

You are advised to follow the instructions as provided in Section IV of this NOFO.

Are there page limits for the submitted application?

Yes, the R40 MCH SDAR NOFO specifies strict page limitations for the overall submission and for specific sections of the application. You are required to comply with these page limitations, or the application will not be considered for funding.

What counts towards the page limits?

- *The total size of all uploaded files may not exceed the equivalent of 80 pages when printed by HRSA as indicated in the NOFO. The page limit applies to the:*
  - *Abstract*
  - *Project and budget narratives*
  - *Attachments*
  - *Letters of commitment and support required in application guide and the NOFO*
  - *Biographical sketches*
- *The page limit does not apply to the following:*
  - *Standard OMB-approved forms that are included in the application package*
  - *Indirect Cost Agreement*
  - *Proof of Non-Profit Status*

Are there any page limitations to the narrative?

- *The current R40 MCH SDAR Program NOFO requires the following page limitations:*
  - ***R40 MCH SDAR Grant:** a six-page limit for the research strategy section of the narrative.*
- *The research strategy includes: Significance, Innovation, and Approach.*
- *Preliminary studies can be included in the Approach section of the Research Strategy, if applicable, and would be included in the six-page limit as described above.*
- *The other parts of the program narrative, which includes Sections A to B and D to G, do not have page limits. However, the entire application is limited to 80 pages total, excluding the SF 424 R&R form pages. It is important that you consult the NOFO you are responding to for any changes to these guidelines.*

- *If an application exceeds required page limitations, it will not be considered for funding.*

Does the Specific Aims section have a page limitation?

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

Where do I include the staffing plan?

The staffing plan information is included in the budget narrative attachment that should be uploaded into the budget form Box K.

Can I submit a proposal on autism spectrum disorder for the R40 MCH SDAR Program competition?

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

When will your next Autism NOFO be released?

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

Who should I talk to if I have further questions?

Please contact:

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

Appendix E: Grant Application Completeness Checklist

Funding Opportunity Number:_____

Application Due Date in Grants.gov: _____

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

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