# U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES


Maternal and Child Health Bureau
Division of Research
Office of Epidemiology and Research

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

**Funding Opportunity Number:** HRSA-20-057
**Funding Opportunity Type(s):** New
**Assistance Listings (CFDA) Number:** 93.110

## NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2020

## Application Due Date: January 8, 2020

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

**Issuance Date: October 11, 2019**

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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) is accepting applications for the fiscal year (FY) 2020 R40 Maternal and Child Health Secondary Data Analysis Research (MCH SDAR) Program. The purpose of this program is to advance the health and well-being of MCH populations through applied and translational research on policy and service delivery issues through 1-year grants for secondary analyses of existing publicly available and accessible national databases and/or administrative records.[1]

The FY 2020 President's Budget does not request funding for this program. This notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. You should note that this program may be cancelled prior to award.

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| Funding Opportunity Title: | R40 Maternal and Child Health Secondary Data Analysis Research (MCH SDAR) Program |
| Funding Opportunity Number: | HRSA-20-057 |
| Due Date for Applications: | January 8, 2020 |
| Anticipated Total Annual Available FY 2020 Funding: | $500,000 |
| Estimated Number and Type of Award(s): | Up to five grants |
| Estimated Award Amount: | Up to $100,000 per year |
| Cost Sharing/Match Required: | No |
| Period of Performance: | July 1, 2020 through June 30, 2021 (1 year) |
| Eligible Applicants: | Only domestic public or non-profit institutions of higher learning and public or private non-profit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs are eligible to apply (See 42 CFR § 51a.3(b)). Domestic faith-based and community-based organizations, tribes, and tribal organizations are also eligible to apply, if they otherwise meet these eligibility criteria.<br><br>See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information. |

[1] In this NOFO, the terms publicly available and accessible are used to refer to national datasets and/or administrative records that any researcher can access before or within the period of performance.

## 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.

## Technical Assistance

HRSA has scheduled the following technical assistance:

*Webinar*

Day and Date: Monday, October 28, 2019
Time: 1–2 p.m. ET
Call-In Number: 1-888-603-9614
Participant Code: 8779-877
Weblink: https://hrsa.connectsolutions.com/fy20_mch_sdar_ta/

HRSA will record the webinar (48-hour turnaround time) and make it available at: https://mchb.hrsa.gov/fundingopportunities/default.aspx for the duration of the application period, approximately 90 days after the call. The webinar will be closed captioned.

# Table of Contents

# I. Program Funding Opportunity Description

## 1. Purpose

This notice announces the opportunity to apply for funding under the R40 Maternal and Child Health Secondary Data Analysis Research (MCH SDAR) Program. The R40 MCH SDAR Program supports applied MCH research that exclusively utilizes the secondary analyses of existing publicly available and accessible national databases and/or administrative records[2] to improve the health and well-being of MCH populations. The program accelerates the pace of research in a cost-effective way by providing researchers with an opportunity to pose new research questions, test new hypotheses, and determine pathways and feasibility of interventions using existing data sets, rather than conducting primary data collection, which is both costly and time-consuming.

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

- Strengthen and expand topics addressed by the Title V MCH Services Block Grant National Performance Domains (see Appendix C). For more background materials on the Title V Program, see: http://mchb.hrsa.gov/programs/titlevgrants/index.html. By supporting research on MCH populations, the R40 MCH SDAR Program aims to inform HRSA Maternal and Child Health Bureau's (MCHB's) other investments and programs, see: https://mchb.hrsa.gov/maternal-child-health-initiatives;
- Address HRSA MCHB's 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 Healthy People 2020 objectives that are relevant to the proposal. Proposals should connect the proposed topic with the Healthy People 2020 objectives;
- Address HRSA's clinical priorities, namely, opioid use disorder,[3] mental health, telehealth, childhood obesity, and maternal mortality. Study findings will further develop the evidence base for the above clinical priority topics; and
- Address emerging research topics of regional and national significance that highlight new data, knowledge, evidence, and strategies for addressing the burden of diseases that affect MCH populations.

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

[2]In this NOFO, the terms publicly available and accessible are used to refer to national datasets and/or administrative records that any researcher can access before or within the period of performance.

[3] HRSA has a number of investments targeting opioid use disorder and substance use disorder across its Bureaus and Offices that you may be able to leverage. For information on HRSA-supported resources, technical assistance, and training, visit here: https://www.hrsa.gov/opioids.

activities include, but are not limited to, peer-reviewed articles, manuscripts, conference presentations, newsletter articles, webcasts, fact sheets, infographics, policy briefs, publically available websites, and social media posts, as appropriate;
- Report study sample information with regards to diversity (i.e., race/ethnicity, gender/sex, disability, geographic location, and socioeconomic status) to HRSA; and
- Develop and implement strategies to sustain and expand the scientific knowledge generated from the award.

### 2. Background

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

Administered by the Division of Research in MCHB's Office of Epidemiology and Research, the R40 MCH SDAR Program is the only federal program supporting foundational opportunities for applied research focused on improving health care service delivery and policies affecting MCH populations through the secondary analysis of extant national databases and/or administrative records. This is expected to lead to advances in health promotion and disease prevention among MCH populations. The R40 MCH SDAR Program also focuses on current as well as emerging MCH policy and service delivery issues.

Since 2010, the R40 MCH SDAR Program recipients produced 154 publications in peer-reviewed journals with significant impact for MCH populations. For example, an SDAR-funded landmark study on nighttime sleep duration and obesity in children and adolescents demonstrated that younger children ages 0–4 with short durations of nighttime sleep were at greater risk for becoming overweight or obese.[4] This paper was later cited 206 times in scholarly journals. It contributed to pediatric sleep recommendations from the American Academy of Pediatrics, which in turn has been cited 170 times.[5] More information about the R40 MCH SDAR Program, funded projects, and current activities are found at http://www.mchb.hrsa.gov/research.

## II. Award Information

### 1. Type of Application and Award

Type(s) of applications sought: New,

HRSA will provide funding in the form of a grant.

[4]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.

[5] Paruthi S, Brooks LJ, D'Ambrosio C, Hall WA, Kotagal S, Lloyd RM, Malow BA, Maski K, Nichols C, Quan SF, Rosen CL, Troester MM, Wise MS. Recommended Amount of Sleep for Pediatric Populations: A Consensus Statement of the American Academy of Sleep Medicine. Journal of Clinical Sleep Medicine. 2016; 12(6): 785–786.

### 2. Summary of Funding

HRSA estimates approximately $500,000 to be available annually to fund five recipients. The actual amount available will not be determined until enactment of the final FY 2020 federal appropriation. You may apply for a ceiling amount of up to $100,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The FY 2020 President's Budget does not request funding for this program. 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, HRSA can process applications and award funds in a timely manner. The period of performance is July 1, 2020 through June 30, 2021 (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 domestic public or non-profit institutions of higher learning and public or private non-profit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs are eligible to apply (See 42 CFR § 51a.3(b)). Domestic faith-based and community-based organizations, tribes, and tribal organizations are also eligible to apply, if they otherwise meet these eligibility criteria.

You are required to submit proof of non-profit status as *Attachment 5*.

### 2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

### 3. Other

HRSA will consider any application that exceeds the ceiling amount non-responsive and will not consider it for funding under this notice.

HRSA will consider any application that fails to satisfy the deadline requirements referenced in Section IV.4 non-responsive and will not consider it for funding under this notice.

NOTE: 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 NOFO.

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.

**Please make sure you submit your application to the correct NOFO number: HRSA-20-057, the R40 MCH SDAR Program competition. Applications submitted to the wrong competition will be deemed nonresponsive and will not be considered for funding under this notice.**

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

- An individual cannot be named as the Project Director (PD) or Principal Investigator (PI) for multiple applications for the R40 MCH SDAR or another R40 competition. For example, an individual cannot be named as PI on an R40 MCH FIRST and R40 MCH SDAR Program application simultaneously **(i.e., an individual can only be named PI once for one NOFO or grant).**
- Applications that overlap in period of performance with a currently-funded R40 MCH Research project by the same PI will not be considered for funding (i.e., an investigator cannot be the PD/PI on more than one R40 MCH grants [R40 MCH SDAR and R40 MCH FIRST] simultaneously. **A 1-year no-cost extension of a current MCH Research project counts as part of the total period of performance** during which an overlap in period of performance with a newly awarded application is not allowable;
- A current PI of an MCH SDAR award is expected to serve for **no more** than 10 percent time on a new proposal;
- Projects addressing autism spectrum disorder will **not** be considered for this competition (a separate competition for R41 Autism Secondary Data Analysis Research Program may be held, if funds are available).

## IV. Application and Submission Information

### 1. Address to Request Application Package

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

The NOFO is also known as “Instructions” on Grants.gov. You must provide your email address when reviewing or preparing the workspace application package in order to receive notifications including modifications and/or republications of the NOFO on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are*

*ultimately responsible for reviewing the For Applicants page for all information relevant to desired opportunities.*

## 2. Content and Form of Application Submission

Section 4 of HRSA's *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. You must submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

See Section 8.5 of the *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 OMB-approved forms that are included in the workspace application package and the table of contents **do not** count in the page limit. Biographical sketches **do** count in the page limitation. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) **do not** count in the page limit. **We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.**

**Applications 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) You, on behalf of the applicant organization certify, by submission of your proposal, that neither you nor your principals are 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 you are unable to attest to the statements in this certification, an explanation shall be included in *Attachment 6: Other Relevant Documents*.

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

**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), 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 funding opportunity number and title. Briefly state the principal needs and problems addressed by the project, including the project's relationship to MCHB Strategic Research Issues (Appendix A). 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, include the name of the database(s) you will analyze. 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, consistent with forms and attachments, and well-organized so that reviewers can understand the proposed project.

Successful applications will contain the information below.

You should use the following section headers for the Project Narrative and align your application with these sections:

***A. INTRODUCTION --Corresponds to Section V's Review Criterion 1 Need***

You should provide a brief introduction and overview of the proposed research project. The purpose of this section is to provide a compelling explanation of your project for the reviewers to clearly understand the scientific impetus behind the proposed study.

***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, HRSA Priorities, and Healthy People 2020**

- Identify relevance to MCHB Strategic Research Issues (Appendix A). You are responsible for explaining the project's relevance to an MCHB Strategic Research Issue.
- Discuss how the research findings will strengthen and expand the MCH Block Grant National Performance Domains (Appendix C).
- Discuss how the research findings will strengthen and expand topics identified as HRSA priorities such as mental health, opioid use disorder, childhood obesity, maternal mortality, and telehealth.
- 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 secondary data analytic research proposed, for example, to test a stated hypothesis, provide data analytic strategies to solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or identify emerging public health needs.
- 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 predictions of findings (hypotheses), as well as justifications for the predictions. Researchers are encouraged to use holistic frameworks such as the life course health development (LCHD) and/or the social determinants of health (SDoH) in framing their study proposals;
- Present a summary table of the variables, classified as independent, intervening, mediating, moderating, and dependent, etc., Specify the nature of the variables, the measures to be employed as indicators for these variables, and the units and levels of measurement of the indicators.
- If possible, construct and present a graphical analytical model or graphical representation of the set of relationships held to be operative among the variables.
- 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. (See p. 23 for more details on the data analysis plan).

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

- Organize the Methodology 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 the published experimental details of the data source you plan to use in the Methodology section and provide the full reference in the Bibliography and References Cited section.
- The **Methodology section (Significance, Work Plan/Approach, Scientific Innovation and Importance) is limited to six 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 MCH or children with special health care needs programs and identify the envisioned application of findings to the clinical management of mothers and children and/or the ways that maternal and child health services are organized and delivered.

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

- Describe the overall study design, strategy, methodology, and analyses you will use to accomplish the specific aims of the project.
- Describe the data collection procedures used for the database(s) or administrative record(s) and instrumentation as appropriate.
- Describe the study sample. Include demographic information on the sample population (i.e., age, gender/sex, race/ethnicity, household income, education level, rural/urban status, etc.).
- Identify at least one HHS/HRSA clinical priority and an MCH Block Grant National Performance Domain as its key independent variable(s) or as the main outcome variable(s).
- Describe any eligibility inclusion/exclusion criteria for the database(s)/administrative record(s).
- Address issues regarding sampling design and randomization as appropriate for the dataset.

- Include the study sample response rates, nonresponse bias analyses, and power analyses as appropriate.
- Include a description of strategies that the database(s) utilized for participant recruitment.
- Include how you will obtain, analyze, and interpret the data.
- Include 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*. Describe how access will be gained to any confidential files, if utilized, in the proposed analyses.
- Include surveys, questionnaires, other data collection instruments, clinical protocols and informed consent documents as necessary, in *Attachment 3*.

**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 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, or analyses used, and any advantage over existing methodologies or policies.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or policies that will be changed if the proposed aims are achieved through this secondary data analysis project.
- 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 through this secondary data analysis project.

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

**Public Health Impact**

- Describe the public health impact that study results may have.
- Describe the impact that the expected outcomes will 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 HRSA priorities.
- Describe the extent to which study results will be generalizable and replicable.
- Describe the extent to which study results will be of regional and national significance.

**Publication and Dissemination Plan**

- Describe plans for dissemination of project results.
- Include information on how you will accomplish the publication of several but no less than two peer-reviewed publications resulting from the MCH research project, clearly indicating the number of peer-reviewed and other publications that will be produced from the proposed project.
- In addition to peer-reviewed publications, provide a plan to advance the transfer of findings into practice by disseminating findings, reports, and/or project outputs to key target audiences, including researchers, providers, state Title V and other program(s) serving MCH populations, policymakers, families, and the general public. Recipients will have implemented their plan to advance the transfer of findings into practice by the end of the period of performance. 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 publicly available 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,[6] 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 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).

[6] An Early Stage Investigator is a Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a Federal independent research award. (https://grants.nih.gov/policy/early-investigators/index.htm)

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. Describe past HRSA research program research review service. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one-half page including figures and citations. A list of citations for key publications can also be included as *Attachment 2*.

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

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

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

This section addresses questions around project feasibility. Provide assurance that the research team will conduct the study as designed. Once funded, it is critical that the recipient 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 period of performance. 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 obtaining the dataset or administrative record, including access to most-recent dataset or administrative record(s) if multiple years exist.
- 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 the plan for project performance evaluation that will contribute to continuous quality improvement. The project performance evaluation should monitor ongoing processes and progress towards the goals and objectives of the project. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key personnel, budget, and other resources), key processes, and expected outcomes of the funded activities.

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

- 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.
- 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-4 24 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.

- 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 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
  - Black or African American
  - Native Hawaiian or Other Pacific Islander
  - White
  - More than One Race
- Gender/sex distribution within each racial category
- Total sample by racial category
- Disability status
- Socioeconomic status
- Geographic Location
  - Urban
  - Rural[7]

- The "Ethnic Category (Hispanic Heritage): Total Sample" must be equal to the "Racial Categories: Total Sample." 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.

[7] For this funding opportunity, an area is considered rural if it is listed in HRSA's Federal Office of Rural Health's Non-Metro Counties (Micropolitan and non-core based counties) and Eligible Census Tracts in Metropolitan Counties data file available at https://www.hrsa.gov/rural-health/about-us/definition/datafiles.html.

- 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**<br>To ensure that you fully address the review criteria, this table provides a crosswalk between the NOFO narrative language and where each section falls within the review criteria. Any attachments referenced in a narrative section may be considered during the objective review. | | |
|---|---|---|
| **Narrative Section** | **Review Criteria** | **Points** |
| A. Introduction | (1) Need | 5 |
| B. Specific Aims: 1) Needs and Alignment | (1) Need | 5 |
| B. Specific Aims: 2) Goals and Hypotheses | (2) Response | 20 |
| C. Methodology: 1) Significance | (2) Response | |
| C. Methodology: 2) Work Plan/ Approach | (3) Evaluative Measures | 20 |
| C. Methodology: 3) Scientific Innovation and Importance | (4) Impact | 20 |
| D. Impact and Dissemination | (4) Impact | |
| E. Resources and Capabilities | (5) Resources/Capabilities | 10 |
| Budget and Budget Justification (below) | (6) Support Requested | 10 |
| F. Feasibility | (7) Program Assurances | 10 |
| G. Evaluation and Technical Support Capacity | (7) Program Assurances | |
| H. Protection of Human Subjects | (7) Program Assurances | |
| I. 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. 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 HRSA selects the application for funding, you will have a well-organized plan, and by carefully following the approved plan can avoid audit issues during the implementation phase.

**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 Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (P.L. 115-245), Division B, § 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 2020, 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 is expected to serve for no more than 10 percent time on a new proposal in a capacity other than as PD/PI.) Copies of biographical sketches for all senior/key personnel and other significant contributors must also be submitted as an attached file to each SF-424 R&R Senior/Key Person Profile.

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

**vi. *Attachments***
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 recently 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*.

**SAM.GOV ALERT:** For your SAM.gov registration, you must submit a notarized letter appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018.

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM located at SAM.gov.

**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, 2020 at 11:59 p.m. ET.*** HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadline** to allow for any unforeseen circumstances.

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 R40 MCH SDAR 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-20-057) may not be used for travel outside of the United States.

You may request funding for a period of performance of up to 1 year, at no more than $100,000 per year (inclusive of direct **and** indirect costs). The FY 2020 President's Budget does not request funding for this program. 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, HRSA can process applications and award funds in a timely manner.

The General Provisions in Division B of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, (P.L. 115-245) are in effect at the time this NOFO is posted. Please see Section 4.1 of HRSA's *SF-424 R&R Application Guide* for additional information. Awards will be made subsequent to enactment of the FY2020 appropriation. The NOA will reference the FY2020 appropriation act and any

restrictions that may apply. Note that these or other restrictions may be updated, as required by law, upon enactment of a FY 2020 appropriations act.

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 considered additional income. Post-award requirements for program income can be found at 45 CFR § 75.307.

## V. Application Review Information

### 1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation.

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 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***

***A. Specific Aims: 1) Needs and Alignment***

**Introduction**

- The extent to which the brief introduction and overview of the proposed research project is compelling.
- The extent to which the project and description of the scientific rationale behind the proposed study is compelling.

**Needs Assessment**

- The extent to which the applicant describes the target population characteristics (including age ranges of children/youth).
- The degree to which the proposed project clearly describes the unmet health needs of the target population and any sociocultural determinants of health and health disparities impacting the target population.

**Alignment with HRSA MCHB Goals, HRSA Priorities, and Healthy People 2020**

- The relevance of the project to an MCHB Strategic Research Issue (Appendix A).
- The extent to which the project will strengthen and expand topics identified as the HRSA priorities, and the MCH Block Grant National Performance Domains (Appendix C).
- The extent to which the research project describes 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: 1) Significance***

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

**Goals and Objectives (5 points)**

- The clarity of the project's goals and objectives and their appropriateness to achieve the unmet health need.
- The relevance and thorough description of the project's goals, objectives, and outcomes.
- The strength with which the outcomes will address the unmet needs of the target population.

**Hypotheses and Specification of Variables (5 points)**

- The strength and feasibility of the research question.

- The reasonableness of the research project's proposed hypotheses.
- The clarity of the defined variables used in the study.
- The quality of the proposal's rationale to relate the study to the Needs Assessment section.

***C. Methodology: 1) Significance (10 points)***

**Background Literature and Statement of Problem (5 points)**

- The strength of investigator's knowledge-base for the previous and current work in the project's subject area.
- The strength of the cited literature as it relates to the research problem and rationale.

**Relevance (5 Points)**

- The strength and effectiveness for the proposed project to appropriately address a critical problem or barrier to progress in the field.
- The relevance of the proposed project to the health of maternal and child populations or HRSA priorities.

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

***C. Methodology: 2) Work Plan/Approach***

**Study Design *(5 points)***

- The appropriateness of the research plan and methodology described as it relates to the hypotheses and data.
- The replicability of the study design and thoroughness with which it is described.
- The strength and effectiveness of the proposed solutions to the identified challenges regarding internal and external validity of the design.
- The extent to which the project results are generalizable.
- The extent to which the project demonstrates an understanding of the culture of the target population in the research project.

**Database *(5 points)***

- The validity of the data collection procedure used for the databases or administrative records and instrumentation.
- The extent to which the proposed database(s) or administrative record(s) is/are clearly stated in the abstract and described in the application.

- The strength of the rationale for using the stated database(s) or administrative record(s) to answer the proposed research questions.
- The degree of availability of the data to the investigator. **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 extent to which the study population is described (e.g., target age or age ranges, sex/gender, racial/ethnic background, socioeconomic status, geographic location).
- The degree to which the sample size is adequate and justified in terms of statistical power.
- The quality of the proposal's description of expected differences between groups in terms of statistical as well as clinical significance.
- The extent to which the participants in the study sample are justified in terms of the scientific goals and research strategy proposed.

**Plan for Data Analysis *(5 points)***

- The degree to which the analysis plans clearly describe the process of data analysis and the rationale for the sequence of steps to be taken.
- The feasibility of the data analysis plans to the nature of the data, design, and samples.
- The appropriateness of the statistical methods proposed.
- The reasonableness of the proposed timeline (i.e., the timeline illustrates that sufficient time is allocated for data analysis and reporting).

***Criterion 4: IMPACT (20 points) -- Corresponds to Program Narrative Sections C. Methodology: 3) Scientific Innovation and Importance and D. Impact and Dissemination***

***C. Methodology: 3) Scientific Innovation and Importance (8 points)***

- The extent to which the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields relevant to MCH populations.
- The extent to which the project will use of novel or innovative, either to the field of research or novel in general, concepts, approaches or methodologies, instrumentation and intervention.
- The likelihood that project results will exert a sustained influence on the research field(s) involved.

### *D. Impact and Dissemination*

**Public Health Impact (6 Points)**

- The effect the expected results will have on health care delivery strategies, health and well-being of MCH populations, and broad public health impact.
- The significance of the problem addressed by the proposed research to the target population.
- The strength of the study's proposed findings, and whether they will be generalizable and of regional and national significance.

**Publication and Dissemination Plan (6 Points)**

- The adequacy and feasibility of the proposal's publication and dissemination plan.
- The feasibility of the proposed plan to produce several, but no less than two (2), peer-reviewed publications.
- The degree to which the PI and other key personnel have demonstrated current and/or past success in publishing the findings of their research. In particular, if investigators are past R40 MCH SDAR recipients, the degree to which they have demonstrated publication success from their previous award(s).
- The strength and feasibility of the proposed 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) Corresponds to E. Resources/Capabilities***

**Organizational Facilities and Resources *(5 points)***

- The extent to which project personnel have sufficient training, qualifications, expertise, and experience to achieve the goals of the project.
- The extent to which the organization has sufficient infrastructure, resources, and facilities to fulfill the needs and requirements of the proposed project.

**Qualifications of Research Team -- Corresponds to (a) Preliminary Studies in C. Methodology 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 PI, collaborators, staff, and other researchers are well qualified by training and/or expertise to conduct the research.

- The appropriateness of the experience and training of early stage investigators or new investigators. Or, if established, the degree to which they have demonstrated an ongoing record of accomplishments that have advanced their field(s).
- The degree to which the proposal describes relevant preliminary studies performed by key personnel, indicating the capacity to conduct the work as described.
- 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.

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

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

***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 feasibility of the proposed timeline to accomplish the project goals.

**Resolution of Challenges**

- The thoroughness of the proposal's identification of barriers and challenges that could affect project progress.
- The effectiveness of the proposal's solutions for potential challenges and barriers that could impact 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 feasibility of accessing the database(s) or administrative record(s) including access to most recent database or administrative records if multiple years exist within the timeline provided.

***G. Evaluation and Technical Support Capacity and H. Protection of Human Subjects (4 points)***

- The extent to which the applicant meets performance metrics specified in the application according to the timeline provided.
- The adequacy of protections afforded to human subjects, including children and youth, and the extent to which measures are in place to ensure the security of the research data (data security).
- The extent to which the proposal is compliant 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 (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html).
- 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 thorough description of the data and assurance of its availability and accessibility.
- The strength and effectiveness of the proposal's plan to include a sample that reflects diversity regarding ethnicity, race, gender/sex, geographic location, and socioeconomic status.

### 2. Review and Selection Process

The objective 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. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

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

### 3. Assessment of Risk

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).

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional programmatic or 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 HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine whether HRSA can make an award, if special conditions are required, and what level of funding is appropriate.

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

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

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

## VI. Award Administration Information

### 1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of July 1, 2020. See Section 5.4 of HRSA's *SF-424 R&R Application Guide* for additional information.

### 2. Administrative and National Policy Requirements

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

**Requirements of Subawards**
The terms and conditions in the NOA apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NOA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients under awards. See 45 CFR § 75.101 Applicability for more details.

**Data Rights**
All publications developed or purchased with funds awarded under this notice must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the recipient owns the copyright for materials that it develops under an award issued pursuant to this notice, and HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for federal purposes, and to authorize others to do so. In addition, pursuant to 45 CFR § 75.322(d), the Federal Government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes, e.g., to make it available in government-sponsored databases for use by others. If applicable, the specific scope of HRSA rights with respect to a particular grant- supported effort will be addressed in the NOA. Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government's copyright license and data rights.

**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 you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

## 3. Reporting

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

1) **DGIS Performance Reports.** Available through the Electronic Handbooks (EHBs), the Discretionary Grant Information System (DGIS) is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report **annually**, by the specified deadline. To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are available at https://grants6.hrsa.gov/MchbExternal/DgisApp/formassignmentlist/R40_6.html. The type of report required is determined by the project year of the award's period of performance.

| Type of Report | Reporting Period | Available Date | Report Due Date |
|---|---|---|---|
| **a) New Competing Performance Report** | October 29, 2020<br><br>*(administrative data and performance measure projections, as applicable)* | Period of performance start date | 120 days from the available date |
| **b) Non-Competing Performance Report** | October 29, 2020 | Beginning of each budget period (Years 2–4, as applicable) | 120 days from the available date |
| **c) Project Period End Performance Report** | September 28, 2021 | Period of performance end date | 90 days from the available date |

The full OMB-approved reporting package is accessible at https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection (OMB Number: 0915-0298 | Expiration Date: 06/30/2022).

2) **Progress Report(s)**. The recipient must submit a progress report narrative to HRSA **annually** via the Non-Competing Continuation Renewal in the EHBs, which should address progress against program outcomes (e.g., accomplishments, barriers, significant changes, plans for the upcoming budget year), and include annual data on performance measures identified in the Project Narrative, if not captured by DGIS. Submission and HRSA approval of a progress report will trigger the budget period renewal and release of each subsequent year of funding. Further information will be available in the NOA.

3) **Integrity and Performance Reporting.** The NOA will contain a provision for integrity and performance reporting in FAPIIS, as required in 45 CFR part 75 Appendix XII.

## VII. Agency Contacts

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

Ernsley Charles
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03

Rockville, MD 20857
Telephone: (301) 443-8329
Fax: (301) 443-6686
Email: Ernsley.Charles@hrsa.hhs.gov

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

Sylvia Sosa, MSc and Maura Maloney, PhD, MS
Program Officers, Division of Research, Office of Epidemiology and Research
Attn: R40 MCH SDAR Program
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 18N-198
Rockville, MD 20857
Telephone: (301) 443-2259 (Ms. Sosa) and (301) 443-1087 (Dr. Maloney)
Email: ssosa@hrsa.gov and mmaloney@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 EHBs. 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

### Technical Assistance

HRSA has scheduled the following technical assistance:

*Webinar*

Day and Date: Monday, October 28, 2019
Time: 1–2 p.m. ET
Call-In Number: 1-888-603-9614
Participant Code: 8779-877
Weblink: https://hrsa.connectsolutions.com/fy20_mch_sdar_ta/

HRSA will record the webinar (48-hour turnaround time) and make it available at: https://mchb.hrsa.gov/fundingopportunities/default.aspx for the duration of the application period, approximately 90 days after the call. The webinar will be closed captioned.

### Websites

While HRSA does not endorse any organization/website, the following list, although not exhaustive, may provide helpful references:

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

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

**HRSA MCHB Division of MCH Workforce Development**
**http://www.mchb.hrsa.gov/training**

**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**

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

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

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

**National Resource Center for Patient/Family-Centered Medical Home (formerly the National Center for Medical Home Implementation)**
**http://www.medicalhomeinfo.org/**

## 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 you 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 interventions 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 you 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 you 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 you 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, § 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 use disorder

***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 |

For more information on the Title V MCH Services Block Grant–National Performance Domains please visit: https://mchb.hrsa.gov/maternal-child-health-initiatives/title-v-maternal-and-child-health-services-block-grant-program. Please consult the following articles:

- Lu, MC, Lauver, CB, Dykton, C, Kogan, MD et al. Transformation of the Title V Maternal and Child Health Services Block Grant. *Maternal and Child Health Journal* 2015; 19(5): 927-931.
- Kogan, MD, Dykton, C, Hirai, AH, Strickland, BB et al. A New Performance Measurement System for Maternal and Child Health in the United States. *Maternal and Child Health Journal* 2015; 19(5): 945–957.

# Appendix D: Frequently Asked Questions (FAQs) about the R40 Secondary Data Analysis Research (R40 MCH SDAR) Program

**Where do I find application materials for the R40 MCH SDAR Program?**

*All application materials are available through Workspace on Grants.gov.*

**How can I download the complete application instructions for the R40 MCH SDAR NOFO?**

*You can download the application by searching for the application number*

*HRSA-20-057 on Grants.gov:*

1. *Click on the hyperlink for HRSA-20-057*
2. *Click on the last blue tab entitled "PACKAGE."*
3. *Scroll down and click on the "Preview" hyperlink under the "Actions" column.*
4. *Select the "Download Instructions" button in the right-hand corner. This will download the application.*

**What is Grants.gov?**

*Grants.gov is the web site that the U.S. Government uses to inform citizens of funding 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 relatively new system. Please visit Grants.gov to access these resources.*
4. *Some business practices will change with the introduction of the 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 the entire period of performance.*

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

*The NOFO from last year's competition is available on MCHB's website. However, we recommend that you carefully follow instructions provided in the current published NOFO (HRSA-20-057) in the preparation of your application. All applications for this competition will be reviewed and scored based on the instructions and evaluation criteria outlined in the current NOFO (HRSA-20-057).*

**What types of institutions can apply?**

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

**We are a foreign organization interested in applying for the R40 MCH SDAR Program. Are foreign entities eligible to apply?**

*The R40 MCH SDAR 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 SDAR grant?**

*The purpose of the 1-year 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 R40 MCH 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, HRSA MCHB defines 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 R40 MCH SDAR Program support a secondary data analysis of substance use/abuse trajectories and patterns of substance/mental health service use among a particular population?**

*No, particular populations are not prioritized. 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*. When you write your application, you would want to highlight how your application shows alignment with each of these. HRSA is interested in proposals addressing 1 or more of the HRSA Priorities (i.e., childhood obesity, mental health, opioid use disorder.). The NOFO has appendices that describe the MCHB Strategic Research Issues and the Title V MCH Services Block Grant National Performance Domains. Information on Healthy People 2020 can be found at the HealthyPeople.gov site. All funding decisions are based on scientific merit as determined by the external review committee, and on availability of funds. Please visit our website to read about how previously awarded R40 MCH SDAR projects have aligned their work with these frameworks.*

**Will my application be ineligible if it does not address the HRSA Priorities?**

*Your application will not be deemed ineligible if it does not address the HRSA priorities. You are expected to consider how your proposal aligns with Title V outcome measures and HRSA priorities which include childhood obesity, mental health, and opioid use disorder.*

**How do we align our project research questions with the MCHB Strategic Research Issues, Healthy People 2020, and Title V MCH Services Block Grant National Performance Domains?**

*The MCHB Strategic Research Issues, Healthy People 2020, and Title V MCH Services 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. These frameworks should be applied broadly to help contextualize your work and its relevance to the MCH field.*

**If I were to receive an R40 MCH 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 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 R40 MCH SDAR Program?**

*The R40 MCH 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 to MCH populations. The external review committee will be taking the suitability of the database into account when assessing proposals. You should also include written confirmation that the proposed dataset for the R40 MCH SDAR project are publically available and 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. See Criterion 4 in the NOFO for further information about how your application will be assessed for public health impact. Please visit our website to read about previously awarded R40 MCH SDAR projects and the datasets they have used. It is not the reviewer's responsibility to automatically know about the public availability of the applicant's proposed dataset. The application should clearly describe the public availability of the dataset, and if this is not described successfully, the reviewer may reduce the application's score accordingly.*

**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 to MCH populations." Therefore, you would want to highlight how findings from your proposed project will have regional and national significance on MCH populations. Funding decisions are based on scientific merit as determined by the external review committee, and on availability of funds.*

**Does the R40 MCH SDAR Program allow the use of administrative records?**

*Yes, administrative records can be used for this grant. The R40 MCH 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)?**

*Yes, multiple applications from an organization are allowable. In order to diversify our research grant portfolio, an individual cannot serve as the Project Director (PD) or Principal Investigator (PI) on more than one active HRSA/MCHB-funded grant. In order to diversify the R40 Competition, a PD/PI on an active MCHB-funded research grant is*

*expected to have no more than 10 percent effort as a Co-Investigator on an existing HRSA/MCHB research grant. HRSA allows one PD/PI to be named on the face page of the SF-424 R&R application, who will serve as the key point of contact. The application can include Co-Investigators as key personnel on the project. If selected for funding, the new awardee will need to verify that percent effort across all federally-funded grants does not exceed 100 percent.*

**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 SDAR Program if they are affiliated with a university?**

*Postdoctoral fellows are allowed to serve as PI on the R40 MCH SDAR grant. 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's grant be a PI on the R40 MCH SDAR grant?**

*Yes, a PI on another (federal non-HRSA/MCHB) agency's grant can be a PI on an R40 MCH SDAR grant; 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 for this program, as long as other application responsiveness criteria are met.*

**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:** 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.*

**I am resubmitting my application, yet I have made substantial revisions to it. Does this still count as a resubmission?**

*The R40 MCH SDAR Program no longer requires applicants to identify whether their application is an initial submission or a resubmission.*
*Submitting an application as a resubmission does not give the application any advantage over other applications in the review process. All review points and review criteria are listed in this NOFO's application guidance.*

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

*No. 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 R41 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 you announce your other research NOFOs?**

*Please join our listserv at http://mchb.hrsa.gov/research to receive an alert whenever 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**? | | | |
| Does this application propose a **secondary data analysis** project? | | | If no, you are applying to the wrong application. |
| 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/applicationguide/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.<br>• System for Award Management (SAM:) https://www.sam.gov/<br>• 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:<br>• Goals and Hypotheses?<br>• Significance of Methodology | | | |
| In the **EVALUATIVE MEASURES Section,** did you fully address your Work Plan Approach? | | | |
| In the **IMPACT Section**, did you fully address:<br>• Scientific Innovation and Importance?<br>• Impact and Dissemination? | | | |
| In the **RESOURCES CAPABILITIES Section,** did you fully address Organizational Information/ Environment? | | | |

| Requirement | Yes | No | Comments |
|---|---|---|---|
| In the **SUPPORT REQUESTED Section**, did you accurately complete the Budget and Budget Justification?<br><br>Did you follow the budget instructions in the **NOFO and** R&R **Application Guide**?<br>Do you know your institution's **indirect cost rate**? | | | The directions offered in the HRSA **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**.<br><br>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:<br>• Feasibility?<br>• Evaluation and Technical Support Capacity?<br>• Protection of Human Subjects? | | | |
| 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 biographical sketches, within the 80-page limit? | | | Face page, Standard OMB-approved forms, Indirect Cost Rate Agreement, proof of non-profit status (if applicable), and budget pages **do not count** toward the 80-page limit. |
| Is the **METHODOLOGY 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 |