U.S. Department of Health and Human Services

Health Resources & Services Administration

Maternal and Child Health Bureau

Office of Epidemiology and Research

Maternal and Child Health Secondary Data Analysis Research

(MCH SDAR)

Funding Opportunity Number: HRSA-22-096

Funding Opportunity Type(s): New

Assistance Listings (AL/CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2022

Application Due Date: January 26, 2022

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 may take up to 1 month to complete.

Issuance Date: October 28, 2021

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See Section VII for a complete list of agency contacts.

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

508 COMPLIANCE DISCLAIMER

Note: Persons using assistive technology may not be able to fully access information in this file. For assistance, please email or call one of the HRSA staff listed in Section VII. Agency Contacts.

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2022 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 program service delivery. This program will fund up to six 1-year grants for secondary analyses of existing national data sets and/or administrative records.[1]

Funding Opportunity Title:	Maternal and Child Health Secondary Data Analysis Research (MCH SDAR)
Funding Opportunity Number:	HRSA-22-096
Due Date for Applications:	January 26, 2022
Anticipated Total Available FY 2022 Funding:	$600,000
Estimated Number and Type of Award(s):	Up to six grants
Estimated Award Amount:	Up to $100,000 per award subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	July 1, 2022 through June 30, 2023 (1 year)
Eligible Applicants:	Eligibility is limited to 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. See 42 CFR §

[1] In this NOFO, the term existing data sets is used to refer to national data sets and/or administrative records that are already collected by other researchers or entities for a different purpose or research questions but will now be used to answer a new research question.

	51a.3(b). Domestic faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply. See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.

Application Guide

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

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Monday, November 8, 2021
Time: 2 – 3:30 p.m. ET
Dial-in Toll-Free #: (833) 568-8864
Meeting ID: 160 446 8826
Passcode: 22601175
Weblink: https://hrsa-gov.zoomgov.com/j/1604468826?pwd=UGZua1NDZ3ZqZFJDWkhrUTJrejk5UT09

In an attempt to more effectively utilize our TA webinar time, if you have questions about the NOFO, please send them prior to the webinar via email to MCHSDAR@hrsa.gov. We will compile and address these questions during the TA webinar.

HRSA will record the webinar and make it available approximately 2 weeks after the webinar at: https://mchb.hrsa.gov/research/pre-app-ta-webinars.asp.

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the Maternal and Child Health Secondary Data Analysis Research (MCH SDAR) Program. The purpose of the MCH SDAR Program is to support applied MCH research that utilizes the secondary analysis of existing national data sets and/or administrative records to improve the health and well-being of MCH populations. The MCH SDAR program provides the opportunity for researchers across the nation to build the MCH evidence base by using existing data sets, such as national data sets and/or administrative records, to identify emerging issues, study new research questions, test hypotheses, and determine pathways for intervention. Existing and emerging public health challenges affecting MCH populations including children with special health care needs require timely, evidence-based responses from MCH programs, policy, and practice. Without sufficient evidence or data, it is challenging to develop interventions addressing both existing and emerging MCH issues. This program will allow us to achieve timely, evidence-based responses to these challenges.

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

- Strengthen and expand the evidence base on topics addressed by the Title V Maternal and Child Health Services Block Grant National Performance Measures (see Appendix A). 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 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 such as improving public health systems and infrastructure, reducing health inequalities, increasing quality of and access to care, addressing health disparities, improving health equity[2], and/or promoting the health of MCH populations;

[2] The term 'equity' means the "consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality." *See* Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 FR 7009, at § 1 (Jan. 20, 2021), https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf. .

- Address Healthy People 2030 objectives that are relevant to the application. Applications should connect the proposed topic with relevant Healthy People 2030 objectives;
- Address MCHB Strategic Plan Goals;
- Address health disparities facing underserved communities[3] using existing data to provide evidence and strategies for improving health equity for all MCH populations regardless of race or ethnicity; and/or
- Address existing and 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 MCH SDAR award recipient to complete the following activities:

- Conduct applied or translational research on critical and emerging MCH issues through secondary analyses of existing national databases and/or administrative records that are aligned with research goals;
- Develop and submit a dissemination plan for the distribution of research findings and products to scientific, professional, and lay audiences. Dissemination activities include, 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;
- Report study sample information with regard to diversity (i.e., race/ethnicity, gender/sex, disability, geographic location, and socioeconomic status) to HRSA in the Electronic Handbooks (EHBs) reports;
- Develop and implement strategies to sustain and expand the scientific knowledge generated from the award; and
- Present findings at the End of Project Presentation (Research Festival) to MCHB staff.

2. Background

This program is authorized by 42 U.S.C. § 701(a)(2) (Title V, § 501(a)(2) of the Social Security Act).

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[3] "[The] populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life." as exemplified by the list in the definition of "equity" in footnote 3. *See* Executive Order 13985, at § 2(b).

About MCHB and Strategic Plan

MCHB administers programs with focus areas in maternal and women's health, adolescent and young adult health, perinatal and infant health, child health, and children with special health care needs. To achieve its mission of improving the health and well-being of America's mothers, children, and families, MCHB is implementing a strategic plan that includes the following four goals:

Goal 1: *Assure access to high quality and equitable health services to optimize health and well-being for all MCH populations*

Goal 2: *Achieve health equity for MCH populations*

Goal 3: *Strengthen public health capacity and workforce for MCH*

Goal 4: *Maximize impact through leadership, partnership, and stewardship*

This program addresses MCHB's Goals 1 and 2 to assure access to high quality and equitable health services to optimize health and well-being for all MCH populations and achieve health equity for MCH populations. Research findings from MCH SDAR projects advance the evidence base for health care providers, other practitioners, researchers, policy makers, public health systems, Title V Block Grant programs, and the MCH community to provide high quality and equitable services to all MCH populations in the United States.

To learn more about MCHB and the bureau's strategic plan, visit https://mchb.hrsa.gov/about.

Secondary data analysis is a cost-efficient way to study new and important research questions using existing data that have already been collected by others. The MCH SDAR program is the only federal program supporting applied research through analysis of existing national databases and/or administrative records to improve the quality, efficiency, and accessibility of health care services and health outcomes for MCH populations. To-date, recipients have published 190 peer-reviewed articles, with an average of 6 articles per grant. Research from MCH SDAR-funded grants have contributed to the advancement of the MCH field. For example, one MCH SDAR study demonstrated that younger children (ages 0-4 years) with short durations of nighttime sleep were at greater risk for becoming overweight or obese, relative to those with longer nighttime sleep duration.[4] This single study was cited 262 times by other journals, and contributed to pediatric sleep recommendations endorsed by the American Academy of Pediatrics, which in turn has been cited 396 times.[5]

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[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.

[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.

This program aims to advance the MCH evidence base for health care providers, public health systems, and Title V programs by producing peer-reviewed publications and disseminating findings to diverse stakeholders, which will be reported on annually. For FY 2022, HRSA/MCHB solicits studies addressing HRSA/MCHB priorities and existing and emerging MCH issues. Successful recipients will conduct and publish studies that identify MCH issues and promising pathways for intervention to develop a strong evidence base that improves access to health services, quality of care, and health outcomes for MCH populations. Successful recipients will also disseminate study findings in innovative ways, including via media (blogs, commentaries, YouTube videos, etc.). More information about the MCH SDAR Program, funded projects, and current activities are found at http://www.mchb.hrsa.gov/research.

Promoting Health Equity

Promoting equity is essential to the Department of Health and Human Services (DHHS)' mission of protecting the health of Americans and providing essential human services. This view is reflected in Executive Order (E.O.) 13985 entitled Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (Jan. 20, 2021). Health inequities in the field of maternal and child health, in particular, among racial/ethnic groups, is a serious public health concern that has social and economic implications including poor health outcomes and increased healthcare costs[6,7].

In order for MCH to effectively address health disparities and inequalities in MCH, more research is needed to understand the status and root causes of health inequity among different MCH populations, especially those associated with race/ethnicity, and develop and evaluate evidence-based solutions/interventions to narrow or eliminate the disparities. MCHB/Office of Epidemiology and Research (OER)/Division of Research (DOR) aims to support research studies to address health equity issues across all of its research programs.

This NOFO aims to support the advancement of health equity research by analyzing existing secondary data. Studies have shown that researchers from underserved communities/groups are more likely to conduct research in minority/underserved populations[8] [9]. A study by NIH showed that black investigators are more likely to

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[6] https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-maternal-infant-health-overview/

[7] https://www.astho.org/Programs/Health-Equity/Maternal-and-Infant-Disparities-Issue-Brief/

[8] Oh SS, Galanter J, Thakur N, Pino-Yanes M, Barcelo NE, White MJ, et al. (2015) Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled. PLoS Med 12(12): e1001918. https://doi.org/10.1371/journal.pmed.1001918 ; and Association of American Medical Colleges. The Diversity Research Forum: The Importance and Benefits of Diverse Faculty in Academic Medicine: Implications for Recruitment, Retention, and Promotion. Washington, DC; 2009.

[9] Association of American Medical Colleges. The Diversity Research Forum: The Importance and Benefits of Diverse Faculty in Academic Medicine: Implications for Recruitment, Retention, and Promotion. Washington, DC; 2009. Cited in Oh SS, Galanter J, Thakur N, Pino-Yanes M, Barcelo NE, White MJ, et al. (2015) Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled. PLoS Med 12(12): e1001918. https://doi.org/10.1371/journal.pmed.1001918

propose health equity research topics than white investigators[10].

In addition, research shows that "diverse research teams are more likely to have diverse ideas"[11]. NIH identified that "diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems" [12,13]. Similarly, "diverse teams which include health disparities investigators and scientists from high-burden and underrepresented communities produce the best science to understand the complexity of health disparities and implement better solutions"[14]. As such, it is important to have diverse MCH researchers in the MCH SDAR program, especially those from high-burden and underserved communities to utilize secondary data to study research topics that affect diverse MCH populations and advance health equity for MCH populations.

Nevertheless, researchers from underserved communities/populations are significantly under-represented in medical and scientific communities. A 2016 presentation by the NIH Office for Scientific Workforce Diversity reported that applications from African American/Black (AA/B) researchers constitute only 1.5% of the application pool.[15]. In 2020, AA/B and Hispanic/Latino awardees for R01 grants only constitute 1.9% and 4.8% of the total R01 awardees, respectively[16].

Although no reliable data is available yet on the diversity of individual researchers who applied for DOR research funding, DOR conducted an internal analysis of researchers' institutional affiliation among applications of its research grants in 2019 and 2020. The findings showed that very few of the applicants and awardees were from MSIs[17], domestic faith-based and community-based organizations, tribes, and tribal organization serving mainly underserved populations[2]. Many of the researchers at MSIs are likely to be from minority/underserved populations, and they are likely to mentor students from

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[10] Hoppe TA, Litovitz A, Willis KA, et al. Topic choice contributes to the lower rate of NIH awards to African-American/black scientists. Sci Adv. 2019;5(10):eaaw7238. doi:10.1126/sciadv.aaw7238PubMed

[11] National Research Council, Committee on the Science of Team Science. Enhancing the Effectiveness of Team Science. Cooke NJ, Hilton ML, editors. Washington (DC): National Academies Press (US); 2015.Cited in Oh SS, Galanter J, Thakur N, Pino-Yanes M, Barcelo NE, White MJ, et al. (2015) Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled. PLoS Med 12(12): e1001918. https://doi.org/10.1371/journal.pmed.1001918

[12] RFA-HG-21-041: New Investigators to Promote Workforce Diversity in Genomics, Bioinformatics, or Bioengineering and Biomedical Imaging Research (R01 Clinical Trial Optional) (nih.gov)

[13] https://grants.nih.gov/grants/guide/pa-files/pa-18-586.html

[14] https://news.feinberg.northwestern.edu/2020/01/funding-disparities-research-and-underrepresented-minority-scientists/

[15] https://diversity.nih.gov/sites/coswd/files/2016-09/AA-B-funding-disparities.pdf

[16] Calculated from data on the NIH website at https://diversity.nih.gov/building-evidence/racial-disparities-nih-funding.

[17] https://www2.ed.gov/about/offices/list/ocr/edlite-minorityinst.html and HEERF II: Minority Serving Institutions (a)(2) (ed.gov)

minority/underserved populations[18]. Additionally, researchers from domestic faith-based and community-based organizations, tribes, and tribal organization serving underserved populations are likely to conduct research into areas/topics impacting the community they serve. Therefore, the participation of researchers from MSIs in HRSA/MCHB-funded research could be an effective strategy to advance health equity research by increasing the diversity of the researchers, especially from underserved communities/groups.

This NOFO aims to increase the diversity of awardees in the MCH SDAR program by increasing the funding probability of researchers from institutions, agencies, and organizations serving underserved populations, as one way to achieve the goal of increasing the diversity of researchers funded by MCHB.[19]

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[20].

2. Summary of Funding

HRSA estimates approximately $600,000 to be available to fund six (6) recipients. The actual amount available will not be determined until enactment of the final FY 2022 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). 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 appropriately.

The period of performance is July 1, 2022 through June 30, 2023 (1 year).

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

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[18] Campbell AG, Leibowitz MJ, Murray SA, et al. Partnered research experiences for junior faculty at minority-serving institutions enhance professional success. CBE Life Sci Educ. 2013;12(3):394-402. doi:10.1187/cbe.13-02-0025 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3763007/

[19] Carnethon, Mercedes R, Kiarri N Kershaw, and Namratha R Kandula. "Disparities Research, Disparities Researchers, and Health Equity." JAMA : the journal of the American Medical Association 323.3 (2019): 211–212. Web.

[20] A grant is a financial assistance mechanism where HRSA anticipates no substantial programmatic involvement with the recipient during performance of the contemplated project.

III. Eligibility Information

1. Eligible Applicants

Eligibility is limited to 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. See 42 CFR § 51a.3(b). Domestic faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

HRSA may not consider an application for funding if it contains any of the non-responsive criteria below:

- Exceeds the ceiling amount
- Fails to satisfy the deadline requirements referenced in Section IV.4

The Project Narrative is limited to 20 pages and the Methods section of the Project Narrative is limited to 6 pages in length. Applications that exceed these 20-page limit for the Project Narrative and the 6-page limit for the Methods section will be deemed nonresponsive and will not be considered for funding under this notice.

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

HRSA will only accept your **last** validated electronic submission, under the correct funding opportunity number, before the Grants.gov application due date as the final and only acceptable application.

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

- An individual cannot be named as the project director (PD) or principal investigator (PI)[21] **on more than one** application for the HRSA-22-096 competition.

- In order to diversify our research grant portfolio, and ensure that investigators devote adequate time and expertise to funded research programs, a current PD/PI of an active HRSA/MCHB/Office of Epidemiology and Research (OER)/Division of Research (DOR) award can serve for **no more than 10 percent time** on a new proposal.

- Applications that **overlap** in period of performance with a currently funded HRSA/MCHB/OER/DOR project by the same PD/PI will not be considered for funding (i.e., a PD/PI cannot have two (2) HRSA/MCHB/OER/DOR awards in effect simultaneously). A no-cost extension year counts as part of the total period of performance during which an overlap in period of performance is not allowed.

- Applications must propose secondary analysis of existing national data sets and/or administrative records.

- All secondary analyses, including those that involve the linkage of multiple data sets, cannot exceed 1 year in length.

- Projects that include the collection of biological specimens will not be considered, as this program funds secondary analysis of existing national databases and administrative data on MCH populations and only allows secondary analysis of existing national databases and administrative data.

- Projects addressing autism spectrum disorder will **not** be considered for this competition (a separate competition for Autism Secondary Data Analysis Research Program may be held, if funds are available).

Additionally, a student/trainee receiving support from award funds must be a citizen, national, or permanent resident of the United States.

[21] 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, yet multiple co-PI/co-PDs are allowed. This application responsiveness criterion only applies to current MCHB PI/PDs, not co-PI/PDs.

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 select "Subscribe" and provide your email address for HRSA-22-096 in order to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. *You are ultimately responsible for reviewing the For Applicants page for all information relevant to this NOFO.*

2. Content and Form of Application Submission

Application Format Requirements

Section 4 of HRSA's *SF-424 R&R Application Guide* provides general instructions for the budget, budget justification, staffing plan and personnel requirements, assurances, certifications, etc. You must submit the information outlined in the HRSA *SF-424 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 HRSA *SF-424 R&R Application Guide* and Appendix D of this NOFO for the Application Completeness Checklists.

Application Page Limitation

The total size of all uploaded files included in the page limit may not exceed the equivalent of **60 pages** when printed by HRSA. The page limit includes a **20-page limitation for the narrative section** and a **6-page limitation for the Methodology/Research Strategy methodology section**; which includes Significance, Innovation, and Approach. All sections combined contribute to the 60-page total limit, including the 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.

Biographical sketches for any key employed personnel that will be assigned to work on the proposed project must be attached to RESEARCH & RELATED Senior/Key Person Profile (OMB Number 4040-0001) found in the application package on Grants.gov. Due to the HRSA 60-page limit, it is recommended that all biographical

sketches are no more than 5 pages in length and must follow the HRSA font/margin requirements. Please be aware that this form does count against the page limit.

Please note: Effective April 22, 2021, the abstract is no longer an attachment that counts in the page limit. The abstract is the standard form (SF) "Project_Abstract Summary." Standard OMB-approved forms included in the workspace application package do not count in the page limit. However, biographical sketch OMB forms **do** count in the page limitation. If you use an OMB-approved form that is not included in the workspace application package for HRSA-22-096, it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **It is therefore important to take appropriate measures to ensure your application does not exceed the specified page limit. Any application exceeding the page limit of 60 will not be read, evaluated, or considered for funding.**

Please note that the Methodology/Research Strategy of the application narrative is **STRICTLY LIMITED TO 6 PAGES as part of the 60-page limit**. If you do not adhere to this page limit, your application will be deemed non-responsive to the NOFO and marked ineligible for review.

Applications must be complete, within the specified page limit, and validated by Grants.gov under HRSA-22-096 before the deadline.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

1) You certify on behalf of the applicant organization, 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. § 3354).
3) If you are unable to attest to the statements in this certification, you must include an explanation in *Attachment: 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*

Use the Standard OMB-approved Project Abstract Summary Form 2.0 that is included in the workspace application package. Do not upload the abstract as an attachment or it will count toward the page limitation. You are limited to 4,000 characters in the summary form's Project Abstract field. For information required in the Project Abstract Summary Form, see Section 4.1.ix of HRSA's *SF-424 R&R Application Guide*.

Include the information requested at the top of the abstract. Because the abstract is often distributed to provide information to the public and Congress, be clear, accurate, concise, and do not refer to other parts of the application. Briefly state the principal needs and problem, goals, proposed data sets including study population(s), planned coordination, anticipated products, and plans for evaluation.

Provide the information below in the Project Abstract field:

- PROBLEM: Briefly state the principal needs and problems that are addressed by the project, including the project's relationship to MCHB Strategic Research Issues.
- GOAL(S) AND OBJECTIVES: Identify the major goal(s) and objectives for the period of performance. Typically, the goal is stated in a sentence or paragraph, and the objectives are presented in a numbered list.
- PROPOSED DATA SETS AND TARGET POPULATION(S): Briefly describe the research design and methods within the abstract and include data collection methods and data set 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.
- PRODUCTS: Provide a brief description of the anticipated products of this Research Network, including modes of dissemination of project activities and findings.
- EVALUATION: Briefly describe the evaluation methods used to assess program outcomes as well as the effectiveness and efficiency of the project in attaining goals and objectives.
- KEY TERMS: From Appendix C select: (a) significant content terms that describe your project (maximum of 10 content terms), (b) targeted populations (select all that apply), and (c) age ranges (select all that apply), and include at the end of your abstract.

NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, the table below provides a crosswalk between the narrative language and where each section falls within the review criteria. Any forms or attachments referenced in a narrative section may be considered during the objective review.

Narrative Section	**Review Criteria**
I Specific Aims: 1) Needs Assessment	(1) Need
I. Specific Aims: 2) Significance	(2) Response
I. Specific Aims: 3) Goals and Hypotheses	
II. Methodology/Research Strategy: 1) Study Design/Approach	(3) Evaluative Measures
II. Methodology/Research Strategy: 2) Scientific Innovation and Importance	(4) Impact
III. Impact and Dissemination	
IV. Organizational Information/Environment	(5) Resources/Capabilities
Budget and Budget Justification	(6) Support Requested
V. Feasibility	(7) Program Assurances
VI. Evaluation and Technical Support Capacity	
VII. Protection of Human Subjects, Data Availability and Diversity of Database Sample	

ii. ***Project Narrative***

This section provides a comprehensive description of all aspects of the proposed project. It should be succinct, self-explanatory, consistent with forms and attachments, and organized in alignment with the sections and format below so that reviewers can understand the proposed project.

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

Section I: SPECIFIC AIMS – CORRESPONDS TO SECTION V'S REVIEW CRITERIA #1 NEED AND #2 RESPONSE

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 value of the proposed study.

1) NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion #1 NEED

- Briefly describe the target population(s) (including age ranges, race/ethnicity, gender/sex and other demographic information) and its unmet health needs; and identify health disparities facing the target population(s);
- As appropriate, include social determinants of health (SDOH)[22] and health inequalities impacting the population that the current project will address;
- Briefly describe how the proposed project will benefit the target population and address health disparities facing underserved populations;
- Briefly describe how the proposed project aligns with Healthy People 2030 objectives;
- Identify relevance to an MCHB Strategic Research Issues and MCHB Strategic Plan Goals;
- Discuss how the research findings will strengthen and expand the evidence base of the MCH Block Grant National Performance Measures (Appendix A);

2) SIGNIFICANCE -- Corresponds to Section V's Review Criterion #2 RESPONSE

- Describe the background literature to provide rationale for the proposed research objectives;
- Explain the critical problem, barrier to progress in the field, and research gaps that the proposed project addresses; and
- Identify how findings may be applied to the field to improve care and/or the ways that services are organized and delivered, and achieve health equity in MCH populations.

[22] Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. Healthy People 2030, U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. Retrieved (08/12/2021), from https://health.gov/healthypeople/objectives-and-data/social-determinants-health

3) GOALS AND HYPOTHESES-- Corresponds to Section V's Review Criterion #2 RESPONSE

a. Goals and Objectives

State clearly and succinctly the specific goals and objectives of the particular secondary data analytic research proposed to be accomplished during the period of performance that addresses the problems, barriers, and gaps identified. The goals and study objectives are specific, measurable, achievable, relevant, and time bound (SMART).

b. 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 frameworks such as health equity, 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 definition of the variables;
- If possible, construct and present a graphical theoretical model, conceptual framework, or representation of the set of relationships held to be operative among the variables; and
- Ensure consistency among the associations depicted by the graphical analytic model (if included), the table of variables, the statement of hypotheses, and the plan for data analysis.

SECTION II: METHODOLOGY/RESEARCH STRATEGY -- CORRESPONDS TO SECTION V'S REVIEW CRITERIA #3 EVALUATIVE MEASURES AND #4 IMPACT

Organize the Methodology/Research Strategy section in the specified order using the instructions provided below. Start each section with the appropriate section heading – Study Design/Approach and Scientific Innovation. Cite published methodological details and provide the full reference in the Bibliography and References Cited section.

The **Methodology/Research Strategy section (Study Design/Approach and Scientific Innovation) is limited to six pages in length.** If you do not adhere to this page limit for this section of your narrative, your application will be deemed **non-responsive** to the NOFO and marked ineligible for review.

1) Study Design/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. Include the following information:

- A short description of the database(s) you propose to use, including but not limited to the data source (including funder), the sampling design and weighting, inclusion and exclusion criteria, response rate, data collection procedure, key information included in the data sets, strengths and limitations of the data for this project. Written confirmation of the availability of the database for the proposed study should be included in Attachment 3. Describe how access will be gained to any confidential files, if utilized, in the proposed analyses;
- If applicable, include information regarding the linkage of multiple data sets; data linkage activities among multiple data sets should be included within the overall study design portion of the Work Plan;
- Describe the study population, including demographic information (e.g., age, racial/ethnic background, socioeconomic status, geographic location);
- Identify the key variables, how they are measured and the validity of the measurements; and
- Describe in detail the statistical methods you will utilize to analyze the data and justify why they are appropriate for testing the proposed hypotheses, and identify the potential biases that the methods cannot address and the direction of the bias.

Preliminary Studies: Include information on preliminary studies as part of the Section (1) Study Design section. Provide a description of the PD/PI's preliminary studies pertinent to this application. This information will also help to establish the experience and competence of the investigator to pursue the proposed project. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.

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

- Explain how the proposed project will advance scientific knowledge and evidence base, and improve technical capability and/or clinical practice; and
- Describe how current concepts, methods, technologies, treatments, services, policies, or preventive interventions will be changed if the proposed aims are achieved through this secondary data analysis project.

SECTION III: IMPACT AND DISSEMINATION – CORRESPONDS TO SECTION V'S REVIEW CRITERION #4 IMPACT

1) Public Health Impact

- Describe the public health impact that study results may have, e.g., 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.
- 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.

2) Publication and Dissemination Plan

It is expected your project will produce **at least two peer-reviewed publications**.

- Provide a publication action plan that includes:
  - Plans for dissemination of project results. Clearly indicate the number, focus area of your proposed peer-reviewed publications, and names and impact factor of targeted journals.
  - Describe how you will facilitate the transfer of findings into practice by disseminating findings, reports, and/or project outputs to key target audiences, including state Title V and other program(s) serving MCH populations, policymakers, scientific, professional, lay audiences, federal partners, families, and the general public. Examples of how past recipients have disseminated research findings and information on project activities include email messages, newsletter articles, conference presentations, webcasts, fact sheets, infographics, policy briefs, and website and social media posts.

SECTION IV: ORGANIZATIONAL INFORMATION/ Environment -- 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.

1) Organizational Facilities and Other Resources

- Identify the facilities you will use (e.g., data platform, data center, 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. If you intend to use restricted data, please indicate your plan and timeline for obtaining necessary approvals and data access;
- Discuss ways in which the proposed study will benefit from the unique features of the scientific environment of the institutions with which the applicants are affiliated;
- For Early Stage Investigators,[23] describe institutional investment in the success of the research project and success of the investigator in obtaining non-federal funding or as a co-investigator. Examples may include computer and software support sufficient for project needs, collegial support such as the availability of organized peer groups and mentors, logistical support such as administrative management and oversight, and financial support such as protected time for research with salary support; and
- If there are multiple performance sites, describe relevant resources available at each site.

2) Qualifications of Research Team's Key Personnel

- To assess the qualifications of the research team's key personnel and research strategy, the following items are used: (a) Preliminary Studies in Section II; Methodology/Research Strategy 2) Study Design; (b) Staffing Plan in Budget Narrative; and (c) Biographical Sketches of key personnel;
- It is encouraged that you use the MCHB biographical sketch form found here: https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-forResearch-Grant-Applicants-Jan2020-2023.docx. NOTE: The biographical sketch form counts against your total page limitation and may not exceed five pages per person; and
- Biographical sketches should follow the instructions provided below. When applicable, biographical sketches should include training, language fluency and experience working with culturally and linguistically diverse study populations.

- **Professional Information:** At the top of page one, include Name, Position Title, and Education/Training including: institution and location,

[23] 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)

degree, month/year degree attained, field of study. Then complete sections as described below:

a) **Ethnicity Data:** Provide ethnicity data for the PI and all key personnel according to the included chart on the MCHB Biographical sketch form. This information allows MCHB to determine to what extent individuals of different backgrounds are participating. This information assists MCHB in ensuring that federal grant and cooperative agreement awards are reaching a broad diversity of populations.
    - https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-forResearch-Grant-Applicants-Jan2020-2023.docx.

b) **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 III of the Project Narrative). You may also 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/or active duty military service.

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

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

e) **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 person identified on the biographical sketch.

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 an award to show other sources of federal grant support for the applicant. 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.

Section V: 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.

1) 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.

2) Resolution of Challenges
   - Discuss any challenges that are likely to be encountered in designing and implementing the research activities described in the Study Design/Approach, and approaches that will be used to resolve such challenges. Discuss alternative strategies should any of these potential challenges arise. Examples include:
     - The feasibility of obtaining the dataset or administrative record within the required timeline to complete the tasks, including access to most-recent dataset or administrative record(s) if multiple years exist; and
     - The feasibility of completing the proposed work within the timeline provided.

Section VI: EVALUATION AND TECHNICAL SUPPORT CAPACITY -- CORRESPONDS TO SECTION V'S REVIEW CRITERION #7 PROGRAM ASSURANCES

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

Section VII: PROTECTION OF HUMAN SUBJECTS, DATA AVAILABILITY AND DIVERSITY OF DATABASE SAMPLE – CORRESPONDS TO SECTION V'S REVIEW CRITERION #7 PROGRAM ASSURANCES

1) Protection of Human Subjects

This section is required only 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 HRSA-22-096 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. For more information, please see the Human Subjects Protection subsection in Award Administration Information.

- Discuss plans to seek Institutional Review Board (IRB) approval or exemption. IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent the page limits of the Methodology/Research Strategy section.

2) Data Availability and Diversity of Database Sample

A. Provide details about the diversity of the sample selected for the study/analysis. Information should include study sample totals by:

1) 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);
- 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"; and

- Describe how the analytic plan will reflect an understanding and valuing of the culture of the target population.

2) Racial Categories

- American Indian/Alaska Native
- Asian
- Native Hawaiian or Other Pacific Islander
- Black or African American
- White
- More than One Race
- Gender/sex distribution within each racial category
- Total sample by racial category

3) Socioeconomic status [24]

- Level of Education
- Income-to-Poverty Ratio or Federal Poverty Level
- Occupational Status

4) Geographic Location

- Urban
- Rural

B. Provide written confirmation that the proposed data that will be used for the 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.

iii. *Budget*

- The directions offered in the *SF-424 R&R Application Guide* may differ from those offered by Grants.gov. Follow the instructions in Section 4.1.iv of HRSA's *SF-424 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 your application for funding, you will have a well-organized plan and, by carefully following

[24] Socioeconomic status can be determined by a family's income level, education level, and occupational status. Despite the differences in definition between poverty and socioeconomic status, researchers agree that there is a clear and established relationship between poverty, socioeconomic status, and health outcomes—including increased risk for disease and premature death. Healthy People 2020, accessed 10/28/20, https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/poverty

the approved plan, may 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) you incur to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by you to satisfy a matching or cost-sharing requirement, as applicable.

As required by the Consolidated Appropriations Act, 2021 (P.L. 116-260), Division H, § 202 and Division A of the FY 2022 Extending Funding and Emergency Assistance Act (P.L. 117-43), "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." 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 the following fiscal years, 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 MCH SDAR Program requires the following:

  Position descriptions (roles, responsibilities, and qualifications of proposed project staff) in the Budget Justification under Personnel costs. The budget justification is uploaded into the Budget Narrative Attachment Form. Biographical sketches for any key personnel must be attached to RESEARCH & RELATED Senior/Key Person Profile (OMB Number 4040-0001) found in the application package on Grants.gov. Due to the HRSA 60-page limit, it is recommended that all biographical sketches are no more than two pages in length and must follow the HRSA font/margin requirements. NOTE: The biographical sketch may not exceed five pages per person. This OMB form does count against your page limit and can be attached to RESEARCH & RELATED Senior/Key Person Profile (OMB Number 4040-0001) found in the application package on Grants.gov. For details on how to format the biographical sketch visit: https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-forResearch-Grant-Applicants-Jan2020-2023.docx.

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 limitation.** Your indirect cost rate agreement and proof of non-profit status (if applicable) will not count toward the page limitation. **Clearly label each attachment**. You must upload attachments into the application. Any *hyperlinked* attachments will *not* be reviewed/opened by HRSA.

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

If you are eligible for the funding special consideration, include letters of verification from your organization in this section. These letters are required in order to be considered for the funding special consideration.

Attachment 2: List of Citations for Key Publications

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 60-page limitation, a list of citations only may be included.

Attachment 3: 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 3. Describe how access will be gained to any confidential files, if utilized, in the proposed analyses, and the timeline for obtaining the data sets for the proposed study.

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, as necessary

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number Transition to the Unique Entity Identifier (UEI) and System for Award Management (SAM)

You must obtain a valid DUNS number, also known as the Unique Entity Identifier (UEI), and provide that number in the application. In April 2022, the *DUNS number will be replaced by the UEI, a "new, non-proprietary identifier" requested in, and assigned by, the System for Award Management (SAM.gov). For more details, visit the following webpages: Planned UEI Updates in Grant Application Forms and General Service Administration's UEI Update.

You must register with 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 you are an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or you have an exception approved by the agency under 2 CFR § 25.110(d)). For

your SAM.gov registration, you must submit a notarized letter appointing the authorized Entity Administrator.

If you are chosen as a recipient, HRSA will not make an award until you have complied with all applicable SAM requirements. If you have not fully complied with the requirements by the time HRSA is ready to make an award, you may be deemed not qualified to receive an award, and HRSA may 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.

*Currently, the Grants.gov registration process requires information in three separate systems:

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

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

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. Effective January 1, 2020, the forms themselves are no longer part of HRSA's application packages instead, 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.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 26, 2022 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 MCH SDAR Program is not 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

You may request funding for a period of performance of up to 1 year, at no more than $100,000 (inclusive of direct **and** indirect costs). 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 appropriately.

The General Provisions in Division H of the Consolidated Appropriations Act, 2021 (P.L. 116-260) and Division A of the FY 2022 Extending Funding and Emergency Assistance Act (P.L. 117-43) apply to this program. See Section 4.1 of HRSA's *SF-424 R&R Application Guide* for additional information. Note that these or other restrictions will apply in the following fiscal years, as required by law.

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

Be aware of the requirements for HRSA recipients and subrecipients at 2 CFR § 200.216 regarding prohibition on certain telecommunications and video surveillance services or equipment. For details, see the HRSA Grants Policy Bulletin Number: 2021-01E.

All program income generated as a result of awarded funds must be used for approved project-related activities. Any program income earned by the recipient must be used under the addition/additive alternative. You can find post-award requirements for program income 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.

Seven review criteria are used to review and rank the MCH SDAR Program applications. Below are descriptions of the review criteria and their scoring points.

Criterion 1.	Need	10 points
Criterion 2.	Response	20 points
Criterion 3.	Evaluative Measures	30 points
Criterion 4.	Impact	10 points
Criterion 5.	Resources/Capabilities	15 points
Criterion 6.	Support Requested	5 points
Criterion 7.	Program Assurances	10 points
TOTAL:		100 points

Criterion 1: NEED (10 points) – Corresponds to Project Narrative Section I Specific Aims: 1) Needs Assessment

1) Needs Assessment (6 points)
   - The extent to which the brief introduction and overview of the proposed research project is compelling.
   - The extent to which the applicant describes the target population characteristics (including age ranges of children/youth). The degree to which the project and description of the scientific rationale behind the proposed study is compelling and clearly describes the health disparities and unmet health needs of the target population

2) Alignment with HRSA MCHB Priorities and Healthy People 2030 (4 points)
   - The extent to which the project aligns with HRSA MCHB priorities, including relevance to an MCHB Strategic Research Issue and the goals identified in the HRSA MCHB Strategic Plan

- The extent to which the project will strengthen and expand topics identified as the HRSA MCHB priorities, and the MCH Block Grant National Performance Domains (Appendix A).
- The extent to which the research project describes its relationship to specific Healthy People 2030 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 Project Narrative Section I. Specific Aims: 2) Significance and 3) Goals and Hypotheses

1) Significance (5 points)

The extent to which:

- The investigators demonstrate knowledge of previous and current scientific research in the area of the project;
- The cited literature is pertinent to the research problem and provides a rationale for the research; and
- The project addresses a critical problem or barrier to the field.

2) Addressing Health Equity (5 points)

The extent to which the proposed project addresses health inequities faced by the underserved population and improves health equity for all MCH populations as its main purpose.

3) Goals and Hypotheses (10 points)

The extent to which:

- The goals and study objectives are SMART;
- The variables and the expected outcomes are clearly and succinctly defined and summarized, with attention to how these outcomes will address the unmet needs of the target population;
  The hypotheses are logically derived from the research literature, clearly stated, and are related to the research questions proposed; and
- There is consistency among the associations depicted by the theoretical framework or model, the variables, the statement of hypotheses, and the plan for data analysis.

Criterion 3: EVALUATIVE MEASURES (30 points) -- Corresponds to Project Narrative Section II. Methodology/Research Strategy: 1) Study Design/Approach

1) Study Design (20 points)
The extent to which:

- The overall research strategy, study design, statistical methodology, and analyses are well reasoned and appropriate to accomplish the specific aims of the project;
- The study population is described, i.e., (targeted age(s) or age ranges, expected racial/ethnic background and socioeconomic status, urban/rural, etc.), and is justified in terms of the scientific goals and methodology/research strategy proposed;
- The variables are clearly defined and the reliability and validity of the measurement of the variables using the data sets are described. E.g., validity of the survey instruments used to collect the data, the validity of using International Classification of Disease codes to identify disease and conditions using claims and electronic medical record data;
- The study statistical methods are appropriate and with scientific rigor; it includes an adequate and justified sample size. The expected differences between groups are defined in terms of statistical as well as clinical significance; sampling weights are applied when is it appropriate. Whenever possible, subgroup analyses, especially on minorities and underserved populations are conducted to address health equity.; and
- Significant threats to internal and external validity of the design have been adequately acknowledged and addressed.

2) Data quality, appropriateness, and availability (5 points)
The extent to which:

- The proposed national database(s) or administrative record(s) is/are clearly stated in the Project Abstract Summary form and described in the application; adequate attention was given to the data quality, and the appropriateness of using the data and data limitations and strengths relevant to this study are identified; and
- The data are available to the investigator for this study. The application must contain written confirmation that the proposed data to be used in the analysis are available to the investigator. If you intend to use restricted data, please indicate your plan and timeline for obtaining necessary approvals and data access.

3) Plan for Data Analysis (5 points)
The extent to which:

- Plans for data analysis are presented in detail and describe the rationale for the sequence of steps to be taken;
- The plans are appropriate to the nature of the data, design and samples; and
- Sufficient time is allocated for data analysis.

Criterion 4: IMPACT (10 points) -- Corresponds to Project Narrative Sections, II *Methodology/Research Strategy: 2) Scientific Innovation and Importance; and III Impact and Dissemination*

1) Innovation and Importance (5 points):
The extent to which:

- The application challenges and seeks to shift current research or clinical practice paradigms by utilizing innovative theoretical concepts, approaches or methodologies, instrumentation, or interventions; and
- A refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions is proposed; or project results are likely to exert a sustained influence on the research field(s) involved.

2) Public Health Impact and Dissemination (5 points)
The extent to which:

- The proposed project will have a broad public health impact to advance scientific knowledge, technical capability, and/or clinical practice in one or more broad fields relevant the MCH populations;
- The proposed study findings will be generalizable and of regional and national significance;
- The applicant presents a sound plan for how they will produce the expected minimum number of peer-reviewed publications;
- The proposal clearly demonstrates a dissemination plan to facilitate 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 children with special health care needs programs and other program(s) serving MCH populations, policymakers, families and the general public.

Criterion 5: RESOURCES/CAPABILITIES (15 points) -- Corresponds to Project Narrative Section IV. Organizational Information/ Environment

The extent to which:

- The organization is capable to provide quality facilities and personnel to fulfill the needs and requirements of the proposed research project;
- The project will benefit from unique features of the scientific environment, the collaborative arrangements, and the communities and stakeholders engaged;
- The Key/Senior Support Personnel Profiles and biographical sketches indicate that the PI, collaborators, staff, and other researchers are well qualified by training and/or expertise to conduct the research, and have demonstrated current and/or past success in publishing the findings of their research;
- If Early Stage Investigators or New Investigators, the appropriateness of experience and training and partnering with senior researchers; if established investigators, the degree to which they have demonstrated an ongoing record of research accomplishments that have advanced the MCH field; and
- The proposal describes relevant preliminary studies performed by key personnel, indicating the capacity to conduct the work as described.

Criterion 6: SUPPORT REQUESTED (5 points) – Corresponds to Budget and Budget Justification Narrative

The extent to which:

- The proposed budget is reasonable in relation to the objectives, the scope of work, the complexity of the research activities, and the anticipated results;
- Budget line items are well described and justified in the budget justification;
- The time allocated to key personnel is realistic and appropriate to achieve project objectives; and
- Other current and pending support is described, as applicable. (Note: A current PI of an MCH Research award (including a No Cost Extension (NCE) year) can serve for no more than 10 percent time on a new MCH Research proposal).

Criterion 7: PROGRAM ASSURANCES (10 points) – Corresponds to Project Narrative Section V. Feasibility; VI. Evaluation and Technical Support Capacity; VII. Protection of Human Subjects, Data Availability and Diversity of Database Sample

Once a project is funded, it is expected that it will demonstrate ongoing progress and completion as proposed and approved. It is important that you demonstrate feasibility that the project can be completed as proposed and approved.

1) Proposed timeline and evaluation (6 points)

The extent to which:

- The proposed project provides a clear, detailed, and feasible timeline for the proposed activities and is feasible to conduct within the proposed timeframe;
- The application demonstrates the feasibility of accessing the database(s) or administrative record(s); and
- Plans are in place to evaluate whether the project objectives are being met according to the timeline provided.

2) Human Subjects Protections (required if you answer yes) (4 points)

The extent to which:

- The proposal complies with the HHS regulations for protection of human subjects (45 CFR part 46). See the instructions in HRSA's SF-424 R&R Application Guide, Appendix: Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy;
- The project includes plans for: 1) protection of human subjects from research risks and 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); and
- Adequate measures are in place to ensure the security of the research data (data security).

2. Review and Selection Process

The objective review process provides an objective evaluation of applications 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. In addition to the ranking based on merit criteria, HRSA approving officials will apply other factors (e.g., geographical distribution) described below in selecting applications for award.

For this program, HRSA will use special consideration.

Funding Special Considerations and Other Factors

This program includes special consideration which is the favorable consideration of an application by HRSA funding officials, based on the extent to which the application addresses the specific area of special consideration. Applications that do not receive special consideration will be given full and equitable consideration during the review process. For this program, HRSA will take into consideration applicants from minority serving institutions (MSIs), including Hispanic-serving institutions, Historically Black Colleges and Universities (HBCUs), Tribally Controlled Colleges and Universities (TCCCUs), Alaska Native and Native Hawaiian Serving Institutions, Asian American Native American Pacific Islander Serving Institutions (AANAPISIs), and domestic faith-based and community-based organizations, tribes, and tribal organization serving mainly underserved populations. Letters of support from these organizations to verify the affiliation of the applicants are required and should be with other letters of support in Attachment 1.

PLEASE NOTE: HRSA will consider all applicants who are eligible to apply for this NOFO. Applications will be funded based on their strengths and scientific merits and depending on the availability of funding. In order to achieve the special consideration described above, HRSA may need to fund applications out of the rank order.

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.

VI. Award Administration Information

1. Award Notices

HRSA will release the Notice of Award (NOA) on or around the start date of July 1, 2022. 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*.

If you are successful and receive a NOA, in accepting the award, you agree that the award and any activities thereunder are subject to:

- all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award,
- other federal regulations and HHS policies in effect at the time of the award or implemented during the period of award, and
- applicable statutory provisions.

Accessibility Provisions and Non-Discrimination Requirements

Federal funding recipients must comply with applicable federal civil rights laws. HRSA supports its recipients in preventing discrimination, reducing barriers to care, and promoting health equity. Non-discrimination legal requirements for recipients of HRSA federal financial assistance are available at the following address: https://www.hrsa.gov/about/organization/bureaus/ocrdi#non-discrimination. For more information on recipient civil rights obligations, visit the HRSA Office of Civil Rights, Diversity, and Inclusion website.

Executive Order on Worker Organizing and Empowerment

Pursuant to the Executive Order on Worker Organizing and Empowerment, HRSA strongly encourages applicants to support worker organizing and collective bargaining and to promote equality of bargaining power between employers and employees. This may include the development of policies and practices that could be used to promote worker power. Applicants can describe their plans and specific activities to promote this activity in the application narrative.

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, and it is the recipient's responsibility to monitor the compliance of all funded subrecipients. 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.

- Refer to instructions provided in HRSA's *SF-424 R&R Application Guide*, Appendix Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy for specific instructions on preparing the human subjects section of the application.
- Refer to HRSA's *SF-424 R&R Application Guide* to determine if you are required to hold a Federal Wide Assurance (FWA) of compliance from the Office of Human Research Protections (OHRP) prior to award. You must provide your Human Subject Assurance Number (from the FWA) in the application. If you do not have an assurance, you must indicate in the application that you will obtain one from OHRP prior to award.
- In addition, you must meet the requirements of the HHS regulations for the protection of human subjects from research risks, including the following: (1) discuss plans to seek IRB approval or exemption; (2) develop all required documentation for submission of research protocol to IRB; (3) communicate with IRB regarding the research protocol; (4) communicate about IRB's decision and any IRB subsequent issues with HRSA.
- 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 any page limitation in the Methodology portion of the Project Narrative section.

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 HRSA 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://grants4.hrsa.gov/DGISReview/ProgramManual?NOFO=HRSA-22-096&ActivityCode=R42. 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	7/1/2022-6/31/2023 *(administrative data and performance measure projections, as applicable)*	Period of performance start date	120 days from the available date
b) Project Period End Performance Report	7/1/2022-6/31/2023	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).

Note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at 2 CFR § 200.340 - Termination apply to all federal awards effective August 13, 2020. No additional termination provisions apply unless otherwise noted.

VII. Agency Contacts

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

David Colwander
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-7858
Email: DColwander@hrsa.gov

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

Fulera Salami, MPH and Maura Maloney, PhD, MS
Project Officers, Division of Research, Office of Epidemiology and Research
Attn: FY 2022 MCH SDAR
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 18N11
Rockville, MD 20857
Telephone: (301) 443-6377 or (301) 443-1087
Email: mchsdar@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 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 the EHBs. Always obtain a case number when calling for support. For assistance with submitting in the EHBs, contact the HRSA Contact Center, Monday–Friday, 7 a.m. to 8 p.m. ET, excluding federal holidays at:

HRSA Contact Center
Telephone: (877) 464-4772 / (877) Go4-HRSA
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, November 8, 2021
Time: 2 – 3:30 ET
Dial-in Toll-Free #: (833) 568-8864
Meeting ID: 160 446 8826
Passcode: 22601175
Weblink: https://hrsa-gov.zoomgov.com/j/1604468826?pwd=UGZua1NDZ3ZqZFJDWkhrUTJrejk5UT09

In an attempt to more effectively utilize our TA webinar time, if you have questions about the NOFO, please send them prior to the webinar via email to MCHSDAR@hrsa.gov. We will compile and address these questions during the TA webinar.

HRSA will record the webinar and make it available approximately 2 weeks after the webinar at: https://mchb.hrsa.gov/research/pre-app-ta-webinars.asp.

Tips for Writing a Strong Application

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

Appendix A: Title V MCH Services Block Grant–National Performance Measures

No.	Performance Measures	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 Measure 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 B: Relevant Websites

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

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

Healthy People 2020 / Developing Healthy People 2030
http://www.healthypeople.gov/2020/
https://www.healthypeople.gov/2020/About-Healthy-People/Development-HealthyPeople-2030

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

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

Inclusion Across the Lifespan - Policy Implementation
http://grants.nih.gov/grants/funding/children/children.htm

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

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)
https://medicalhomeinfo.aap.org/Pages/default.aspx

Appendix C: 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/Inter-conception 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
- 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

Lifespan & Social Determinants

- Neighborhood
- Lifespan
- Social Determinants of Health

b) Underserved Communities (as many as apply):

- African American
- Asian/Pacific Islander
- Hispanic/Latino
- Immigrant
- Indigenous/Native American/Alaskan Native
- Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ+) Persons
- Members of Religious Minorities
- Other Persons of Color
- Persons Otherwise Adversely Affected by Persistent Poverty or Inequality
- Persons who Live in Rural Areas
- Persons with Disabilities or 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 D: Application Completeness Checklist

Funding Opportunity Number: HRSA-22-096 **Application Due Date in Grants.gov:** January 26, 2022	
Requirement	**Yes**
Do you meet the eligibility criteria?	
Did you read the *R&R Application Guide* (https://www.hrsa.gov/sites/default/files/hrsa/grants/apply/applicationguide/sf-424-rr-app-guide.pdf)?	
Do you have a DUNS number (https://www.dnb.com/duns-number.html)?	
Did your Authorized Organization Representative (AOR) register in SAM (https://www.sam.gov/)?	
Did your AOR register in Grants.gov (https://www.grants.gov/)?	
Is your Abstract in plain language, no more than 4,000 characters and single spaced?	
Does the Narrative Section of your application fully address: • Background and Significance? • Specific Goals and Objectives? • Project Design, Methods, and Evaluation? • Plan/Schedule of Implementation and Capability of Applicant? • Feasibility? • Evaluation and Technical Support Capacity? • Protection of Human Subjects? • Targeted/Planned Enrollment?	
Did you confirm that your application addressed all of the NOFO Review Criteria?	
Is your proposal less than 60 pages with the Narrative Section within the 20-page limit and the Methods Section within the 6-page limit?	
Are your budget and budget justification narrative completed accurately and in the yearly funding limit? **NOTE:** 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**.	
Did you clearly label all of your attachments?	
Did you include the Biographical Sketches of Key Personnel in the Application?	
Do you know your institution's indirect cost rate?	

Funding Opportunity Number: HRSA-22-096 **Application Due Date in Grants.gov:** January 26, 2022	
Requirement	**Yes**
Did you use no less than 12-point font and are your page margins at least 1 inch wide in the Narrative and Attachment Sections of the Application? **NOTE:** The Biographical Sketches of Key Personnel can have .5" margins.	
Are your pages, including attachments, within the 60-page limit? **NOTE:** Pages which do not count toward the 60-page limit include: Cover Page, Indirect Cost Rate Agreement, Proof of Non-Profit Status, and Standard OMB approved forms.	

Appendix E: Logic Model

The following logic model illustrates HRSA's expectations and goals for the MCH Secondary Data Analysis Research Program (MCH SDAR)

PROGRAM PROCESS What is the planned work for the program?		PROGRAM OUTCOMES What are the program's intended results?	
ACTIVITIES (What will program inputs do?)	OUTPUTS / PRODUCTS (What will be created as a result of the activity?)	SHORT-TERM / INTERMEDIATE (What will change as a result of the product/system implemented?)	LONG-TERM / IMPACT (What will change if short-term / intermediate outcomes are achieved?)
Design and conduct secondary data analysis within 1 year of award	Complete secondary data analysis within 1 year of award	• Increase the number of secondary data analyses addressing current and emerging issues relevant to the MCH populations	• Increase MCH SDAR research sustainability and contribute to the knowledge base in MCH • Advance the evidence base for, health care providers, other practitioners, researchers, policy makers, public health systems, Title V Block Grant programs, and the
Develop and implement a dissemination plan for communicating research findings to diverse stakeholders; disseminate research findings through a variety of mechanisms	• Dissemination plan with a timeline and list of proposed products is developed • Manuscripts accepted or published in peer-reviewed journals	• Increase awareness of existing data sources to a wide audience who are interested in studying emerging issues in MCH	

PROGRAM PROCESS What is the planned work for the program?		PROGRAM OUTCOMES What are the program's intended results?	
ACTIVITIES (What will program inputs do?)	OUTPUTS / PRODUCTS (What will be created as a result of the activity?)	SHORT-TERM / INTERMEDIATE (What will change as a result of the product/system implemented?)	LONG-TERM / IMPACT (What will change if short-term / intermediate outcomes are achieved?)
	• Non-peer-reviewed publications aimed at stakeholders beyond the scientific research community (e.g., tools, toolkits, reports, blogs, web posting, videos, infographics, lay summary of research publications) • At least 2 peer-reviewed publications within 1 year of award	• Increase the accessibility of HRSA funded MCH research findings to the scientific and lay community	MCH community
Prepare and submit grant applications for external funding opportunities outside of HRSA/MCHB's	Grant applications completed and submitted for external funding opportunities	Increase the capacity of grantees to expand/sustain research initiated by the MCH SDAR program	Increase the use/translation of study findings into intervention research that may ultimately inform changes in

PROGRAM PROCESS What is the planned work for the program?		PROGRAM OUTCOMES What are the program's intended results?	
ACTIVITIES (What will program inputs do?)	OUTPUTS / PRODUCTS (What will be created as a result of the activity?)	SHORT-TERM / INTERMEDIATE (What will change as a result of the product/system implemented?)	LONG-TERM / IMPACT (What will change if short-term / intermediate outcomes are achieved?)
research grant program			practice and policy in the public health system or related settings
Train and mentor junior/new investigators in MCH secondary data research	Junior/new investigators trained/mentored	Increase the number of junior/new investigators trained/mentored in foundational research and current/emerging issues relevant to MCH populations	Increase MCH secondary data research sustainability

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

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

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

2. **How can I download the complete application package for the HRSA-22-096 NOFO?**

You can download the application by searching for the application number HRSA-22-096 on Grants.gov:

1) *Click on the hyperlink for HRSA-22-096*
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.*

3. **What is Grants.gov?**

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

4. **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, 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.

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

1) *Make sure that the Authorized Organization Representative from your university/organization is registered in Grants.gov NOW. This process can take up to 1 month and it is better to complete it and have it out of the way before starting any grant application.*
2) *Read the instructions on Grants.gov carefully and allow time for corrections. Enter information in fields even if it is 0 or the form will remain incomplete.*

Required fields are highlighted in yellow.

3) *There are resources available on the Grants.gov web site to help you navigate this new system. Please visit Grants.gov to access these resources.*
4) *Some business practices will change with the introduction of the new SF-424 R&R Form:*
   - *With the HRSA SF-424 R&R, you will be reporting faculty and staff time in calendar month equivalents.*
   - *Budget details about subcontracts will now be described in a section of the SF424 R&R Form called sub-awards.*

6. Can I get a copy of the NOFO from the previous competition?

The past funding announcement will not be distributed to avoid confusion among potential applicants. 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-22-096) 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-22-096).

7. What types of institutions can apply?

Eligibility is limited to 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 (See 42 CFR § 51a.3(b)). Domestic faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.

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

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

9. How do I know whether to apply to the 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 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?"

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

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

11. If I were to receive an MCH SDAR award, 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 set(s) that will be used in the proposal. HRSA does not make data available to recipients for the MCH 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.

12. 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 Uniform Administrative Requirements and the HRSA SF-424 R&R Application Guide, "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 SF424 R&R also contains information on how to negotiate the indirect cost rate.

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

Your 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.

14. 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.

15. How do I know if the database I am considering for my analysis is appropriate for the MCH SDAR Program?

The 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, since this is part of the criterion on Public Health Impact that the external review committee will be assessing all proposals on. You should also include written confirmation that the proposed dataset for the 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. 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 SDAR projects and the data sets they have used.

16. Does the MCH SDAR program allow the use of administrative records?

Yes, administrative records can be used for this grant. The 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 will yield information that addresses a critical problem or barrier to progress the field of MCH, since this is part of the criterion on Public Health Impact that the external review committee will be assessing all proposals on.

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

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 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. See ***Criterion 4 (Impact)*** *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 MCH SDAR projects and the data sets they have used. It is not the reviewer's responsibility to automatically know about the availability of the*

applicant's proposed dataset. The application should clearly describe the availability of the dataset, and if this is not described successfully, the reviewer may reduce the application's score accordingly.

18. Does the HRSA-22-096 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 PD or PI on more than one active HRSA/MCHB/OER/DoR-funded grant. In order to diversify the MCH SDAR, a PD/PI on an active MCHB/OER/DoR-funded research grant is expected to have no more than 10 percent time as a co-investigator on an existing HRSA/MCHB/OER/DoR 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 time across all federally-funded grants does not exceed 100 percent.

19. 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 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 related research question or specific MCH population, then the best available 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.

20. 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 PD/PI, but we anticipate that applicant PDs/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 PD/PI meets these review criteria and how the proposed PD/PI's allocated time would potentially be sufficient for the success of the project.

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

Postdoctoral fellows are allowed to serve as PD/PI on the MCH SDAR grant. Ultimately, the determination of who may or may not serve as PD/PI depends on the rules of your institution.

22. Can someone who is currently a PI on a grant funded by another agency be a PI on an MCH SDAR grant?

Yes, a PI on another (non-HRSA/MCHB) agency's grant can be a PI on an MCH SDAR grant; however, if selected for funding, the new recipient will need to verify that percent time across all federally funded grants does not exceed 100 percent.

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

Yes, more than one application per institution is allowable under the MCH SDAR program, as long as all other application responsiveness criteria are met.

24. Which format should we follow for the biographical sketch?

Include biographical sketches for persons occupying key positions. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch. Given the 60-page limit, it is recommended that biographical sketches be no more than two pages in length per person. Please use the MCHB biographical sketch form found here: https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-for-Research-Grant-Applicants-Jan2020-2023.docx. Please note that even though the document has an OMB clearance number, it is not a standard form and your response counts against the page limit. The biographical sketch may not exceed five pages per person. This OMB form does count against your page limit and can be attached to RESEARCH & RELATED Senior/Key Person Profile (OMB Number 4040-0001) found in the application package on Grants.gov.

25. Are there page limits for the submitted application?

Yes, the MCH SDAR Program NOFO specifies strict page limitations for the overall submission and for specific sections of the application. You are required to comply with these page limitations, or the application will not be considered for funding. The total size of all uploaded files included in the page limit may not exceed 60 pages

when printed by HRSA. The page limit includes a 20-page limitation for the narrative section, and 6-page limitation for the Methodology/Research Strategy section; which includes Significance, Innovation, and Approach. All sections combined contribute to the 60-page total limit, including the 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.

26. What counts towards the page limits?

- *The page limit applies to the:*
  - *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 (including the new Project Abstract Summary) that are included in the application package*
  - *Indirect Cost Rate Agreement*
  - *Proof of Non-Profit Status*

- *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 application is limited to 60 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.*

27. 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.

28. 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.

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

MCHB is no longer treating resubmissions differently than new, original applications. All applications whether new or otherwise, will be reviewed equally. Applicants should follow the standard NOFO submission guidelines as they are outlined in this NOFO.

30. 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.

31. Whom should I talk to if I have further questions?

Please contact:

- *For programmatic questions, contact the program officer listed in the NOFO via email.*
- *For budget questions, contact the grants management specialist listed in the NOFO via email.*

32. *Can I ask the program officer listed in the NOFO to read my proposal for their comments and suggestions?*

No. Though questions are welcome throughout the open competition phase, please be aware that the point of contact/project officer has no authority to determine the validity or success of your proposal. The project officer cannot provide feedback or guidance on your draft proposal. Your proposal will be reviewed by an independent review panel comprised of experts in the field.