U.S. Department of Health and Human Services



NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2023

Maternal and Child Health Bureau

Division of Research

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

Funding Opportunity Number: HRSA-23-068
Funding Opportunity Type(s): New
Assistance Listings Number: 93.110

Autism Secondary Data Analysis Research (Autism SDAR)

Funding Opportunity Number: HRSA-23-069
Funding Opportunity Type(s): New
Assistance Listings Number: 93.877

Application Due Date: February 13, 2023

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: November 14, 2022

MODIFIED on December 12, 2022: Clarified application due date throughout NOFO and funding special consideration on pages 6 and 7. Updated R42 PO details.

Maternal & Child Health SDAR Maura Maloney, Ph.D. Office of Epidemiology and Research Division of Research

Phone: (301) 443-1087

Email: MCHSDAR@hrsa.gov

Autism SDAR

Evva Assing-Murray, Ph.D.

Office of Epidemiology and Research

Division of Research Phone: (301) 594-4113

Email: AutismSDAR@hrsa.gov

See Section VII for a complete list of agency contacts.

Authorities:

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

Autism SDAR: 42 U.S.C. § 280i-1(f) (Title III, § 399BB(f) of the Public Health Service Act)

508 COMPLIANCE DISCLAIMER

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for two (2) separate Secondary Data Analysis Research (SDAR) competitions for fiscal year (FY) 2023: HRSA-23-068, Maternal and Child Health Secondary Data Analysis Research (MCH SDAR) and HRSA-23-069, Autism Secondary Data Analysis Research (Autism SDAR). The purpose of these programs is to improve the health and well-being of MCH populations, including children and adolescents with autism spectrum disorder and other developmental disabilities (ASD/DD) through research on policy and program service delivery, with a special focus on addressing the needs of underserved communities.¹

If you meet the eligibility criteria for both funding opportunities, you may apply for both the MCH SDAR program and the Autism SDAR program. Make sure to submit each application to the appropriate opportunity; applications submitted to the wrong opportunity will be deemed non-responsive and will be disqualified. Although eligible applicants can apply to both funding opportunities, only **one** application will be funded if successful in both competitions. **HRSA** will determine which successful application gets funded depending on factors such as the number and quality of the applications and the availability of funds.

HRSA-23-068: Maternal and Child Health Secondary Data Analysis (MCH SDAR) supports applied research through analysis of existing databases and/or administrative records² to improve the quality, efficiency, and accessibility of health care services and health outcomes for MCH populations. This program will fund up to <u>five</u> 1-year grants.

HRSA-23-069: Autism Secondary Data Analysis (Autism SDAR) supports applied research through analysis of existing databases and/or administrative records to

¹ Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 FR 7009, at § 2(b) (Jan. 20, 2021), https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf defines underserved communities as "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." Underserved communities may include Black, Latino, and 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, at § 2(a).

² 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.

determine the evidence-based practices for interventions to improve the physical and behavioral health of **children and adolescents with Autism Spectrum Disorder** (ASD) and other Developmental Disabilities (DD) across the lifespan, with a focus on addressing the needs of underserved populations for whom there is limited evidence of the effectiveness of interventions, and limited access to screening, diagnosis, and treatment for ASD/DD. In addition, develop guidelines for those interventions, and broadly disseminate information related to such research and guidelines. This program will fund up to <u>four</u> 1-year grants.

This notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately. You should note that this program may be cancelled before award.

Funding Opportunity Titles:	Maternal and Child Health Secondary Data Analysis Research (MCH SDAR) Autism Secondary Data Analysis Research (Autism SDAR)
Funding Opportunity Numbers:	HRSA-23-068 (MCH SDAR) HRSA-23-069 (Autism SDAR)
Due Date for Applications:	February 13, 2023
Anticipated FY 2023 Total Available	MCH SDAR: \$600,000
Funding:	Autism SDAR: \$480,000
Estimated Number and Type of Award(s):	HRSA-23-068 (MCH SDAR): Up to five (5) grants
	HRSA-23-069 (Autism SDAR) Up to four (4) grants
Estimated Award Amount:	MCH SDAR: Up to \$120,000 per award subject to the availability of appropriated funds
	Autism SDAR: Up to \$120,000 per award subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	July 1, 2023 through June 30, 2024 (1 year)

Eligible Applicants:

MCH SDAR: Eligibility is limited to 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). Faithbased and community-based organizations, tribes, and tribal organizations are eligible to apply.

AUTISM SDAR: Eligible applicants include any public or private entity, including research centers or networks. Faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

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

iii

Application Guide

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in this NOFO and in HRSA's SF-424 R&R Application Guide. Visit HRSA's How to Prepare Your Application page for more information.

Technical Assistance

HRSA has scheduled the following webinar:

Tuesday, November 29, 2022 3 – 4 p.m. ET

Weblink:

https://hrsagov.zoomgov.com/j/1612371819?pwd=c2lwMWxMRmZISER3QWF4aEdRMVRldz09

Attendees without computer access or computer audio can use the dial-in information below

Call-In Number: 1-833-568-8864

Meeting ID: 161 237 1819 Passcode: Wk9JNXKV

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 or AutismSDAR@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

HRSA-23-068: MCH SDAR and HRSA-23-069: Autism SDAR

İ۷

Table of Contents

I. PROGRAM FUNDING OPPORTUNITY DESCRIPTION	1
1. Purpose	1
2. Background	3
II. AWARD INFORMATION	8
1. Type of Application and Award	8
2. SUMMARY OF FUNDING	8
III. ELIGIBILITY INFORMATION	8
1. ELIGIBLE APPLICANTS	8
2. Cost Sharing/Matching	8
3. Other	9
IV. APPLICATION AND SUBMISSION INFORMATION	. 11
1. Address to Request Application Package	. 11
2. CONTENT AND FORM OF APPLICATION SUBMISSION	
i. Project Abstract	
ii. Project Narrative	
iii. Budget	
iv. Budget Justification Narrative	
v. Program-Specific Forms	
vi. Attachments	
3. UNIQUE ENTITY IDENTIFIER (UEI) AND SYSTEM FOR AWARD MANAGEMENT (SAM)	
4. Submission Dates and Times	
5. Intergovernmental Review	
6. Funding Restrictions	
V. APPLICATION REVIEW INFORMATION	
1. Review Criteria	. 25
2. Review and Selection Process	. 31
3. Assessment of Risk	. 32
VI. AWARD ADMINISTRATION INFORMATION	. 32
1. Award Notices	. 32
2. Administrative and National Policy Requirements	. 32
3. Reporting	. 35
VII. AGENCY CONTACTS	. 36
VIII. OTHER INFORMATION	. 37
APPENDIX A: TITLE V MCH SERVICES BLOCK GRANT-NATIONAL PERFORMANCE	
MEASURES	
APPENDIX B: LOGIC MODELAPPENDIX C: RESEARCH PROGRAM APPLICATION COMPLETENESS CHECKLIST	
APPENDIX C: RESEARCH PROGRAM APPLICATION COMPLETENESS CHECKLIST APPENDIX D: FREQUENTLY ASKED QUESTIONS (FAQS) ABOUT THE MCH & AUTISM	. 42
SECONDARY DATA ANALYSIS RESEARCH (SDAR) PROGRAM	. 43
APPENDIX E: KEY TERMS FOR PROJECT ABSTRACTS	
APPENDIX F: GUIDANCE ON BIOGRAPHICAL SKETCHES	. 54
APPENDIX G: RELEVANT WEBSITES	. 56

I. Program Funding Opportunity Description

1. Purpose

The purpose of the SDAR program is to support research that analyzes existing national data sets and/or administrative records to answer questions that can improve the health and well-being of MCH populations, including children and teenagers with autism spectrum disorders and other developmental disabilities (ASD/DD). The SDAR program helps researchers use existing data sets to identify new issues, study new research questions, test hypotheses, and determine pathways for intervention. Existing and new public health challenges affecting MCH populations, including children with special health care needs (MCH SDAR) and children and adolescents with ASD/DD (Autism SDAR), require timely, evidence-based responses from programs, policy, and practice. Without sufficient evidence or data, it is hard to develop interventions addressing both existing and new issues. SDAR research projects should help address any of the following HRSA's Strategic Plan Objectives:

- 1.4 Incorporate health equity concepts and measures into programs and policies;
- 2.3 Improve the quality, safety, and effectiveness of health services for underserved populations and those in need; and
- 2.4 Enhance maternal and child health efforts and reduce disparities in morbidity, mortality, and health outcomes.

HRSA-23-068: Maternal & Child Health Secondary Data Analysis Research (MCH SDAR)

The goals of research supported by the MCH SDAR Program are 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 <u>Appendix A</u>), <u>HRSA MCHB's Strategic Research Issues</u>, MCHB <u>Strategic Plan Goals</u>, or <u>Healthy People 2030 objectives</u>;
- Address health inequities facing underserved communities to enhance the evidence and strategies for improving health equity³ for all MCH populations; and

1

³ Health equity means that all people, including mothers, fathers, birthing people, children, and families achieve their full health potential. Achieving health equity is an active and ongoing process that requires commitment at the individual and organizational levels, and within communities and systems. Achieving health equity requires valuing

 Address existing and new research topics of regional and national significance and highlight new data, knowledge, evidence, and strategies for addressing the burden of diseases that affect MCH populations. <u>For more details</u>, <u>see Program</u> <u>Requirements and Expectations</u>.

The following objectives should be accomplished by the end of the period of performance:

- 1. Complete a secondary data analysis research project that addressed MCH priorities and health equity;
- 2. At least two manuscripts submitted to or published in peer-reviewed journals; and
- 3. A junior investigator mentored through all stages of the project.

HRSA-23-069: Autism Secondary Data Analysis Research (Autism SDAR)

The goals of research supported by the Autism SDAR Program are to:

- Generate new evidence to address the needs of underserved ASD/DD populations for whom there is limited evidence of the effectiveness of interventions, and limited access to screening, diagnosis, and treatment for ASD/DD;
- Address health inequities facing underserved communities to enhance the evidence and strategies for advancing health equity for children and teenagers with ASD/DD; and,
- Contribute to a broad public health impact by improving patient engagement and care delivery through studies that are generalizable and replicable across underserved children and teenagers with ASD/DD.

The following objectives should be accomplished by the end of the period of performance:

- 1. Complete a secondary data analysis research project in ASD/DD field;
- 2. At least two manuscripts submitted to or published in peer-reviewed journals; and

everyone equally, eliminating systemic and structural barriers including poverty, racism, ableism, gender discrimination and other historical and contemporary injustices, and aligning resources to eliminate health and health care inequities. The Maternal and Child Health Bureau created this definition of health equity. It is a working definition that encompasses concepts of equity as reflected in Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 FR 7009, at § 2(a) (Jan. 20, 2021), https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf.

3. A junior investigator mentored through all stages of the project.

2. Background

Authority

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

Autism SDAR is authorized by 42 U.S.C. § 280i-1(f) (Title III, § 399BB(f) of the Public Health Service Act), as amended by the Autism Collaboration, Accountability, Research, Education, and Support Act of 2019 (Autism CARES Act of 2019) (Pub. L.116-60)).

Secondary data analysis is a low-cost way to study new and important research questions using existing data. The SDAR program is the only federal program supporting analysis of existing national databases and/or administrative records in the maternal and child health field. The SDAR program aims to improve the quality, efficiency, and accessibility of health care services and health outcomes for all MCH populations, including inequities in access to ASD/DD screening, diagnosis, and treatment, and to identify effective ASD/DD interventions.

MCH populations face challenges, including high rates of maternal mortality and morbidity, high rates of infant mortality, and increasing rates of behavioral health conditions in children and adolescents. Severe inequities in MCH, particularly between racial/ethnic groups raise public health concerns. Black women are three times more likely to die from a pregnancy-related cause than white women.⁴ In 2016, black infants had 2.5-2.8 times higher risk of mortality from perinatal conditions, sudden infant death syndrome, influenza/pneumonia, and unintentional injuries, and 1.3 times higher risk of mortality from birth defects compared to white infants.⁵ The United States has poorer child health outcomes compared to other wealthy nations and children in the US faces high morbidity compared to children from peer countries.⁶

Children and teenagers with ASD/DD have more health service needs compared with those without ASD/DD, which can place a large financial and emotional burden on their families.⁷ Also, 83 percent of children with ASD/DD have at least one other non-ASD/DD condition such as seizures, sleep problems, gastrointestinal disorders,

⁴ https://www.cdc.gov/healthequity/features/maternal-mortality/index.html

⁵ Singh GK, Yu SM. Infant Mortality in the United States, 1915-2017: Large Social Inequalities have Persisted for Over a Century. Int J MCH AIDS. 2019;8(1):19-31. doi:10.21106/ijma.271

⁶ Child Mortality In The US And 19 OECD Comparator Nations: A 50-Year Time-Trend Analysis. Health Affairs 2018;**37**(1):140-49 doi: 10.1377/hlthaff.2017.0767[published Online First: Epub Date]|.

⁷ Vohra, R, Madhavan, S, Sambamoorthi, U, St Peter, C. Access to services, quality of care, and family impact for children with autism, other developmental disabilities, and other mental health conditions. Autism, 2014; 18(7):815-26.

nutritional deficiencies, and metabolic conditions.^{8,9,10} Children and teenagers with ASD/DD from underserved populations encounter ongoing disparities in screening, diagnosis, and health service access, increasing their vulnerability to poor physical and behavioral outcomes across the lifespan.^{9,10} In a recent study of children with ASD indicators, 25% did not have a clinical diagnosis.¹¹ Children without a clinical diagnosis were more likely to be three years of age or older and were more likely to be Black, Hispanic, or Asian.¹⁰

To-date, SDAR Program recipients have published 222 peer-reviewed papers. These papers have helped advance the MCH field. For example, one study showed that younger children (ages 0-4 years) with short durations of nighttime sleep were more likely to become overweight or obese, compared to those with longer nighttime sleep duration. This single study was cited 279 times by other journals, and contributed to pediatric sleep recommendations endorsed by the American Academy of Pediatrics. These

For FY 2023, HRSA/MCHB solicits studies addressing HRSA/MCHB priorities as well as existing and new issues impacting MCH and children and youth with ASD/DD. More information about the SDAR Program, funded projects, and current activities can be found at http://www.mchb.hrsa.gov/research.

About MCHB and its Strategic Plan

The HRSA Maternal and Child Health Bureau (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

⁸ Levy SE, Giarelli E, Li-Ching L, Schieve LA, Kirby RS, Cuniff C, et al. Autism spectrum disorder and co-occurring developmental, psychiatric, and medical conditions among children in multiple populations of the United States. Journal of Developmental and Behavioral Pediatrics. 2010;31:267–275.

⁹ Lavelle TA, Weinstein MC, Newhouse JP, Munir K, Kuhlthau KA, Prosser LA. Economic burden of childhood autism spectrum disorders. Pediatrics. 2014;133(3):e520-9.

¹⁰ Doshi-Velez F, Ge Y, Kohane I. Comorbidity clusters in autism spectrum disorders: an electronic health record

¹⁰ Doshi-Velez F, Ge Y, Kohane I. Comorbidity clusters in autism spectrum disorders: an electronic health record time-series analysis. Pediatrics. 2014;133(1):e54–e63. doi:10.1542/peds.2013-0819

¹¹ Wiggins LD, Durkin M, Esler A, et al. Disparities in Documented Diagnoses of Autism Spectrum Disorder Based on Demographic, Individual, and Service Factors. Autism Res. 2020;13(3):464-473. doi:10.1002/aur.2255

¹² 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.

¹³ 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.

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, 2, and 3 to assure access to high quality and equitable health services to optimize health and well-being for all MCH populations, achieve health equity for MCH populations, and strengthen public health capacity and workforce for MCH. Research findings from SDAR program 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 plan, visit Mission, Vision, and Work MCHB.

Promoting Health Equity

Promoting equity ¹⁴ 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. ^{15,16}

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

¹⁶ https://www.astho.org/Programs/Health-Equity/Maternal-and-Infant-Disparities-Issue-Brief/

¹⁴ The term "equity" means "[T]he 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 § 2(a) (Jan. 20, 2021), https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf.

¹⁵ https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-maternal-infant-health-overview/

populations.^{17,18} A study by NIH showed that black investigators are more likely to propose health equity research topics than white investigators.¹⁹.

In addition, research shows that "diverse research teams are more likely to have diverse ideas". ²⁰ 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". ^{21,22} 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". ²³ As such, it is important to have diverse MCH researchers in the MCH SDAR and Autism SDAR programs, 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 pool²⁴. In 2020, AA/B and Hispanic/Latino awardees for R01 grants only constitute 1.9% and 4.8% of the total R01 awardees, respectively.²⁵

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

¹⁷ 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.

¹⁸ 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

¹⁹ 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.aaw7238

²⁰ 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.1001 ²¹ RFA-HG-21-041: New Investigators to Promote Workforce Diversity in Genomics, Bioinformatics, or Bioengineering and Biomedical Imaging Research (R01 Clinical Trial Optional) (nih.go

²² https://grants.nih.gov/grants/guide/pa-files/pa-18-586.ht

²³ https://news.feinberg.northwestern.edu/2020/01/funding-disparities-research-and-underrepresented-minority-scient ²⁴ https://diversity.nih.gov/sites/coswd/files/2016-09/AA-B-funding-disparities.pd

²⁵ Calculated from data on the NIH website at https://diversity.nih.gov/building-evidence/racial-disparities-nih-fund

findings showed that very few of the applicants and awardees were from MSIs²⁶, domestic faith-based and community-based organizations, tribes, and tribal organization serving mainly underserved populations Many of the researchers at MSIs are likely to be from minority/underserved populations, and they are likely to mentor students from minority/underserved populations.²⁷ 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.

Additionally, mentoring is important to career development since mentors can assist in networking, pass along skills and knowledge, and identify important career opportunities.²⁸ Early stage researchers with mentors are more confident, have higher career satisfaction, more likely to have productive careers, and feel more supported compared to their peers. Error! Bookmark not defined. However, researchers from underrepresented minority backgrounds are less likely to receive mentoring compared to their peers not from underrepresented communities.^{29,30} By expecting a junior-senior partnership, DOR hopes to provide resources to further early-stage researchers' careers and to increase the diversity of researchers in the MCH field.³¹

This NOFO aims to increase the diversity of recipients in the MCH SDAR and Autism SDAR programs 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.³²

²⁶ For purposes of this NOFO, a Minority Serving Institution (MSI) is defined as an institution that has a demonstrated record of or historical commitment to serving underrepresented or disadvantaged students, including racial and ethnic minorities.

²⁷ 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/PMC376

²⁸ Beech BM, Calles-Escandon J, Hairston KG, Langdon SE, Latham-Sadler BA, Bell RA. Mentoring programs for underrepresented minority faculty in academic medical centers: a systematic review of the literature. Acad Med. 2013;88(4):541-549. doi:10.1097/ACM.0b013e31828589e3

²⁹ Thomas DA. The truth about mentoring minorities. Race matters. Harv Bus Rev. 2001;79:98–107. 168.

³⁰ Morzinski JA, Fisher JC. A nationwide study of the influence of faculty development programs on colleague relationships. *Acad Med.* 2002;77:402–406

³¹ 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. ³² 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.

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.

2. Summary of Funding

HRSA estimates approximately \$600,000 to be available to fund five (5) recipients for HRSA-23-068 MCH SDAR and approximately \$480,000 to be available to fund four (4) recipients for HRSA-23-069 Autism SDAR. The actual amount available will not be determined until enactment of the final FY 2023 federal appropriation. You may apply for a ceiling amount of up to \$120,000 total cost (includes both direct and indirect costs) for HRSA-23-068 MCH SDAR and a ceiling amount of up to \$120,000 total cost (includes both direct and indirect costs) for HRSA-23-069 Autism SDAR. 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, 2023 through June 30, 2024 (1 year).

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

III. Eligibility Information

1. Eligible Applicants

MCH SDAR: Eligibility is limited to 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). Faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

AUTISM SDAR: Eligible applicants include any public or private entity, including research centers or networks. Faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

You are required to submit proof of non-profit status as Attachment 5. A foreign applicant will need to be affiliated with a U.S. entity (i.e., university, institution) with a U.S. EIN established and recognized by HRSA to be considered a public or nonprofit institution of higher learning or a public or private nonprofit agency.

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 funding ceiling amount (MCH SDAR: \$120,000; Autism SDAR: \$120,000)
- Fails to satisfy the deadline requirements referenced in <u>Section IV.4</u>

NOTE: Multiple applications from an organization with the same <u>Unique Entity Identifier</u> (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.

If you meet the eligibility criteria for both funding opportunities, you may apply for both the MCH SDAR program and the Autism SDAR program. Make sure to submit each application to the appropriate opportunity; applications submitted to the wrong opportunity will be deemed non-responsive and will be disqualified. For example, an application that address ASD/DD (that should be submitted to HRSA-23-069) but rather submitted to the MCH SDAR (HRSA-23-068) will be deemed non-responsive. Although eligible applicants can apply to both funding opportunities, only one application will be funded if successful in both competitions. HRSA will determine which successful application gets funded depending on factors such as the number and quality of the applications and the availability of funds.

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 HRSA/MCHB/OER/DOR research portfolio, and ensure that investigators devote substantial time to funded grants, the following are additional application responsiveness criteria. All applications that do not comply with these criteria will be deemed nonresponsive and will not be considered for funding under this notice.

• An individual cannot be named as the project director (PD) or principal investigator (PI)³³ **on more than one** application for the HRSA-23-068 **or** HRSA-23-069 competition;

HRSA-23-068: MCH SDAR and HRSA-23-069: Autism SDAR

9

³³ 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.

- o **Please Note:** If you apply to both the MCH SDAR and Autism SDAR and are successful in both competitions, you can only be awarded **one. HRSA will determine which successful application gets funded.**
- The 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;
- A PD/PI <u>cannot</u> have two (2) active HRSA/MCHB/OER/DOR awards at the same time. An award in a no-cost extension year is considered active and the PD/PI is not allowed to receive another award;
- Applications must propose analysis of existing national data sets and/or administrative records:
- Project must be completed within 1 year;
- Projects that include the collection of biological specimens will <u>not</u> be considered, as this program funds secondary analysis of existing national databases and administrative data on MCH populations, including children and adolescents with autism spectrum disorders and ASD/DD, and only allows secondary analysis of existing national databases and administrative data.
- You are expected to have a junior-senior pair as coinvestigators;
- Applications on Autism Spectrum Disorder submitted to HRSA-23-068 MCH
 SDAR will not be considered. Ensure you apply to the correct opportunity or your application will be disqualified; and
- Applications on general MCH submitted to **HRSA-23-069 Autism SDAR** will not be considered. *Ensure you apply to the correct opportunity or your application will be disqualified.*

IV. Application and Submission Information

1. Address to Request Application Package

HRSA **requires** you to apply electronically. HRSA encourages you to apply through <u>Grants.gov</u> 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 <u>Grants.gov</u>: <u>HOW TO APPLY FOR GRANTS</u>. If you use an alternative electronic submission, see <u>Grants.gov</u>: <u>APPLICANT SYSTEM-TO-SYSTEM</u>.

Form Alert: For the <u>Project Abstract Summary</u>, applicants using the SF-424 R&R Application Package are encountering a "Cross-Form Error" associated with the Project Summary/Abstract field in the "Research and Related Other Project Information" form, Box 7. To avoid the "Cross-Form Error," you must attach a blank document in Box 7 of the "Research and Related Other Project Information" form, and use the Project Abstract Summary Form in workspace to complete the Project Abstract Summary. See Section IV.2.i Project Abstract for content information.

The NOFO is also known as "Instructions" on Grants.gov. You must select "Subscribe" and provide your email address for HRSA-23-068 or HRSA-23-069 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 <u>For Applicants</u> page for all information relevant to this NOFO.

2. Content and Form of Application Submission

Application Format Requirements

Section 4 of HRSA's <u>SF-424 R&R Application Guide</u> provides general instructions for the budget, budget justification, staffing plan and personnel requirements, assurances, and certifications. You must submit the information outlined in HRSA <u>SF-424 R&R</u> <u>Application Guide</u> in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in this NOFO and HRSA's <u>SF-424 R&R Application Guide</u>. 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 <u>SF-424 R&R Application Guide</u> for the Application Completeness Checklist to assist you in completing your application. In addition, please refer to the Research Program Application Completeness Checklist (Appendix C).

Application Page Limit

The total of uploaded attachment pages that count against the page limit shall be no more than the equivalent of **60 pages** when printed by HRSA. All sections combined count towards the 60-page total limit, including the project and budget narratives,

attachments including biographical sketches (biosketches), works cited, and letters of commitment and support required in HRSA's SF-424 R&R Application Guide and this NOFO.

Forms that DO NOT count in the Page Limit

- Standard OMB-approved forms included in the workspace application package do not count in the page limit. The abstract is the standard form (SF) "Project Abstract Summary." It does not count in the page limit.
- The Indirect Cost Rate Agreement **does not** count in the page limit.
- The proof of non-profit status (if applicable) does not count in the page limit.

If there are other attachments that do not count against the page limit, this will be clearly denoted in Section IV.2.vi. Attachments.

If you use an OMB-approved form that is not included in the workspace application package for HRSA-23-068 / HRSA-23-069, 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.

➤ HRSA will flag any application that exceeds the page limit and <u>delete</u> any pages considered over the page limit. The altered copy of the application will move forward to the objective review committee.

It is important to take appropriate measures to ensure your application does not exceed the specified page limit.

Applications must be complete and validated by Grants.gov under HRSA-23-068 MCH SDAR or HRSA-23-069 Autism SDAR before the <u>deadline</u>.

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); and
- 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 <u>SF-424 R&R Application Guide</u> for additional information on all certifications.

Program Requirements and Expectations

HRSA expects each SDAR Program award recipient to do the following:

- Complete the proposed project you described in your application;
- Submit a dissemination plan of research findings and products to study participants, scientific, professional, and lay audiences; include a timeline for implementation. Dissemination activities can include manuscripts, conference presentations, newsletter articles, webcasts, fact sheets, infographics, policy briefs, publicly available websites, and social media posts;
- Report study sample demographic information to HRSA in the Electronic Handbooks (EHBs) reports;
- Produce at least two peer-reviewed publications; and
- Present findings at the virtual End of Project Presentation (Research Festival) to MCHB staff.

Program-Specific Instructions

In addition to application requirements and instructions in Section 4 of HRSA's <u>SF-424</u> <u>R&R Application Guide</u> (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 that is included in the workspace application package. Do not upload the abstract as an attachment or it may count toward the page limit. See <u>Form Alert</u> in Section IV.1 Application Package. For information required in the Project Abstract Summary Form, see Section 4.1.ix of HRSA's <u>SF-424 R&R Application Guide</u>.

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 needs and problems that are addressed by the project, including the project's relationship to <u>MCHB Strategic Research</u> <u>Issues</u>;
- 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 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 how project activities and findings will be distributed;
- 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; and
- KEY TERMS: At the end of your abstract, include the following key terms found in Appendix E to describe: (a) your project (maximum of 10 content terms), (b) targeted populations (select all that apply), and (c) age ranges (select all that apply).

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	
Specific Aims: 2) Significance		
I. Specific Aims: 3) Goals and Hypotheses	(2) Response	
II. Methodology: 1) Study Design/Approach	(3) Study Design/Approach	
II. Methodology: 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\ D A	
VI. Evaluation	(7) Program Assurances	

Narrative Section	Review Criteria
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 brief, self-explanatory, consistent with forms and attachments, and organized by the sections and format below so that reviewers can understand the proposed project. Unless otherwise stated, the narrative elements described below apply to both MCH SDAR and Autism SDAR.

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 study's population(s)' unmet health needs; and identify health disparities facing the study population(s);
- If relevant, include the social determinants of health (SDOH)³⁴ and health inequalities of the study population(s) you will address;
- Briefly outline how the project will benefit the study population(s) and address health disparities;
- Briefly outline how the project aligns with one of the following: <u>Healthy</u>
 <u>People 2030 objectives</u>, <u>MCHB Strategic Research Issues</u>, and MCHB
 Strategic Plan Goals, or <u>MCH Block Grant National Performance</u>
 <u>Measures; and</u>
- Applicants to HRSA-23-069 (Autism SDAR) must also address how their project aligns with the Interagency Autism Coordinating Committee's <u>Strategic Plan Objectives.</u>

15

³⁴ 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

- 2) SIGNIFICANCE -- Corresponds to Section V's Review Criterion #2 RESPONSE
 - Detail the existing literature to show why your study's research objectives are important;
 - Explain the problems and research gaps that your study addresses; and
 - Identify how your results may improve care and/or the ways that services are organized and delivered, and/or achieve health equity in MCH populations (HRSA-23-068), including children and teenagers with ASD/DD (HRSA-23-069).
 - 3) GOALS AND HYPOTHESES-- Corresponds to Section V's Review Criterion #2 RESPONSE
 - a. Goals and Objectives
 - Briefly state the specific goals and objectives of your research study that you will accomplish during the award cycle that address the problems, barriers, and gaps identified. The study objectives should be specific, measurable, achievable, relevant, and time bound, inclusive, and equitable (SMARTIE).
 - b. Hypotheses and Specification of Variables
 - Briefly state the specific questions that your study will answer. These should include predictions of findings (hypotheses), as well as your reasoning behind your predictions; and
 - Include a summary table of the relevant variables. You should define your variables, including the type of variables (e.g., independent, dependent, mediating, and moderating):
 - o You can create a graphic describing the theoretical model, conceptual framework, or the variables' relationships; and
 - o Make sure that any relationships shown in the graphic are consistent with your variable table, the statement of hypotheses, and the plan for data analysis.

SECTION II: METHODOLOGY -- CORRESPONDS TO SECTION V'S REVIEW CRITERIA #3 Study Design/Approach AND #4 IMPACT

Organize the Methodology section in the same order as 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.

MCHB/OER highly recommends the methodology section (Study Design/Approach and Scientific Innovation) be no more than 6 pages.

1) Study Design/Approach -- Corresponds to Section V's Review Criterion #3 Study Design/Approach

Describe the overall study design, strategy, methodology, and analyses you will use to achieve the specific aims of the project. Include the following information:

- A short description of the database(s) you plan to use, including
 information such as the data source (including funder), overall study
 population, 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 and
 why this data set is appropriate for your project, and the target population
 for your study. If you plan to use restricted files, describe how you will
 access them:
- If you are linking multiple data sets, provide information on how you will link them in this section;
- Identify the key variables, how they are measured and the validity of the measurements; and
- Detail the statistical methods you will use in your data analysis and explain
 why they are appropriate for testing the proposed hypotheses. Identify
 potential biases in the database that the methods cannot address and the
 direction that the data is biased.
- 2) Scientific Innovation and Importance -- Corresponds to Section V's Review Criterion #4 Impact
 - Explain how your project will add scientific knowledge and evidence base, and improve technical capability and/or clinical practice; and
 - Describe any novel, refined, or improved theoretical concepts, approaches or methodologies, policies, or analyses used, and any advantage over existing methodologies, or policies.

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., how the study can affect care delivery and/or the health and well-being of MCH populations; and

Describe how the study results will be generalizable.

2) Publication and Dissemination Plan

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

- Provide a publication action plan that:
 - Clearly details the number and focus of your proposed peer-reviewed publications, as well as the names and impact factor of the journals where you plan to submit your papers; and
 - Describes how you will help put your findings into practice by distributing findings, reports, and/or project results to the MCH field.

SECTION IV: ORGANIZATIONAL INFORMATION/ ENVIRONMENT--CORRESPONDS TO SECTION V'S REVIEW CRITERION #5 RESOURCES/CAPABILITIES

This information is used to judge the ability of your organization, your organization's resources, and staff to complete your study. NOTE: The <u>SF-424 R&R</u> 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 resources you will use in your study (e.g., data platform, data center, computer lab, office, and/or other). As appropriate, detail their capacities, relevant capabilities, proximity, and availability of these resources;
- Discuss ways in which your study will benefit from your organization's scientific environment;
- Briefly describe how the senior investigator³⁵ will mentor their junior³⁶ mentee in this project and any institutional investment in their success as a co-investigator. Examples may include computer and software support, collegial support such as the availability of organized peer groups, logistical support

³⁵ A senior investigator is an established investigator who has completed their terminal research degree or end of post-graduate clinical training more than ten years ago and has successfully obtained and completed federal research awards.

³⁶ For this NOFO, a junior mentee will be the same as an early stage investigator who is someone 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)

- such as administrative management and oversight, and financial support such as protected time for research with salary support; and
- If there are multiple sites, describe each site's resources.
- 2) Qualifications of Research Team's Key Personnel
 - To evaluate the research team's qualifications and research strategy, reviewers will use: (a) Preliminary Studies in Section II: Methodology 2) Study Design; (b) Staffing Plan in Budget Narrative; and (c) Biographical Sketches of key personnel;
 - Please 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. This information allows MCHB to determine to what extent individuals of different backgrounds are participating. This information, in addition to other information including career stage, geographic location of the institution, educational level, assists MCHB in ensuring that federal grant and cooperative agreement awards are reaching a broad diversity of populations. A detailed description of information that should be included in the biographical sketches is available in Appendix F.

Section V: FEASIBILITY – CORRESPONDS TO SECTION V'S REVIEW CRITERION #7 PROGRAM ASSURANCES

This section addresses questions around project feasibility. If funded, it is important that the recipient implements and completes the study as proposed and approved.

- 1) Proposed Sequence or Timetable
 - Provide a project sequence or timetable. This should include the steps that will be taken to do 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 you are likely to face in creating and doing the research activities described in the <u>Study Design/Approach</u>, and how you will resolve these challenges. Discuss alternative strategies should any of these potential challenges arise. Examples include:
 - The ability to access the dataset or administrative record within the required timeline to complete the tasks, including the most-recent dataset or administrative record(s) if multiple years exist; and

The ability to complete the proposed work within the timeline.

Section VI: EVALUATION CORRESPONDS TO SECTION V'S REVIEW CRITERION #7 PROGRAM ASSURANCES

 Describe a plan for evaluating the project's progress towards achieving its specific goals and objectives. The project performance evaluation should reflect the goals and objectives described in Section I above, as well as the 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

For more information, please see the <u>Human Subjects Protection</u> 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 submission but must be received prior to the study.
- The project should be in compliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR part 46) (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). 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.
- All institutions that are engaged in nonexempt human subjects research as part
 of the project, including foreign applicants, must be covered by a Federalwide
 Assurance (FWA) approved by the Office for Human Research Protections
 (OHRP). Instructions on how to submit an FWA application, if awarded, can be
 found on OHRP's website at https://www.hhs.gov/ohrp/register-irbs-and-obtainfwas/fwas/index.html.

- 2) Data Availability and Diversity of Database Sample
 - A. Detail the diversity of your study's sample. 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." List any proposed racial/ethnic subpopulations; and
- The "Total Sample" means the number of subjects in the dataset that will be used in your analysis. They will be reported in two ways in the table: by self-reported "Ethnic Category (Hispanic Heritage)" and by self-reported "Racial Categories".

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, as applicable 37

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

4) Geographic Location

- Urban
- Rural

³⁷ 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

B. Provide written confirmation that your proposed data will be available to you (Attachment 3). Include 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 <u>SF-424 R&R Application Guide</u> may differ from those offered by Grants.gov. Follow the instructions in Section 4.1.iv of HRSA's <u>SF-424 R&R Application Guide</u> 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 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, 2022 (P.L. 117-103), "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 <u>SF-424 R&R Application Guide</u> 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 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 be 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.

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 your application. **Unless otherwise noted, attachments count toward the application page limit.**Your indirect cost rate agreement and proof of non-profit status (if applicable) will not count toward the page limit. **Clearly label each attachment**. You must upload attachments into the application. HRSA and the objective review committee will not open/review any *hyperlinked* attachments.

Attachment 1: Letters of Agreement/Letters of Support

Provide any documents that describe the relationships between your organization and other organizations named in the proposal. Documents on actual or pending contractual agreements should describe the roles of the subcontractors and any deliverables. Include only letters of support that indicate a commitment to the project (in-kind services, dollars, staff, space, equipment, etc.). Letters of agreement and letters of support must be signed and dated.

If you are eligible for the <u>funding special consideration</u>, 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. Because of the 60-page limitation, only list the citations.

Attachment 3: Information regarding the database(s) you propose to use.

Provide written confirmation of your study's database availability.

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) [Only applicable to HRSA-23-068 MCH SDAR applicants].

Attachments 6–15: Other Relevant Documents, as necessary.

3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

Effective April 4, 2022:

- The UEI assigned by <u>SAM</u> has replaced the Data Universal Numbering System (DUNS) number.
- Register at <u>SAM.gov</u> and you will be assigned a UEI.

You must register with SAM and continue to maintain active SAM registration with current information at all times when you have: an active federal award, an active

application, or an active 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 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 the registration is still active and that the Authorized Organization Representative (AOR) has been approved.

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

- System for Award Management (SAM) (https://sam.gov/content/home | SAM Knowledge Base).
- Grants.gov (https://www.grants.gov/)

For more details, see Section 3.1 of HRSA's <u>SF-424 R&R Application Guide</u>.

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 application due date under this NOFO is *February 13, 2023 at 11:59 p.m. ET*. HRSA suggests you submit your application 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 in HRSA's <u>SF-424 R&R Application Guide</u> for additional information.

5. Intergovernmental Review

The 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 <u>SF-424 R&R Application Guide</u> for additional information.

6. Funding Restrictions

You may request funding for a period of performance of up to <u>1 year</u>, at no more than \$120,000 per year (inclusive of direct **and** indirect costs) for **HRSA-23-068 MCH SDAR**

and \$120,000 per year (inclusive of direct **and** indirect costs) for **HRSA-23-069 Autism SDAR**. 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, 2022 (P.L. 117-103) apply to this program. See Section 4.1 of HRSA's <u>SF-424 R&R Application</u> <u>Guide</u> for additional information. Note that these and 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 specific uses of funding. It is imperative that you review and adhere to the list of statutory restrictions on the use of funds detailed in Section 4.1 of HRSA's <u>SF-424 R&R Application Guide</u>. 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 https://example.com/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 processes for evaluating the technical merit of applications in order to have an objective review and to help you to understand how your application will be reviewed. HRSA has guides for each review criterion to help you to present relevant information related to that criterion and to provide the reviewer with a standard for evaluation.

Reviewers will evaluate and score the merit of your application based upon these criteria.

Seven review criteria are used to review and rank the 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.	Study Design/Approach	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 application:

- Provides a compelling introduction and overview of the research project;
- States clearly the scientific rationale for this project; and
- Describes the health disparities and unmet health needs of the study population.

2) Alignment with HRSA MCHB Priorities and Healthy People 2030 (4 points)

- The extent to which the project explains its alignment with <u>MCHB Strategic Research Issues</u>, the <u>HRSA MCHB Strategic Plan</u>, the MCH Block Grant National Performance Domains (<u>Appendix A</u>) or specific <u>Healthy People 2030 objectives</u> (See HRSA's SF-424 R&R Application Guide, Section 2.2: Administrative and National Policy Requirements).
- HRSA-23-069 (Autism SDAR): The extent to which the application addresses how the project aligns with the Interagency Autism Coordinating Committee's <u>Strategic Plan Objectives</u>.

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 applicant shows knowledge of previous and current scientific research in the area of the project;
- The cited literature is relevant to the research problem and supports a rationale for the research; and

• The project addresses a critical problem or barrier to the field.

2) Addressing Health Equity (5 points)

 The degree the application addresses health inequities faced by underserved populations and is likely to advance health equity for MCH populations, including children and adolescents with ASD/DD.

3) Goals and Hypotheses (10 points)

The extent to which:

- The goals are clear, and the study objectives are SMARTIE (Specific, Measurable, Attainable, Realistic, Time-bound, Inclusive, and Equitable);
- The variables and the expected outcomes are clearly and briefly defined and summarized, especially how these outcomes will address the unmet needs of the target population;
- The hypotheses are rooted in the research literature, clearly stated, and are related to the research questions; and
- The associations depicted by the theoretical framework or model, the variables, the hypotheses, and the plan for data analysis are consistent.

Criterion 3: Study Design/Approach (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 suitable to complete the project's specific aims;
- The study population is clearly described, i.e., (targeted age(s) or age ranges, expected racial/ethnic background and socioeconomic status, urban/rural, etc.), and supports the scientific goals and methodology/research strategy proposed;
- The dataset's variables are clearly defined and the measurement's reliability and validity is 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 statistical methods are appropriate and thorough. The description includes an adequate and justified sample size. The expected differences between groups are defined by statistical and clinical significance and sampling weights are to be included, if appropriate. Subgroup analyses, especially on underserved populations should be clearly described; and
- Major threats to the design's internal and external validity 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 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 (Attachment 3). If the study
 proposes to use restricted data, there must be a 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 detailed and describe the rationale for the order of steps to be taken;
- The plans are appropriate to the nature of the data, design, and sampling methods; and
- Sufficient time is given for data analysis.

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

1) Innovation and Importance (5 points):

The extent to which:

- The application challenges and seeks to change current research or clinical or public health practice by using novel theoretical concepts, approaches or methodologies, instrumentation, or interventions;
- An enhancement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions is proposed; and
- The project results will be generalizable and likely to have an ongoing 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 to MCH populations, including children and adolescents;
- The applicant presents a sound plan for how they will write at least two peer-reviewed publications;
- The application includes a strong dissemination plan that clearly describes how it will help transfer findings into practice by distributing findings, reports, and/or project findings 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. <u>Organizational Information/ Environment</u>

Mentorship (5 pts)

The extent to which the application:

 Details the collaboration of junior mentees with the established investigator, highlighting meaningful contribution of the mentee across all stages of the project.

Other Response Areas (10 pts)

The extent to which:

- The organization can provide quality facilities and staff to fulfill the needs and requirements of the proposed research project;
- The project will benefit from the organization's scientific environment, the collaborative arrangements, and the communities and stakeholders engaged; and
- The Key/Senior Support Personnel Profiles and biographical sketches show that the PI, Co-PI, collaborators, staff, and other researchers are well qualified to conduct the research, and demonstrate current and/or past success in publishing the findings of their research.

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 supported in the budget justification;
- The time given to key personnel is realistic and appropriate to achieve project objectives; and
- Other current and pending support is clearly 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 as Co-PI).

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

Once a project is funded, it is expected that it will show ongoing progress and completion as proposed and approved. It is important that applicants show 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 can be conducted within the proposed timeframe; and Appropriate plans are in place to determine if the project objectives are being met according to the timeline, and to resolve potential challenges.

2) Human Subjects Protections (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 <u>HRSA's SF-424 R&R Application Guide</u>, Appendix: Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy;
- The project includes clear and adequate plans for the protection of human subjects from research risks and the applicant discusses plans to seek IRB approval (IRB approval is not required at the time of application submission but must be received prior to starting any activities involving human subjects); and
- Adequate measures are in place to protect 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 <u>SF-424 R&R Application Guide</u> 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 after the objective review, 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),³⁸ and faith-based and community-

³⁸ For purposes of this NOFO, a Minority Serving Institution (MSI) is defined as an institution that has a demonstrated record of or historical commitment to serving underrepresented or disadvantaged students, including racial and ethnic minorities.

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. 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, 2023. See Section 5.4 of HRSA's <u>SF-424 R&R Application Guide</u> 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 <u>45 CFR part 75</u>, 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

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- For guidance on meeting your legal obligation to take reasonable steps to
 ensure meaningful access to your programs or activities by limited English
 proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html
 and https://www.hhs.gov/conscience/religious-freedom/index.html

Please contact the <u>HHS Office for Civil Rights</u> for more information about obligations and prohibitions under federal civil rights laws or call 1-800-368-1019 or TDD 1-800-537-7697.

The HRSA Office of Civil Rights, Diversity, and Inclusion (OCRDI) offers technical assistance, individual consultations, trainings, and plain language materials to supplement OCR guidance and assist HRSA recipients in meeting their civil rights obligations. Visit OCRDI's website to learn more about how federal civil rights laws and

accessibility requirements apply to your programs, or contact OCRDI directly at HRSACivilRights@hrsa.gov.

Executive Order on Worker Organizing and Empowerment

Pursuant to the Executive Order on Worker Organizing and Empowerment (E.O. 14025), 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

Certificate of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, HRSA-supported research

commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to the award. For additional information which may be helpful in ensuring compliance with this term and condition, see Centers for Disease Control and Prevention (CDC) Additional Requirement 36 (https://www.cdc.gov/grants/additional-requirements/ar-36.html).

3. Reporting

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

1) DGIS Performance Reports. Available through the Electronic Handbooks (EHBs), the Discretionary Grant Information System (DGIS) is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report annually, by the specified deadline. Please be advised the administrative forms and performance measures for MCHB discretionary grants will be updated on May 4, 2023. DGIS reports created on or after May 4, 2023 will contain the updated forms. To prepare successful applicants for their reporting requirements, the administrative forms and performance measures for MCH SDAR are Form 1, Form 2, Form 3, Form 6, Form 7. Form 8. Products. Publications and Submissions Data Collection. Form, Core 3, Capacity Building (CB 4), Capacity Building (CB 5), Capacity Building (CB 6) and Capacity Building (CB 8) and for Autism SDAR are Form 1, Form 2, Form 3, Form 6, Form 7, Form 8, Products, Publications and Submissions Data Collection Form, Core 3, and Capacity Building (CB 8). The type of report required is determined by the project year of the award's period of performance. The full OMB-approved reporting package is accessible at https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-datacollection (OMB Number: 0915-0298 | Expiration Date: 08/31/2025).

Type of Report	Reporting Period	Available Date	Report Due Date
a) New Competing Performance Report	7/1/2023-6/31/2024 (administrative data and performance measure projections, as applicable)	Period of performance start date	120 days from the available date

Type of Report	Reporting Period	Available Date	Report Due Date
b) Project Period End Performance Report	7/1/2023-6/31/2024	Period of performance end date	90 days from the available date

- 2) **Mid-year Progress Report:** Six months into the period of performance, the recipient must submit a mid-year progress report to HRSA. This is to ensure that the recipient is accomplishing their project's goals and making progress in their set timeline.
- 3) Comprehensive Final Report: The recipient must submit a final report narrative to HRSA after the conclusion of the project. In this narrative, the recipient will discuss their project, challenges and resolutions, findings, and the impact their study has on public health. This report will be made publicly available on the HRSA/MCHB webpage.

Note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at <u>2 CFR § 200.340 - Termination</u> 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

Phone: (303) 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:

For HRSA-23-068 MCH SDAR

Maura Maloney, PhD, MS

Project Officer, Division of Research, Office of Epidemiology and Research

Attn: FY 2023 MCH SDAR

Maternal and Child Health Bureau

Health Resources and Services Administration

Phone: (301) 443-1087 Email: mchsdar@hrsa.gov

For HRSA-23-069 Autism SDAR

Evva Assing-Murray, Ph.D.

Project Officer, Division of Research, Office of Epidemiology and Research

Attn: FY 2023 Autism SDAR Maternal and Child Health Bureau

Health Resources and Services Administration

Phone: (301) 594-4113

Email: AutismSDAR@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

Phone: 1-800-518-4726 (International callers dial 606-545-5035)

Email: support@grants.gov

Self-Service Knowledge Base

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (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

Phone: (877) 464-4772 / (877) Go4-HRSA

TTY: (877) 897-9910

Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

VIII. Other Information

Technical Assistance

See <u>TA details</u> in Executive Summary.

Tips for Writing a Strong Application

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

HRSA-23-068: MCH SDAR and HRSA-23-069: Autism SDAR

37

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: Logic Model

The following logic model illustrates HRSA's expectations and goals for both MCH and Autism Secondary Data Analysis Research Programs)

PROGRA	AM PROCESS	PROGRAM	OUTCOMES
What is the planned work for the program?		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?)
Training & Workforce Development (MCH SDAR only) Train and mentor junior/new investigators in foundational research (using secondary) and current/emerging issues relevant to MCH populations.	Junior/new investigators trained/mentored (at least 1 early-stage investigator)	Increase knowledge in conducting secondary research among new investigators Increase diversity of new investigators (# of PIs from minority serving institutions)	Increase secondary data analysis to advance the evidence base in MCH research and practice Increase secondary data research sustainability/ and advance the evidence base
Partnerships, Collaboration, & Family Engagement	Collaborate with health care providers, PHS, Title V, family organizations, Autism organizations, etc. to disseminate research findings	Increase the awareness of existing data sources to wide audiences who are interested in studying emerging issues in MCH and ASD/DD. Increase the accessibility of the research findings from HRSA-funded research to the scientific and lay community Increased quality of MCH and ASD/DD materials developed	Advance and contribute to the MCH and ASD/DD evidence base to inform the work of health care providers, other practitioners, public health systems, and Title V Block Grant programs
Education & Outreach Develop and implement a dissemination plan for communicating research	Dissemination plan with a timeline and list of proposed products is developed Non-peer-reviewed publications aimed at stakeholders beyond the	Increase awareness of existing data sources to a wide audience who are interested in studying emerging issues in MCH and ASD/DD.	Advance the evidence base for health care providers, other practitioners, researchers, policy makers, public health systems, Title V Block

PROGRA	AM PROCESS	PROGRAM	OUTCOMES
What is the planne	d work for the program?	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?)
findings to diverse stakeholders. Develop non-peer reviewed educational products	scientific research community created. (e.g., tools, toolkits, reports, blogs, web posting, videos, infographics, lay summary of research publications) (# of non-peer-reviewed publications completed)	Increase the accessibility of HRSA funded MCH and ASD/DD research findings to the scientific and lay community (# of conferences/poster presentations attended)	Grant programs, Autism organizations, and the MCH community (CB5, CB6, and Products, Publications and Submissions Data Collection Form)
Research Design and conduct secondary data analysis within 1 year of award	Completed secondary data analysis within 1 year of award Two peer-reviewed publications in scientific journals (by the end of the 1-year period of performance) submitted (# of peer-reviewed publications accepted by scientific journals)	Increased knowledge in emerging issues relevant to the MCH and children and teenagers with ASD/DD populations (DGIS Core 1)	Advance the evidence base for health care providers, other practitioners, researchers, policy makers, public health systems, Title V Block Grant programs, Autism organizations, and the MCH community (CB5, CB6, and Products, Publications and Submissions Data Collection Form)
Data & Information Systems Track and report data on study participant demographics (including ethnicity, race, gender/sex, geographic location, and socioeconomic status, etc.) Report data on trainee demographics (including ethnicity, race,	Demographic data of study populations drawn from secondary data sources (E.g., demographics by race, ethnicity, primary language, etc.) Socio-demographic-economic characteristics of trainees collected	Improved ability to access, link, and analyze timely data across multiple systems and programs (e.g., capture race/ethnicity of participants and researchers)	Secondary data are more widely known to and used by researchers to conduct innovative MCH and ASD/DD research Increase the diversity of populations represented in HRSA-supported research

PROGRAM PROCESS		PROGRAM OUTCOMES	
What is the planned work for the program?		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?)
gender/sex, geographic location, and socioeconomic status, etc.)			
Assessment, Evaluation, & QI Develop a plan for program quality improvement	Continuous quality improvement conducted. Continuous monitoring of ongoing processes and progress towards the goals and objectives of the project	Increased understanding of program needs, areas for improvement, and impact	Improved efficacy of activities, programs, and systems

Appendix C: Research Program Application Completeness Checklist

Funding Opportunity Number: HRSA-23-068 and HRSA-23-069 Application Due Date in Grants.gov: February 13, 2023	
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 <u>Unique Entity Identifier (UEI)</u> that's been assigned by System for Award Management (SAM)?	
Did your Authorized Organization Representative (AOR) register in SAM	
(https://www.sam.gov/)?	
Did your AOR register in <u>Grants.gov</u> (<u>https://www.grants.gov/</u>)?	
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 and the Methods Section within the recommended 6-page limit?	
Are your <u>budget</u> and <u>budget justification narrative</u> completed accurately and in the funding limit?	
NOTE: The directions offered in the HRSA <u>SF-424 R&R Application Guide</u> differ from those offered by <u>Grants.gov</u> . Please follow the instructions included in the <u>R&R Application Guide</u> and, <i>if applicable</i> , the additional budget instructions in the	
NOFO.	
Did you clearly label all of your <u>attachments</u> ?	
Did you include the Biographical Sketches of Key Personnel in the Application?	
Do you know your institution's indirect cost rate?	

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

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

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

2. How can I download the complete application package for the HRSA-23-068 or HRSA-23-069 NOFO?

You can download the application by searching for the application number HRSA-23-068 or HRSA-23-069 on Grants.gov:

- 1) Click on the hyperlink for HRSA-23-068 or HRSA-23-069
- 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?

<u>Grants.gov</u> 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 <u>Grants.gov</u> 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 organization has registered the organization and himself/herself in <u>Grants.gov.</u> In order to submit your application, your university and your Authorized Organization Representative MUST be registered in <u>Grants.gov.</u> When your Authorized Organization Representative registers in Grants.gov, they will receive a Credential User Name and Password, which will allow that individual to submit application forms in <u>Grants.gov.</u>

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

- 1) Make sure that the Authorized Organization Representative from your university/organization is registered in <u>Grants.gov</u> 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 <u>Grants.gov</u> 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; and
- 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?

Past funding announcements are not shared to avoid confusion among potential applicants. You can find past NOFOs on Grants.gov <u>but</u> the criteria for the SDAR Program have changed. Follow instructions provided in <u>this</u> NOFO (HRSA-23-068 and HRSA-23-069). All applications for this competition will be reviewed and scored based on the instructions and evaluation criteria outlined in <u>this</u> NOFO (HRSA-23-068 and HRSA-23-069).

7. What types of institutions can apply?

MCH SDAR: Eligibility is limited to 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)). Faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

AUTISM SDAR: Eligible applicants include any public or private entity, including research centers or networks. 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 SDAR Program. Are foreign entities eligible to apply?

Yes, the SDAR program (HRSA-23-068 / HRSA-23-069) is open to organizations that meet the eligibility criteria as outlined in the NOFO.

9. How do I know whether to apply to the SDAR grants?

The purpose of the 1-year grants are to support the analysis of large, pre-existing national data sets in order to answer scientific questions related to the MCH field, including children and teenagers with ASD/DD. If you have a study question related to MCH health, including children and teenagers with ASD/DD, that can be investigated using such a large, pre-existing dataset, we invite you to apply.

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

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 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 data that I would need to sift through?

You are responsible for finding the particular data set(s) that will be used in the proposal. HRSA does not make data available to SDAR recipients. You are also responsible for making sure 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 Pl'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 SDAR Program?

The SDAR Program supports research projects that only use 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 including children with special health care needs if applying to the MCH SDAR, or to children and youth with ASD/DD if applying to the Autism SDAR, 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 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 SDAR program allow the use of administrative records? Yes, administrative records can be used for this grant. The SDAR Program supports research projects that exclusively utilize existing national databases and/or administrative records. You should highlight in your proposal how the administrative records 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 look to see if the database is appropriate to the study when reviewing proposals. You should also include written confirmation that the dataset is available to you, 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 SDAR projects and the data sets they have used. It is not the reviewer's responsibility to 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-23-068 and HRSA-23-069 competition allow for multiple principal investigators (PIs), also known as project directors (PDs)?

Yes, multiple applications from an organization are allowable. In order to expand our research grant portfolio, an individual cannot serve as the PD or PI on more than one active HRSA/MCHB/OER/DoR-funded grant. 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 recipient 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 SDAR Program?

If no existing national database adequately addresses your research question or specific population, then the best available data set can be used. In the NOFO we ask you to explain why your data is appropriate for your study question, you will want to explain why a state or regional level dataset is the best. In all cases, the NOFO requires that findings will be generalizable and of regional and national significance to MCH populations. 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?

The NOFO does not specify any minimum or maximum time requirement for the PD/PI, but applicant PDs/PIs should allocate and devote sufficient time to justify their commitments to the project. You must demonstrate in the proposal how the time devoted by the PD/PI meets the review criteria and how the proposed PD/PI's allocated time would potentially be sufficient for the success of the project. Additionally, 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.

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

Postdoctoral fellows are allowed to serve as PD/PI on the SDAR grant. 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 SDAR grant?

Yes, a PI on another (non-HRSA/MCHB) agency's grant can be a PI on an 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?

Multiple applications from an organization with the same <u>Unique Entity Identifier</u> (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.

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

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.

For the sake of page limit, you may include/role-up the race and ethnicity data for all other key personnel on the section that reads "Please provide race and ethnicity data for the program's key staff" on the form by indicating the total for each row/column.

25. Are there page limits for the submitted application?

Yes, the total size of all uploaded files included in the page limit may not exceed 60 pages when printed by HRSA. Any pages that go over the limit will be deleted, and the modified application will be sent to the review committee.

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.
- If an application exceeds required page limitations, the pages over the limit will be deleted.

27. Does the Specific Aims section have a page limitation?

No. 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 does not treat 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 listsery 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 <u>program officers</u> listed in the NOFO via email.
- For budget questions, contact the grants management specialists 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.

Appendix E: 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

- 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

Special Health Care Needs & Disabilities

- Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder
- Asthma
- Autism Spectrum Disorder
- · 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/Prenatal)
- 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 F: Guidance on Biographical Sketches

As described under <u>Budget Justification Narrative</u>, biographical sketches should use the appropriate <u>MCHB form</u>, may not exceed five pages per person, and count against the total page limitation for the application.

The following information should be included on all biographical sketches:

- Race/Ethnicity Data: Provide race and ethnicity data for the PI (required) and all key personnel (optional) according to the chart on the MCHB Biographical sketch form. The race/ethnicity chart can be modified to include only the relevant rows and columns. This information helps MCHB ensure that federal grant and cooperative agreement awards are reaching diverse populations.
- Personal Statement: Briefly describe why you are well suited for your role(s) in this network. The relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise. You may also list up to four peer-reviewed publications that highlight your experience and qualifications for this project.
- Positions and Honors: List in chronological order previous positions, ending with your current position. List relevant honors. Include current membership on any federal government public advisory committee.
- Contribution to Science: Briefly describe one to three of your most important contributions to science. For each contribution, detail the background that frames the scientific problem, the central finding(s), and the impact of the findings to the field or the how the findings apply to health or technology, and your specific role in the work. For each of contribution, list up to **four** peer-reviewed publications or other relevant products. The description of each contribution should be no longer than half a page, including figures and citations.
- Research Support: List both selected ongoing and completed research projects for the past 3 years (federal or non-federal). Begin with the projects that are most relevant to the research proposed in the application. Briefly name the overall goals of the projects and your responsibilities.
- Do not confuse "Research Support" with "Other Support."
 - "Research Support" highlights your accomplishments, and those
 of your colleagues, as scientists. This information will be used
 by the reviewers to judge your qualifications for your role in the
 proposed project.
 - "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 your research has not already been federally funded.

Appendix G: 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/

Developing Healthy People 2030

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