U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

HRSA
Health Resources & Services Administration

Maternal and Child Health Bureau
Office of Epidemiology and Research

Autism Secondary Data Analysis Research Program

Funding Opportunity Number: HRSA-21-052
Funding Opportunity Type(s): New
Assistance Listings (CFDA) Number: 93.877

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

Application Due Date: April 12, 2021

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

Issuance Date: January 12, 2021

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2021 Autism Secondary Data Analysis Research (SDAR) Program. The purpose of these grants is to support applied Maternal and Child Health (MCH) research that exclusively utilizes secondary analyses of existing national databases and/or administrative records to 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.[1] HRSA supports programs to improve the quality of care for those diagnosed with ASD/DD through education, early detection, and intervention.

Funding Opportunity Title:	Autism Secondary Data Analysis Research (SDAR) Program
Funding Opportunity Number:	HRSA-21-052
Due Date for Applications:	April 12, 2021
Anticipated Total Annual Available FY 2021 Funding:	$400,000
Estimated Number and Type of Award(s):	Up to 4 grants
Estimated Award Amount:	Up to $100,000 per grant per year, subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2021 through August 31, 2022 (1 year)
Eligible Applicants:	Eligible applicants include any domestic public or private entity, including research centers or networks. Domestic faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply. See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.

[1] The Department of Health and Human Services (HHS) characterizes underserved, vulnerable, and special needs populations as communities that include members of minority populations or individuals who have experienced health disparities. For this announcement, underserved populations include low-income, racial/ethnic minorities, immigrant, female, tribal, the geographically remote, and other groups that are not already well represented in current pediatric research.

Application Guide

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

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Thursday, January 21, 2021
Time: 2– 3 p.m. ET
Call-In Number: 1-888-917-8041
Participant Code: 4138140

Weblink: https://hrsa.connectsolutions.com/autism_sdar/

Playback Number: 1-866-358-4518
Passcode: 42221
Available until: April 22, 2021

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the Autism Secondary Data Analysis Research (SDAR) Program. This program supports applied Maternal and Child Health (MCH) research that exclusively utilizes the secondary analysis of existing national databases and/or administrative records to 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), Programs should address ASD/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.[2]

HRSA supports programs to improve the quality of care for those diagnosed with ASD/DD through education, early detection, and intervention. More specifically, the Autism SDAR program accelerates the pace of research by providing researchers with the opportunity to pose new research questions, test hypotheses, challenge existing paradigms or clinical practices, and explore the feasibility of interventions using existing data sets. The use of existing data sets helps researchers obtain results more efficiently, at a lower cost. Innovative methods (e.g., meta-analyses) and secondary analysis of existing national databases and/or administrative records are encouraged (e.g., National Survey of Children's Health (HRSA), National Database for Autism Research (National Institutes of Health (NIH)), Medicaid (Centers for Medicare and Medicaid Services), National Health Interview Survey (Centers for Disease Control and Prevention (CDC)) and Mental Health Research Network Database (NIH)).

The Autism SDAR program's goals and objectives are to:

- Generate new evidence to address the needs of underserved ASD/DD populations[3] for whom there is limited evidence of the effectiveness of interventions, and limited access to screening, diagnosis, and treatment for ASD/DD;
- Contribute to a broad public health impact by improving patient engagement and care delivery through studies that are generalizable and replicable across underserved ASD/DD populations;
- Develop and implement a plan to disseminate applied and/or translational research through at least two peer-reviewed research articles related to the project (e.g., findings on research planning, participant recruitment, methods, implementation and/or research challenges, preliminary or unexpected research findings, in addition to final research findings) and to scientific, professional, lay audiences, and federal partners.

[2] The Department of Health and Human Services (HHS) characterizes underserved, vulnerable, and special needs populations as communities that include members of minority populations or individuals who have experienced health disparities. For this announcement, underserved populations include low-income, racial/ethnic minorities, immigrant, female, tribal, the geographically remote, and other groups that are not already well represented in current pediatric research.

2. Background

The Autism SDAR program 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)). The Autism CARES Act of 2019 emphasizes improving health outcomes and the well-being of individuals with ASD/DD across the lifespan. In carrying out these provisions, HRSA supports various programs to improve the quality of care for those who have, or are at risk for developing ASD/DD through education, early detection, and intervention. Specifically, these programs are designed to:

- Increase awareness of ASD/DD;
- Reduce barriers to screening and diagnosis;
- Support research on evidence-based interventions for individuals with ASD/DD;
- Promote guideline development for interventions; and
- Train professionals to utilize valid screening tools to diagnose and provide research-informed interventions, through an interdisciplinary approach that focuses on specific issues for children and adolescents who are not receiving an early diagnosis and subsequent interventions.

ASD is a complex neurodevelopmental disorder, and individuals with this condition may experience core behavioral challenges with social interactions and communication, as well as restrictive and repetitive behaviors, which can be lifelong and pervasive.[4] Children and adolescents with ASD/DD also have greater health service needs, which can place a significant financial and emotional burden on their families.[5] Additionally, 83 percent of children with ASD have at least one co-occurring non-ASD/DD condition.[6] Children and adolescents with ASD also experience more physical health problems than neuro-typical individuals, including seizures, sleep problems, gastrointestinal disorders, nutritional deficiencies, and metabolic conditions.[7,8,9] Consequently, these children and adolescents have greater health service needs, which can place a significant financial and emotional burden on their families.[5] Children and adolescents with ASD/DD from underserved populations encounter persistent disparities in screening, diagnosis, and health service access, increasing their vulnerability to adverse physical and behavioral outcomes across the lifespan.[10,11]

A comprehensive picture of ASD among children in the U.S is best understood by examining two key estimates of ASD prevalence[12]. The Centers for Disease Control

[4] American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders V*. Washington, DC: American Psychiatric Publishing; 2013.
[5] 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.
[6] 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.
[7] Coury D. Medical treatment of autism spectrum disorders. *Curr Opin Neurol*. 2010;23(2):131-136.
[8] 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.
[9] 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
[10] Zuckerman KE, Lindly OJ, Reyes NM, Chavez AE, Macias K, Smith KN, Reynolds A. Disparities in diagnosis and treatment of autism in Latino and non-Latino white families. *Pediatrics*. 2017; 139(5):e20163010.
[11] Bishop-Fitzpatrick L, Kind AJH. A scoping review of health disparities in autism spectrum disorder. *J Autism Dev Disord*. 2017;47(11):3380-3391.
[12] Kogan, et al. (2018) The Prevalence of Parent-Reported Autism Spectrum Disorder Among US Children. Pediatrics 142(6).

and Prevention used population-based ASD prevalence estimates for U.S. children reported from the Autism Developmental Disabilities Monitoring Network (ADDM) – a surveillance system in local population-based areas in which ASD cases are identified through education and health records review – to report that approximately one in 54 children have ASD.[13] Parent-reported data from the 2016 National Survey of Children's Health, a study published in 2018, documented that one in 40 children aged 3-17 years have a diagnosis of ASD.[14] Estimates from these two systems reflect different years, populations (11 local U.S. populations versus the entire U.S.), and ages of children (children aged 8 years in ADDM versus 3-17 years in NSCH) and contribute unique information, that when combined, help form a comprehensive picture of ASD among children in the U.S. Furthermore, even though children can be diagnosed as early as age 2, on average, children identified with ASD were not diagnosed until after age four.[15] Although 2016 Autism and Developmental Disabilities Monitoring Network (ADDM) data suggest no overall difference in ASD prevalence between 8-year-old Black and White children, there were disparities for Black children in early evaluation and diagnosis of ASD. Hispanic children were identified as having ASD less frequently than White or Black children.[16] The impact of these disparities on health outcomes may be compounded by other social determinants of health (SDOH) across the lifespan; conditions in which people are born, grow, live, work, and age.[17] SDOH include factors like socioeconomic status, education, neighborhood and physical environment, community violence, employment, and social support networks, as well as access to health care. Addressing SDOH, which affect a wide range of health, functioning, and quality-of-life outcomes and risks, is in line with HRSA's objective to improve the health and well-being of individuals and the communities in which they reside.

The Autism SDAR Program is the only federal program that supports foundational applied research through analysis of existing national databases and/or administrative records to evaluate inequalities in access to screening, diagnosis, and treatment and to identify effective ASD/DD interventions. The MCH Research Program in HRSA's Maternal and Child Health Bureau's Office of Epidemiology and Research administers the Autism SDAR Program. The Program has supported groundbreaking studies that have influenced clinical practice, organization and delivery of health care services, delivery of preventive care, and early intervention(s) for MCH populations, including children with special health care needs. Prior Autism SDAR recipients published an average of two peer-reviewed scholarly papers per grant totaling approximately 23 articles by the 12 funded recipients. These articles have been cited 422 times. Autism SDAR recipients have also delivered 44 scientific conference presentations. More information about the Autism SDAR Program, funded projects, and current activities can be found at http://www.mchb.hrsa.gov/research.

[13] Autism and Developmental Disabilities Monitoring Network (2016 data) (http://www.cdc.gov/ncbddd/autism/data.html)
[14] Kogan, et al. (2018) The Prevalence of Parent-Reported Autism Spectrum Disorder Among US Children. Pediatrics 142(6).
[15] National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention. (2019) Spotlight On: Delay Between First Concern to Accessing Services
[16] Maenner et al. (2020) Prevalence of Autism Spectrum Disorder Among Children Aged 8 Years — Autism and Developmental Disabilities Monitoring Network, 11 Sites, United States, 2016. MMWR Surveillance Summary, 69(4).
[17] Wiggins LD, Durkin M, Esler A, Lee LC, Zahorodny W, Rice C, Yeargin-Allsopp M, Dowling NF, Hall-Lande J, Morrier MJ, Christensen D, Shenouda J, Baio J.
Disparities in Documented Diagnoses of Autism Spectrum Disorder Based on Demographic, Individual, and Service Factors. Autism Res. 2019 Dec 23. [PMID: 31868321]

For additional details, please see Appendix A.

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 $400,000 to be available annually to fund four (4) recipients. The actual amount available will not be determined until enactment of the final FY 2021 federal appropriation. You may apply for a ceiling amount of up to $100,000 total cost (includes both direct and indirect, facilities and administrative costs). The period of performance is September 1, 2021 through August 31, 2022 (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

Eligible applicants include any domestic public or private entity, including research centers or networks. Domestic faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

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

HRSA will consider any application that fails to satisfy the deadline requirements referenced in Section IV.4 non-responsive and will not consider it for funding under this notice.
NOTE: Multiple applications from an organization **are** allowable. Multiple applications from an organization with the same DUNS number are allowable if the applications propose separate and distinct projects. For example, different investigators (or research teams) from the same institution can apply for the same funding opportunity.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates) an application is submitted more than once prior to the

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

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

- An individual cannot be named as the project director (PD) or principal investigator (PI)[18] on more than one application for the HRSA-21-052 competition;
- In order to diversify our research grant portfolio, and ensure that investigators devote adequate time and expertise to funded research programs, a current PD/PI of an active HRSA/MCHB Research award can serve for no more than 10 percent time on a new proposal;
- Applications must propose secondary analysis of existing national datasets and/or administrative records;
- All secondary analyses, including those that involve the linkage of multiple datasets, cannot exceed 1 year in length; and
- Projects that include the collection of biological specimens will not be considered, as this program funds only applied or translational research on ASD/DD populations and allows secondary analysis of existing national databases and administrative data.

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

Additionally, a student/trainee receiving support from grant funds must be a citizen of the United States or a foreign national having in his/her possession a visa permitting permanent residence in the United States, or a non-citizen national.

IV. Application and Submission Information

1. Address to Request Application Package

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

[18] 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.

The NOFO is also known as "Instructions" on Grants.gov. You must select "Subscribe" and provide your email address for each NOFO you are reviewing or preparing in the workspace application package in order to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. *You are ultimately responsible for reviewing the For Applicants page for all information relevant to this NOFO.*

2. Content and Form of Application Submission

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

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

Application Page Limit
The total size of all uploaded files included in the page limit may not exceed the equivalent of 60 pages when printed by HRSA. The page limit includes a 20-page limitation for the narrative section, and 6-page limitation for the Methodology/Research Strategy methodology section; which includes Significance, Innovation, and Approach. All sections combined contribute to the 60-page total limit, including the abstract, project and budget narratives, attachments including biographical sketches (biosketches), and letters of commitment and support required in HRSA's SF-424 R&R Application Guide and this NOFO.

Biographical sketches for any key employed personnel that will be assigned to work on the proposed project must be attached to RESEARCH & RELATED Senior/Key Person Profile (OMB Number 4040-0001) found in the application package on grants.gov. Due to the HRSA 60-page limit, it is recommended that all biographical sketches are no more than five pages in length and must follow the HRSA font/margin requirements. For details on how to format the biographical sketch visit: https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-for-Research-Grant-Applicants-Jan2020-2023.docx. Please be aware that this form does count against the page limit.

Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. However, biographical sketch OMB forms **do** count in the page limitation. Please note: If you use an OMB-approved form that is not included in the workspace application package for HRSA-21-052, it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **It is therefore important to take appropriate measures to ensure your application does not exceed the specified page limit.**

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

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

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

1) You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. § 3321).
3) Where you are unable to attest to the statements in this certification, an explanation shall be included in *Attachment: Other Relevant Documents*.

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

Program-Specific Instructions

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

i. Project Abstract

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

ii. Project Narrative (20 page limit)

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

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

A. 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*

This section outlines the unmet needs of the targeted population that the proposed project will address, and should help reviewers understand how the targeted population will benefit from the proposed project.

- Briefly describe the target population(s) (including age ranges, race/ethnicity, gender/sex and other demographic information) and its unmet health needs.
- As appropriate, include SDOH and health inequalities impacting the population that the current project will address.

2) *SIGNIFICANCE -- Corresponds to Section V's Review Criterion #2 RESPONSE*
   - Describe the background literature, and explain how it is pertinent to and provides rationale for the proposed research objectives.
   - Explain the critical problem or barrier to progress in the field that the proposed project addresses.
   - Indicate the relevance of the problem to children and adolescents with ASD/DD and their families.
   - Identify how findings may be applied to the field to improve care and/or the ways that services are organized and delivered.

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

Goals and Objectives

- State clearly and succinctly the specific research objectives. This includes addressing any critical barriers to progress in the field.
- Clearly and concisely, summarize the expected research outcome(s) and how these will address the unmet needs of the target population.

Hypotheses and Specification of Variables

- Clearly and logically, present the specific questions that the study will answer and link to unmet target population needs. Include hypotheses and provide justifications. Ensure scientific approach is thoughtful and logical.
- Present a summary table of the variables, classified as independent, intervening, mediating, moderating, and dependent, etc., the measures you

will employ as indicators for these variables, and the units and levels of measurement of the indicators.

- If possible, construct and present a model or graphical representation of the set of relationships held to be operative among the variables. Ensure alignment throughout the graphic analytic model (if included), the table of variables, the statement of hypotheses, and the plan for data analysis.

B. METHODOLOGY/RESEARCH STRATEGY -- Corresponds to Section V's Review Criteria #3 EVALUATIVE MEASURES and #4 IMPACT

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

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

1) *WORK PLAN -- Corresponds to Section V's Review Criterion #3 Evaluative Measures*

- Study Design: Describe the overall study design, strategy, methodology, and analyses you will use to accomplish the specific aims of the project. Include the following information:
  - Information regarding the database(s) you propose to use; written confirmation of the availability of the database for the proposed study should be included in Attachment 4. Describe how access will be gained to any confidential files, if utilized, in the proposed analyses;
  - Information regarding the linkage of multiple datasets; data linkage activities among multiple datasets should be included within the overall study design portion of the Work Plan;
  - The data collection procedures used for the database(s) or administrative record(s) and instrumentation as appropriate;
  - The study sample, including demographic information (e.g., age, racial/ethnic background, socioeconomic status, geographic location);
  - The eligibility inclusion/exclusion criteria for the database(s) and/or administrative record(s);
  - Issues regarding sampling design and randomization as appropriate;
  - Estimated study sample response rates, nonresponse bias analyses, and power analyses as appropriate;
  - Strategies that the database(s) utilized for participant recruitment;
  - The reliability and validity of instruments (psychometric properties); and
  - Methods to collect, analyze, and interpret the data, as well as any resource sharing plans as appropriate.

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

2) *SCIENTIFIC INNOVATION AND IMPORTANCE -- Corresponds to Section V's Review Criterion #4 Impact*

- Explain how the proposed project will advance scientific knowledge and the limited availability of evidence, and improve technical capability and/or clinical practice.
- Describe the impact that the results of the proposed research will exert on the research field(s) involved.
- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, policies, or analyses used, and any advantage over existing methodologies, or policies.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or policies that will be changed if the proposed aims are achieved through this secondary data analysis project.
- Describe how current concepts, methods, technologies, treatments, services, policies, or preventive interventions will be changed if the proposed aims are achieved through this secondary data analysis project.

C. IMPACT AND DISSEMINATION – CORRESPONDS TO SECTION V'S REVIEW CRITERION #4 IMPACT

Public Health Impact

- Describe the impact that the expected outcomes are likely to have on patient engagement, care delivery strategies involved and/or the physical and behavioral health of targeted ASD/DD populations.
- Peer-reviewed publications: It is expected your project will produce at least two peer-reviewed publications. Clearly indicate the number and focus area of your proposed peer-reviewed publications.
- Describe the extent to which study results will be generalizable and replicable.
- Describe how the proposed study contributes to broad public health impact.

Publication and Dissemination Plan

Provide a publication action plan that includes:

- How you will publish several peer-reviewed articles describing outcomes, results, and challenges of your research project.

- Describe how you will facilitate the transfer of findings into practice by disseminating findings, reports, and/or project outputs to key target audiences, including scientific, professional, lay audiences, and federal partners. Examples of how past recipients have disseminated research findings and information on project activities include email messages, newsletter articles, conference presentations, webcasts, fact sheets, infographics, policy briefs, and website and social media posts.

D. Organizational Information/ Environment -- CORRESPONDS TO SECTION V'S REVIEW CRITERION #5 RESOURCES/CAPABILITIES

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

Organizational Facilities and Other Resources

- Identify the facilities you will use (laboratory, clinical setting, computer lab, office, and/or other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work.
- Describe how you will collaborate with pertinent partners, such as other HRSA-supported Autism CARES Act Programs (available here: https://mchb.hrsa.gov/maternal-child-health-initiatives/autism), Title V grantees, and MCH Research Network recipients which are available here: https://mchb.hrsa.gov/research.
- Discuss ways in which the proposed study will benefit from the unique features of the scientific environment or target population.
- For Early Stage Investigators[19], describe institutional investment in the success of the research project and success of the investigator in obtaining funding. Examples may include laboratory space sufficient for project needs, collegial support such as the availability of organized peer groups, logistical support such as administrative management and oversight, and financial support such as protected time for research with salary support.
- If there are multiple performance sites, describe relevant resources available at each site.

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

Qualifications of Research Team's Key Personnel

- The qualifications of the research team's key personnel are assessed as part of Section V's Review Criterion #5 Resources/Capabilities. To assess the qualifications of the research team's key personnel and research strategy, the following items are used: (a) Preliminary Studies in Section C. Methodology/Research Strategy 2) Work Plan/Approach; (b) Staffing Plan in Budget Narrative; and (c) Biographical Sketches of key personnel.
- Biographical sketches should follow the instructions provided below. When applicable, biographical sketches should include training, language fluency and experience working with culturally and linguistically diverse study populations.
- It is encouraged that you use the MCHB biographical sketch form found here: https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-for-Research-Grant-Applicants-Jan2020-2023.docx. NOTE: The biographical sketch form counts against your total page limitation and may not exceed five pages per person.

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

A. Ethnicity Data: Provide ethnicity data for the Principal Investigator and all key staff according to the included chart on the MCHB Biographical sketch form to catalogue diversity among research staff. https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-for-Research-Grant-Applicants-Jan2020-2023.docx.

B. Personal Statement Briefly describe why you are well suited for your role(s) in the project described in this application. The relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). You may also identify up to four peer-reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and/or active duty military service.

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

D. Contribution to Science Briefly describe one to three of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem, the central finding(s), the influence of the finding(s) on the progress of science or the application of those finding(s) to

health or technology, and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products, patents, data and research materials, databases, educational aids or curricula, instruments or equipment, models, protocols, and software or NetWare) that are relevant to the described contribution. The description of each contribution should be no longer than half a page, including figures and citations.

E. Research Support List both selected ongoing and completed research projects for the past 3 years (federal or non-federally-supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the projects and responsibilities of the person identified on the biographical sketch.

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

E. FEASIBILITY – CORRESPONDS TO SECTION V'S REVIEW CRITERION #7 PROGRAM ASSURANCES

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

Proposed Sequence or Timetable

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

Resolution of Challenges

- Discuss any challenges that are likely to be encountered in designing and implementing the research activities described in the Work Plan/Approach, and approaches that will be used to resolve such challenges. Discuss alternative strategies should any of these potential challenges arise. Examples include:
    - Staff training, putting culturally/linguistically competent project staff in place quickly, etc.

- The feasibility of obtaining the dataset or administrative record within the required timeline to complete the tasks, including access to most-recent dataset or administrative record(s) if multiple years exist.
- The feasibility of completing the proposed work within the timeline provided.

F. EVALUATION AND TECHNICAL SUPPORT CAPACITY -- CORRESPONDS TO SECTION V'S REVIEW CRITERION #7 PROGRAM ASSURANCES

- Describe a plan for performance evaluation (evaluating project progress towards achieving its specific aims) that will contribute to continuous quality improvement of project efforts. The project performance evaluation should reflect the Specific Aims described in Section B above, as well as the specific timeline goals set in the Proposed Sequence or Timetable under Section E 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.

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

Protection of Human Subjects

Human Subjects Protection:
Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

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

IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent the page limits of the Methods portion of the Project Narrative section.

This section is required if you answer "yes" to the question: "Are human subjects involved?" on the R&R Other Project Information form. If the answer is "No" to the HRSA-21-052 question but the proposed research involves data from human subjects, you must provide a justification in this section for the claim that no human subjects are involved.

- If human subjects are involved, the project should be in compliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR part 46) (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). Please refer to instructions provided in HRSA's *SF-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.
- Discuss plans to seek Institutional Review Board (IRB) approval or exemption. IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent the page limits of the Methodology/Research Strategy section.

Data Availability and Diversity of Database Sample

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

1) Ethnic Category (Hispanic Heritage): "Hispanic or Latino" or "Not Hispanic or Latino"

- Gender/sex distribution within each Ethnic Category (Hispanic Heritage)
- Total distribution by Ethnic Category (Hispanic Heritage)

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[20]

[20] 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

4) Geographic Location

- Urban
- Rural

- The "Ethnic Category (Hispanic Heritage): Total Sample" must be equal to the "Racial Categories: Total Sample." Also, list any proposed racial/ethnic subpopulations, if applicable.
- The "Total Sample" means the number of subjects in the dataset that will be used to evaluate the research question. They will be reported in two ways in the table: by self-reported "Ethnic Category (Hispanic Heritage)" and by self-reported "Racial Categories."
- Describe how the analytic plan will reflect an understanding and valuing of the culture of the target population.
- Provide written confirmation that the proposed data that will be used for the Autism 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.

iii. Budget -- CORRESPONDS TO SECTION V'S REVIEW CRITERION 6: SUPPORT REQUESTED

The directions offered in the *SF-424 R&R Application Guide* may differ from those offered by Grants.gov. Follow the instructions in Section 4.1.iv of HRSA's *SF-424 R&R Application Guide* and the additional budget instructions provided below. A budget that follows the *R&R Application Guide* will ensure that, if HRSA selects the 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.

The Consolidated Appropriations Act, 2021(P.L. 116-260), Division H, § 202 states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." See Section 4.1.iv Budget – Salary Limitation of HRSA's *SF-424 R&R Application Guide* for additional information. Note that these or other salary limitations may apply in the following fiscal years, as required by law.

iv. Budget Justification Narrative -- CORRESPONDS TO SECTION V'S REVIEW CRITERION 6: SUPPORT REQUESTED

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

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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

In addition, the Autism SDAR Program requires the following:

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

v. Program-Specific Forms

Program-specific forms are not required for application.

vi. Attachments

Provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. **Clearly label each attachment**.

Attachment 1: Letters of Agreement/Letters of Support

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

Attachment 2: Key Publications or Condensed Citations with Abstracts

A list of citations for key publications by the key personnel that are relevant to the proposal can be included. Do not include unpublished theses, or abstracts/ manuscripts **submitted** (but not yet accepted) for publication. In consideration of the 60-page limitation, a list of citations only may be included.

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

Surveys, questionnaires, other data collection instruments, clinical protocols and informed consent documents may be submitted as an attachment as necessary, keeping in mind that these count in the 60-page limitation.

Attachment 4: Information regarding the database(s) you propose to use

Written confirmation of the availability of the database for the proposed study should be included in Attachment 4. Describe how access will be gained to any confidential files, if utilized, in the proposed analyses.

Attachment 5: Explanation on Delinquent Federal Debt, if applicable

Attachments 6 -15: Other Relevant Documents, as necessary

NARRATIVE GUIDANCE

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

Narrative Section	Review Criteria
A Specific Aims: 1) Needs Assessment	(1) Need
A. Specific Aims: 2) Significance	(2) Response
A. Specific Aims: 3) Goals and Hypotheses	
B. Methodology/Research Strategy: 1) Work Plan/Approach	(3) Evaluative Measures
B. Methodology/Research Strategy: 2) Scientific Innovation and Importance	(4) Impact
C. Impact and Dissemination	
D. Organizational Information/Environment	(5) Resources/Capabilities
Budget and Budget Justification	(6) Support Requested
E. Feasibility	(7) Program Assurances
F. Evaluation and Technical Support Capacity	
G. Protection of Human Subjects, Data Availability and Diversity of Database Sample	

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

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

You must also register with SAM and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR §

25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d)).

If you are chosen as a recipient, HRSA would not make an award until you have complied with all applicable DUNS (or UEI) and SAM requirements and, 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 use that determination as the basis for making an award to another applicant.
If you have already completed Grants.gov registration for HRSA or another federal agency, confirm that it is still active and that the Authorized Organization Representative (AOR) has been approved.

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

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

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

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

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the forms themselves are no longer part of HRSA's application packages and the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM located at SAM.gov.

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

4. Submission Dates and Times

Application Due Date
The due date for applications under this NOFO is ***April 12, 2021 at 11:59 p.m.ET.***
HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadline** to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's *SF-424 R&R Application Guide* for additional information.

5. Intergovernmental Review

The Autism SDAR Program is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

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

6. Funding Restrictions

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

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

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

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

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

V. Application Review Information

1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation.
These criteria are the basis upon which the reviewers will evaluate and score the merit of the application. The entire proposal will be considered during objective review. Review criteria are used to review and rank applications. The Autism SDAR Program has seven (7) review criteria. See the review criteria outlined below with specific detail and scoring points.

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

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

The extent to which:

- The demographic characteristics of the underserved study population (including age ranges of children/adolescents/young adults) are clearly stated;
- The proposed project clearly describes the unmet health needs of the targeted population and, as appropriate, the social determinants of health and health disparities impacting the targeted population; and
- The relevance to children and adolescents with ASD/DD and their families and rationale for the research problem are clearly described.

Criterion 2: RESPONSE (20 points) – Corresponds to Project Narrative Section B. Specific Aims: 2) Significance and 3) Goals and Hypotheses

Significance

The extent to which:

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

Goals and Hypotheses

The extent to which:

- The goals and objectives are specific, measurable, achievable, relevant, and time bound (SMART);
- The expected outcomes are clearly and succinctly summarized, with attention to how these outcomes will address the unmet needs of the targeted population;
- The hypotheses are logically derived from the research literature, clearly stated, and are related to the defined problem;

- Variables are clearly defined; and
- There is congruence among the associations depicted by the graphic model (if included), the variables, the statement of hypotheses, and the plan for data analysis.

Criterion 3: EVALUATIVE MEASURES (30 points) -- Corresponds to Project Narrative Section C. Methodology/Research Strategy: 1) Work Plan/Approach

Study Design

The extent to which:

- The overall strategy, methodology, and analyses are well reasoned and appropriate to accomplish the specific aims of the project;
- Significant threats to internal and external validity of the design have been adequately acknowledged and addressed;
- The project activities are generalizable and replicable;
- As appropriate, the project reflects an understanding and value of the culture of the target population in the research project; and
- The proposed national database(s) or administrative record(s) is/are clearly stated in the abstract and described in the application.

Data Collection

The extent to which:

- Instruments were selected or developed and were adequate and appropriate;
- Adequate attention was given to the reliability and validity of instruments (psychometric properties);
- Any self-reported data can provide convincing validity for intended measurements, (e.g., self-reported blood pressure, parent-reported anthropometric data); and
- The data are available to the investigator and are appropriate for this study. **The application must contain written confirmation that the proposed data to be used in the analysis are available to the investigator.**

Population Description and Sampling

The extent to which:

- The study population is described (i.e., targeted age(s) or age ranges, expected racial/ethnic background and socioeconomic status, urban/rural, etc.);

- The sampling design is appropriate and includes an adequate and justified sample size; The expected differences between groups are defined in terms of statistical as well as clinical significance;
- The application describes expected differences between groups in terms of statistical as well as clinical significance;
- There is a basis for the quality of sample estimates and the degree to which the quality is adequate for the purpose of the study; and
- The inclusion of under-represented populations and members of both sexes/genders, those who are gender-neutral, as well as the inclusion of children, is justified in terms of the scientific goals and methodology/research strategy proposed.

Plan for Data Analysis

The extent to which:

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

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

Methodology/Research Strategy:

The extent to which:

- The proposed project will advance scientific knowledge, technical capability, and/or clinical practice in one or more fields relevant to children, adolescents, and young adults with ASD/DD and their families as appropriate, if the aims of the project are achieved;
- The application challenges and seeks to shift current research or clinical practice paradigms by utilizing innovative theoretical concepts, approaches or methodologies, instrumentation, or interventions; and
- A refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions is proposed; or project results are likely to exert a sustained influence on the research field(s) involved.

Impact and Dissemination

Public Health Impact

The extent to which:

- The expected outcomes are likely to help improve the health and/or well-being of children, adolescents, and young adults with ASD/DD in underserved populations; and
- The findings will be generalizable and replicable to a community, region or nationally.

Publication and Dissemination Plan

The extent to which:

- The applicant presents a sound plan for how they will produce the expected minimum number of peer-reviewed publications;
- The PD/PI and other key personnel demonstrate current and/or past success in publishing the findings of their research; and
- The proposal clearly demonstrates a dissemination plan to facilitate the transfer of findings into practice by disseminating findings, reports, and/or project outputs to key target audiences, including researchers, providers, State Title V and children with special health care needs programs and other program(s) serving ASD/DD populations, policymakers, families and the general public.

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

Organizational Capacities

The extent to which:

- The capabilities of the organization, and quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed research project;
- The scientific environment in which the work will be done contributes to the probability of project success; and
- The project will benefit from unique features of the scientific environment, available populations, or collaborative arrangements.

Key Personnel

The extent to which:

- The Key/Senior Support Personnel Profiles and biographical sketches indicate that the PI, collaborators, staff, and other researchers are well qualified by training and/or expertise to conduct the research;

- If Early Stage Investigators or New Investigators, the appropriateness of experience and training; if established investigators, the degree to which they have demonstrated an ongoing record of research accomplishments that have advanced the ASD/DD field; and
- The proposal describes relevant preliminary studies performed by key personnel, indicating the capacity to conduct the work as described.

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

The extent to which:

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

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

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

Proposed Sequence or Timetable

The extent to which:

- The proposed project provides a clear timeline and is feasible to conduct within the proposed timeframe;
- The timeline presents clear, detailed, and feasible goals throughout the duration of the project; and
- The application demonstrates the feasibility of accessing the database(s) or administrative record(s).

Evaluation and Technical Support Capacity

- The extent to which plans are in place to evaluate whether the project objectives are being met according to the timeline provided.

Human Subjects Protections (required if you answer yes)

The extent to which:

- The proposal complies with the HHS regulations for protection of human subjects (45 CFR part 46). See the instructions in HRSA's SF-424 R&R Application Guide, Appendix: Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy;
- The project includes plans for: 1) protection of human subjects from research risks;
- Adequate measures are in place to ensure the security of the research data (data security); and
- The applicant discusses plans to seek Institutional Review Board (IRB) approval. (IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects).

2. Review and Selection Process

The objective review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. In addition to the ranking based on merit criteria, HRSA approving officials will apply other factors (, (e.g., geographical distribution, scores in key sections of the proposal such as methodology/research strategy, relevance of topic, agency priorities, etc.). See Section 5.3 of HRSA's *SF-424 R&R Application Guide* for more details.

3. Assessment of Risk

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

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional programmatic or administrative information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will

determine whether HRSA can make an award, if special conditions are required, and what level of funding is appropriate.
Award decisions are discretionary and are not subject to appeal to any HRSA or HHS official or board.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of September 1, 2021. See Section 5.4 of HRSA's *SF-424 R&R Application Guide* for additional information.

2. Administrative and National Policy Requirements

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

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions

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

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

Human Subjects Protection
Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

3. Reporting

The Discretionary Grant Information System (DGIS) reporting system will continue to be available through the Electronic Handbooks (EHBs). HRSA enhanced the DGIS and these improvements are available for recipient reporting. The agency will communicate with recipients and provide instructions on how to access the system for reporting. HRSA will also provide technical assistance via webinars, written guidance, and one-on-one sessions with an expert, if needed.

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

1) **DGIS Performance Reports.** Available through the Electronic Handbooks (EHBs), the Discretionary Grant Information System (DGIS) is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report **annually**, by the specified deadline. To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are available at https://grants4.hrsa.gov/DGISReview/FormAssignmentList/R41.html. The type of report required is determined by the project year of the award's period of performance.

Type of Report	Reporting Period	Available Date	Report Due Date
a) New Competing Performance Report	9/1/2021-8/31/2022 *(administrative data and performance measure projections, as applicable)*	Period of performance start date	120 days from the available date
c) Project Period End Performance Report	9/1/2021-8/31/2022	Period of performance end date	90 days from the available date

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

Please note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at 2 CFR § 200.340 - Termination apply to all federal awards effective August 13, 2020.

VII. Agency Contacts

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

Stanley Gordon
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 945-3935
Email: SGordon2@hrsa.gov

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

Sylvia Sosa, MSc
Program Officer, Division of Research, Office of Epidemiology and Research
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane,
Rockville, MD 20857
Telephone: (301) 443-2259
Email: SSosa@hrsa.gov

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

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

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

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

VIII. Other Information

Logic Models

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

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

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Thursday, January 21, 2021
Time: 2– 3 p.m. ET
Call-In Number: 1-888-917-8041
Participant Code: 4138140

Weblink: https://hrsa.connectsolutions.com/autism_sdar/

Playback Number: 1-866-358-4518
Passcode: 42221
Available until: April 22, 2021

Tips for Writing a Strong Application

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

Appendix A: Relevant Websites

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

MCHB Goals of the Autism Cares Act
https://mchb.hrsa.gov/maternal-child-health-initiatives/autism.

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

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

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

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)
http://www.medicalhomeinfo.org/

Appendix B: Key Terms for Project Abstracts

a) Content Terms (maximum of 10)

Health Care Systems & Delivery

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

Primary Care & Medical Home

- Adolescent Health
- Coordination of Services
- Community-Based Approaches
- Integration of Care
- Medical Home
- Oral Health
- Preconception/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
- 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) Targeted Population(s) (as many as apply):

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

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

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

Appendix C: Application Completeness Checklist

Funding Opportunity Number: HRSA-21-052 **Application Due Date in Grants.gov:** April 12, 2021	
Requirement	**Yes**
Do you meet the eligibility criteria?	
Did you read the R&R Application Guide (https://www.hrsa.gov/sites/default/files/hrsa/grants/apply/applicationguide/sf-424-rr-app-guide.pdf)?	
Do you have a DUNS number (https://www.dnb.com/duns-number.html)?	
Did your Authorized Organization Representative (AOR) register in SAM (https://www.sam.gov/)?	
Did your AOR register in Grants.gov (https://www.grants.gov/)?	
Is your Abstract no more than one page in length and single spaced?	
Does the Narrative Section of your application fully address: • Background and Significance? • Specific Goals and Objectives? • Project Design, Methods, and Evaluation? • Plan/Schedule of Implementation and Capability of Applicant? • Feasibility? • Evaluation and Technical Support Capacity? • Protection of Human Subjects? • Targeted/Planned Enrollment?	
Did you confirm that your application addressed all of the NOFO Review Criteria?	
Is your proposal less than 60 pages with the Narrative Section within the 20-page limit and the Methods Section within the 6-page limit?	
Are your budget and budget justification narrative completed accurately and in the yearly funding limit? **NOTE:** The directions offered in the HRSA SF-424 R&R Application Guide differ from those offered by Grants.gov. Please follow the instructions included in the R&R Application Guide and, *if applicable*, the additional budget instructions in the **NOFO**.	
Did you clearly label all of your attachments?	
Did you include the Biographical Sketches of Key Personnel in the Application?	
Do you know your institution's indirect cost rate?	
Did you use no less than 12-point font and are your page margins at least 1 inch wide in the Narrative and Attachment Sections of the Application? **NOTE:** The Biographical Sketches of Key Personnel can have .5" margins.	
Are your pages, including attachments, within the 60-page limit? **NOTE:** Pages which do not count toward the 60-page limit include: Cover Page, Indirect Cost Rate Agreement, Proof of Non-Profit Status, and Standard OMB-approved forms.	

Appendix D: Logic Model

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

PROGRAM PROCESS **What is the planned work for the program?**		**PROGRAM OUTCOMES** **What are the program's intended results?**	
ACTIVITIES **(What will program inputs do?)**	**OUTPUTS / PRODUCTS** **(What will be created as a result of the activity?)**	**SHORT-TERM / INTERMEDIATE** **(What will change as a result of the product/system implemented?)**	**LONG-TERM / IMPACT** **(What will change if short-term / intermediate outcomes are achieved?)**
Design and conduct Autism SDAR project	Complete Autism SDAR project within 1 year of award.	Increase the number of foundational studies (using secondary data analyses) addressing current and emerging issues relevant to Autism` populations.	Advance and contribute to the Autism evidence base to inform the work of health care providers, other practitioners, public health systems, and Title V Block Grant programs.
Develop and implement a dissemination plan for communicating research findings to diverse stakeholders.	• Dissemination plan with a timeline and list of proposed products. • Manuscripts published in peer-reviewed journals. • Non-peer-reviewed products aimed at stakeholders beyond the scientific research community (e.g., reports, blogs, web postings, videos, infographics, and lay summaries of research publications).	Increase the accessibility of HRSA funded Autism research to the scientific and lay community. Increase the awareness of research findings about funded Autism research among diverse stakeholder groups.	

PROGRAM PROCESS What is the planned work for the program?		PROGRAM OUTCOMES What are the program's intended results?	
ACTIVITIES (What will program inputs do?)	**OUTPUTS / PRODUCTS (What will be created as a result of the activity?)**	**SHORT-TERM / INTERMEDIATE (What will change as a result of the product/system implemented?)**	**LONG-TERM / IMPACT (What will change if short-term / intermediate outcomes are achieved?)**
Prepare and submit grant applications for external funding opportunities outside of HRSA/MCHB's research grant program.	Grant applications completed and submitted for external funding opportunities	Increase the capacity of grantees to expand/sustain research initiated by the Autism SDAR program.	Increase the use/translation of study findings into intervention research that may ultimately inform changes in practice and policy in the public health system or related settings.
Train and mentor junior/new investigators in Autism secondary data research.	Junior/new investigators trained/mentored	Increase the number of junior/new investigators trained/mentored in foundational research and current/emerging issues relevant to Autism populations that generate relevant peer-reviewed publications and non-peer-reviewed products in the field.	Increase Autism secondary data research sustainability.

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

Where do I find application materials for the Autism SDAR Program?

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

How can I download the complete application package for the HRSA-21-052 NOFO?

You can download the application by searching for the application number HRSA-21-052 on Grants.gov:

1) *Click on the hyperlink for HRSA-21-052*
2) *Click on the last blue tab entitled "PACKAGE."*
3) *Scroll down and click on the "Preview" hyperlink under the "Actions" column.*
4) *Select the "Download Instructions" button in the right-hand corner. This will download the application.*

What is Grants.gov?

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

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

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

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

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

3) *There are resources available on the Grants.gov web site to help you navigate this new system. Please visit Grants.gov to access these resources.*

Some business practices will change with the introduction of the new SF-424 R&R Form:

- *With the HRSA SF-424 R&R, you will be reporting faculty and staff time in calendar month equivalents.*
- *Budget details about subcontracts will now be described in a section of the SF-424 R&R Form called sub-awards.*

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

The past funding announcement will not be distributed to avoid confusion among potential applicants. The NOFO from last year's competition is available on MCHB's website. However, we recommend that you carefully follow instructions provided in the current published NOFO (HRSA-21-052) in the preparation of your application. All applications for this competition will be reviewed and scored based on the instructions and evaluation criteria outlined in the current NOFO (HRSA-21-052).

What types of institutions can apply?

Eligible applicants include any domestic public or private entity, including research centers or networks. Domestic faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

This is a domestic research grant program and open only to U.S. entities that meet the eligibility criteria as outlined in the NOFO. Foreign entities are not eligible to apply.

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

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

How do I know whether to apply to the Autism SDAR grant?

The purpose of the 1-year grant is to support the analysis of large, pre-existing national data sets on questions relevant to the field of autism spectrum disorder and developmental disabilities (e.g., National Survey of Children's Health (HRSA), National Database for Autism Research (NIH), Medicaid (Centers for Medicaid and Medicare Services), National Health Interview Survey (Centers for Disease Control and Prevention) and Mental Health Research Network Database (NIH)). Alternatively, it

might consist of state or local administrative records, which would typically represent universal participation within a program among a particular population (e.g., Medicaid records for the population of children within a state who receive Medicaid.). A proposal to the Autism SDAR Program would typically identify such a large, pre-existing dataset, and then identify particular research questions that can be answered through analyzing the data, such as, "What factors will predict which outcomes among X population?"

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

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

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

You are responsible for identifying the particular data set(s) that will be used in the proposal. HRSA does not make data available to applicants for the SDAR Program. You are also responsible for ensuring that you have or will have access to the national database and/or administrative records that you will use for your grant applications.

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

According to the 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 SF-424 R&R also contains information on how to negotiate the indirect cost rate.

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

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.

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

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

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

The Autism SDAR Program supports research projects that exclusively utilize the analysis of existing national databases and/or administrative records. You should highlight in your proposal how the dataset of choice will yield information that is relevant to ASD populations, since this is part of the criterion on Public Health Impact that the external review committee will be assessing all proposals on. You should also include written confirmation that the proposed dataset for the Autism 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 datasets they have used.

Does the Autism SDAR program allow the use of administrative records?

Yes, administrative records can be used for this grant. The Autism 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 ASD/DD, since this is part of the criterion on Public Health Impact that the external review committee will be assessing all proposals on.

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

You should provide written confirmation that the proposed dataset for the Autism 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.

The external review committee will be taking the suitability of the database into account when assessing proposals. You should also include written confirmation that the proposed dataset for the Autism SDAR project are available to the investigator, including information such as name of dataset, year of dataset, and date of data availability, and correspondence from the organization overseeing the dataset. See ***Criterion 4 (Impact)*** *in the NOFO for further information about how your application will be assessed for public health impact. Please visit our website to read about previously awarded Autism SDAR projects and the datasets they have used. It is not the*

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

Does the HRSA-21-052 competition allow for multiple Principal Investigators (PIs), also known as project directors (PDs)?

Yes, multiple applications from an organization are allowable. In order to diversify our research grant portfolio, an individual cannot serve as the project director (PD) or Principal Investigator (PI) on more than one active HRSA/MCHB-funded grant. In order to diversify the Autism SDAR, a PD/PI on an active MCHB-funded research grant is expected to have no more than 10 percent time as a Co-Investigator on an existing HRSA/MCHB research grant. HRSA allows one PD/PI to be named on the face page of the SF-424 R&R application, who will serve as the key point of contact. The application can include Co-Investigators as key personnel on the project. If selected for funding, the new awardee will need to verify that percent time across all federally-funded grants does not exceed 100 percent.

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 Autism SDAR Program?

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

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

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

- *The capabilities of the applicant organization, and quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed research project; and*

- *The extent to which time allocated by key personnel is realistic and appropriate to achieve project objectives.*

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

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

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

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

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

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

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

Which format should we follow for the biographical sketch?

It is encouraged that you use the MCHB biographical sketch form found here: https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-for-Research-Grant-Applicants-Jan2020-2023.docx. NOTE: The biographical sketch may not exceed five pages per person. Follow the formats and instructions below. This OMB form does count against your page limit and can be attached to RESEARCH & RELATED Senior/Key Person Profile (OMB Number 4040-0001) found in the application package on grants.gov.

Are there page limits for the submitted application?

Yes, the Autism SDAR Program NOFO specifies strict page limitations for the overall submission and for specific sections of the application. You are required to comply with these page limitations, or the application will not be considered for funding. The total size of all uploaded files included in the page limit may not exceed 60 pages when printed by HRSA. The page limit includes a 20-page limitation for the narrative section,

and 6-page limitation for the Methodology/Research Strategy section; which includes Significance, Innovation, and Approach. All sections combined contribute to the 60-page total limit, including the abstract, project and budget narratives, attachments including biographical sketches (biosketches), and letters of commitment and support required in HRSA's SF-424 R&R Application Guide and this NOFO.

What counts towards the page limits?

- *The page limit applies to the:*
  - *Abstract*
  - *Project and budget narratives*
  - *Attachments*
  - *Letters of commitment and support required in application guide and the NOFO*
  - *Biographical sketches,*

- *The page limit does not apply to the following:*
  - *Standard OMB-approved forms that are included in the application package*
  - *Indirect Cost Rate Agreement*
  - *Proof of Non-Profit Status*

- *Preliminary studies can be included in the Approach section of the Research Strategy, if applicable, and would be included in the six-page limit as described above.*
- *The application is limited to 60 pages total, excluding the SF 424 R&R form pages. It is important that you consult the NOFO you are responding to for any changes to these guidelines.*
- *If an application exceeds required page limitations, it will not be considered for funding.*

Does the Specific Aims section have a page limitation?

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

Where do I include the staffing plan?

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

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

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

When will you announce your other research NOFOs?

Please join our listserv at http://mchb.hrsa.gov/research to receive an alert whenever our NOFOs are released.

Whom should I talk to if I have further questions?

Please contact:

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

Can I ask the Program Officer listed in the NOFO to read my proposal for their comments and suggestions?

Please do not send the Program Officer your proposal for comments. All proposals are reviewed by an independent review committee comprised of experts from the field. You may wish to ask a colleague to review your proposal prior to submitting. Please contact the Program Officer and/or Grants Management Specialist for clarification on the NOFO instructions and OMB forms.