

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**



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

***R41: Autism Secondary Data Analysis Research Program***

**Funding Opportunity Number:** HRSA-19-090  
**Funding Opportunity Type(s):** Initial: New, Resubmission  
**Catalog of Federal Domestic Assistance (CFDA) Number:** 93.877

**NOTICE OF FUNDING OPPORTUNITY**

Fiscal Year 2019

**Application Due Date: January 22, 2019**

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

**Issuance Date: October 25, 2018**

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Authority: Public Health Service Act, § 399BB(f) (42 U.S.C. § 280i-1(f)), as amended

## EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for fiscal year (FY) 2019 R41: Autism Secondary Data Analysis Research (SDAR) Program. The purpose of this program is to improve the physical and behavioral health of children and adolescents with autism spectrum disorder (ASD) and other developmental disabilities (DD) by (1) reviewing and evaluating the effectiveness of ASD/DD interventions and (2) assessing disparities in access to ASD/DD screening, diagnosis and treatment through 1-year grants for secondary analyses of existing publicly available and accessible national datasets and/or administrative records.

Funding Opportunity Title:	R41: Autism Secondary Data Analysis Research Program
Funding Opportunity Number:	HRSA-19-090
Due Date for Applications:	January 22, 2019
Anticipated Total Annual Available FY 2019 Funding:	\$400,000
Estimated Number and Type of Award(s):	Up to four grants
Estimated Award Amount:	Up to \$100,000
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2019 through August 31, 2020 (1 year)
Eligible Applicants:	<p>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.</p> <p>See <a href="#">Section III-1</a> of this notice of funding opportunity (NOFO) for complete eligibility information.</p>

### **Application Guide**

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

## **Technical Assistance**

HRSA has scheduled the following technical assistance:

### *Webinar*

Day and Date: Monday, November 5, 2018

Time: 2:00 pm – 3:30 pm ET

Call-In Number: 1- 888-566-5772

Participant Code: 4176887

Weblink: [https://hrsa.connectsolutions.com/r41\\_autism\\_nofo\\_ta](https://hrsa.connectsolutions.com/r41_autism_nofo_ta)

Playback Number: 1- 888-562-7630

Passcode: 2259

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# I. Program Funding Opportunity Description

## 1. Purpose

This notice announces the opportunity to apply for funding under the R41 Autism Secondary Data Analysis Research (SDAR) Program, previously referred to as the R40 Autism Secondary Data Analysis Studies (SDAS) Program. The Autism SDAR Program supports secondary data analysis of existing publicly available and accessible national databases and/or administrative records<sup>1</sup> to advance best practices and determine the evidence-based practices for interventions that improve the physical and behavioral health of children and adolescents with autism spectrum disorder (ASD) and other developmental disabilities (DD), referred to as ASD/DD.

The 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 determine pathways and the feasibility of interventions using existing data sets. This is more efficient and cost-effective than conducting primary data collection, which is both costly and time-consuming.

Findings from the research supported by the program are expected to:

- Generate new evidence to address the needs of underserved populations<sup>2</sup> for whom there is limited evidence of the effectiveness of interventions, and limited access to screening, diagnosis, and treatment for ASD/DD;
- Contribute to the broad public health impact to improve patient engagement and care delivery through studies that are generalizable and replicable for the targeted ASD/DD populations through dissemination activities. These may include development and publication of several peer-reviewed manuscripts as well as conference presentations, newsletter articles, webcasts, fact sheets, infographics, policy briefs, websites, and social media posts, as appropriate, clearly indicating the number of peer-reviewed and other publications that will be produced from the proposed project; and
- Address the following U.S. Department of Health and Human Services' (HHS) and Health Resources and Services Administration (HRSA) priority areas as they relate to ASD/DD populations and align with the research and surveillance activities identified in the Autism Cares Act of 2014:<sup>3</sup>
  - Combatting the opioid crisis,
  - Bringing down the high cost of prescription drugs,
  - Addressing the cost and availability of health insurance,
  - Implementing value-based care delivery and quality improvement initiatives,

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<sup>1</sup> In this NOFO, the terms publicly available and accessible are used to refer national datasets and/or administrative records that any researcher can access before or within the project period.

<sup>2</sup> Underserved populations include low-income, racial/ethnic minorities, immigrant, female, the geographically remote and other groups that are not already well represented in current research on children and adolescents with ASD/DD.

<sup>3</sup> <https://www.hrsa.gov/opioids>

- Targeting the health workforce need,
- Enhancing access to mental health services, and
- Reducing childhood obesity and maternal mortality.

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

- Conduct applied or translational research on critical and emerging ASD/DD issues through appropriate secondary data analyses of existing national databases and/or administrative records, that are aligned with research goals;
- Write and publish several peer-reviewed research articles about your project. Articles could include findings on research planning, participant recruitment, methods, implementation and/or research challenges, preliminary or unexpected research findings, in addition to final research findings. It is expected that the project will produce and publish several peer-reviewed publications, but no less than two. Please clearly indicate the number of peer-reviewed publications proposed;
- Distribute research findings and products to scientific, professional, and lay audiences, including HRSA and other HHS agencies; and
- Report target population study sample with regards to diversity (i.e., ethnicity, race, gender/sex, geographic location, and socioeconomic status).

Innovative secondary use of existing data from national datasets, administrative records and other publicly available datasets from a variety of sources (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)) is encouraged. Innovative methods such as meta-analysis are also encouraged.

## **2. Background**

This program is authorized by the Public Health Service Act, § 399BB(f) (42 U.S.C. § 280i-1(f)), as amended.

ASD is a developmental disorder that can cause significant physical and behavioral health challenges (e.g., unhealthy weight, difficulty communicating, etc.). The CDC estimates that 1 in every 59 children in the United States meets ASD diagnostic criteria<sup>4</sup>. In response to this public health need, the Autism CARES Act of 2014 reauthorized research, surveillance, and education activities related to ASD/DD. Specifically, the Autism SDAR Program addresses the critical need that exists for research on the barriers to screening, diagnosis, and receipt of evidence-based interventions for underserved populations of children and adolescents with ASD/DD.

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<sup>4</sup> U.S. Centers for Disease Control and Prevention, Autism Spectrum Disorder (ASD), Data & Statistics Prevalence. <https://www.cdc.gov/ncbddd/autism/data.html>.

The Autism SDAR Program is the only federal program supporting 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 establish potential pathways for effective ASD/DD interventions.

The Maternal and Child Health (MCH) Research Program in HRSA/Maternal and Child Health Bureau's Office of Epidemiology and Research, administers the Autism SDAR Program. The MCH Research Program has supported groundbreaking studies that have significantly 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. The 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>.

### **Autism CARES Act of 2014**

In carrying out the provisions of the Autism CARES Act, HRSA supports programs to improve the quality of care among those diagnosed with ASD/DD through education, early detection, and intervention. Specifically, these activities 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 to provide research-informed interventions through an interdisciplinary approach that will also focus on specific issues for children who are not receiving an early diagnosis and subsequent interventions.

The four program areas supported by HRSA include (1) Training for Professionals, (2) Autism Research Programs (3) Autism Policy Programs and (4) National Evaluation. For additional details, please see <https://mchb.hrsa.gov/maternal-child-health-initiatives/autism>.

## II. Award Information

### 1. Type of Application and Award

Type(s) of applications sought: New, Resubmission<sup>5</sup>

HRSA will provide funding in the form of a grant.

### 2. Summary of Funding

HRSA expects approximately \$400,000 to be available to fund four recipients for 1 year. You may apply for a ceiling amount of up to \$100,000 total cost (includes both direct and indirect, facilities and administrative costs). The period of performance is September 1, 2019 through August 31, 2020 (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.

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<sup>5</sup> A resubmission is a subsequent application from the same investigator for a revised proposal following an earlier unsuccessful application and review.



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)<sup>6</sup> on more than one application for the HRSA-19-090 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 to analyze publicly available and accessible longitudinal data<sup>7</sup> are allowed;
- Analysis of secondary data previously collected by the applicant PD/PI will not be considered for funding;
- Applications cannot propose to analyze linked datasets where one of the datasets proposed for analysis is not publicly available and accessible as all proposed datasets must be publicly available and accessible;
- Applications must propose the use of existing publicly available and accessible 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 the use of existing databases and administrative data.

## IV. Application and Submission Information

### 1. Address to Request Application Package

HRSA **requires** you to apply electronically. HRSA encourages you to apply through [Grants.gov](https://www.grants.gov) using the SF-424 Research and Related (R&R) workspace application package associated with this NOFO following the directions provided at <https://www.grants.gov/applicants/apply-for-grants.html>. If you're reading this notice of funding opportunity (NOFO) (also known as "Instructions" on Grants.gov) and reviewing or preparing the workspace application package, you will automatically be notified in the

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<sup>6</sup>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.

<sup>7</sup>In this NOFO, the term dataset refers to both national datasets and administrative data.

event HRSA changes and/or republishes the NOFO on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are ultimately responsible for reviewing the [For Applicants](#) page for all information relevant to desired opportunities.*

## **2. Content and Form of Application Submission**

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

See Section 8.5 of the [SF-424 R&R Application Guide](#) for the Application Completeness Checklist.

### **Application Page Limit**

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

Please note that the Methodology/Research Strategy of the application narrative is **STRICTLY LIMITED TO 6 PAGES as part of the 80-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 to be considered under this notice.**

### **Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification**

- 1) The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).

- 3) Where the prospective recipient is unable to attest to the statements in this certification, an explanation shall be included in an 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**

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. INTRODUCTION – (for resubmission only)**

**Note: For resubmissions, mark the application as “Resubmission” for item #8 “Type of Application” on the first page of the SF-424 R&R.**

For a resubmission of a previously reviewed proposal, begin the Introduction by specifying that it is a resubmission; state the application/tracking number of the prior submission, its title, and HRSA notice number of the prior submission. **Example: This is a resubmission of application #, ‘Determinants of Racial Disparities in Access to Screening Services for Autism,’ that was submitted for HRSA-15-032.** There is no limitation to the amount of time lapsed from initial submission of an application to resubmission.

The following requirements pertain to a resubmission:

- Resubmitted applications will not be reviewed by the prior reviewers/review panel;
- The PD/PI must make significant changes to the application;
- This section must summarize the substantial additions, deletions, and changes to the application. It must also include a response to the issues and criticism raised in the Summary Statement of the previous application.
- The Introduction **should not exceed three pages in length**; and

The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or changing the typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the

changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. The Preliminary Studies/Progress Report section should incorporate work completed since the prior version of the application was submitted. Resubmissions must address all of the current NOFO requirements.

## ***B. SPECIFIC AIMS – CORRESPONDS TO SECTION V’S REVIEW CRITERIA #1 NEED AND #2 RESPONSE***

### ***1) Needs Assessment -- Corresponds to Section V’s Review Criterion #1 Need***

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

- Briefly describe the target population(s) (including age ranges and other demographic information) and its unmet health needs
- As appropriate, include sociocultural determinants of health and health inequalities impacting the population that the current project will address.

### ***2) Significance -- Corresponds to Section V’s Review Criterion #2 Response***

- Describe the background literature, with focus on its pertinence to and rationale for the current research problem.
- Explain the critical problem or barrier to progress in the field that the proposed project addresses.
- Indicate the relevance of the problem to children and adolescents with ASD/DD and their families; and identify the envisioned application of findings to practice 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, identify new research questions, test hypotheses, determine pathways and feasibility of interventions, challenge an existing paradigm or clinical practice, or address a critical barrier to progress in the field.
- Clearly and concisely, summarize the expected outcome(s) and how these will address the unmet needs of the targeted population.

#### **Hypotheses and Specification of Variables**

- Clearly and logically, present the specific questions that the study will answer and link to your program need. These should include not only predictions as to findings (hypotheses) but also justifications for the predictions. Ensure scientific approach is thoughtful and logical.
- Present a summary table of the variables, classified as independent, intervening, mediating, moderating, and dependent, etc. specifying the nature of the variables, 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 congruence among the associations depicted by the graphic analytic model (if included), the table of variables, the statement of hypotheses, and the plan for data analysis.

***C. METHODOLOGY/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 in the Methodology/Research Strategy section and provide the full reference in the Bibliography and References Cited section.

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

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

- Peer-reviewed publications: It is expected your project will produce several peer-reviewed publications. Clearly indicate the number and focus area of your proposed peer-reviewed publications.
- 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:
  - The data collection procedures used for the database(s) or administrative record(s) and instrumentation as appropriate;
  - The study sample. Include demographic information on the participant population (i.e., ages, racial/ethnic background and socioeconomic status, geographic location, etc.);
  - 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);
  - Methods to collect, analyze, and interpret the data, as well as any resource sharing plans as appropriate; and

- 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.

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

*2) Scientific Innovation -- 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 the concepts, methods, technologies, treatments, services, policies, or preventive interventions that drive this field will be changed if the proposed aims are achieved through this secondary data analysis project.

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

**Public Health Impact**

- Describe the 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.
- Describe the extent to which study results will be generalizable and replicable.
- Describe how the proposed study specifically addresses issues with expected broad public health impact.

## **Publication and Dissemination Plan**

- Your “publication action plan” should include information on:
  - How you will publish several peer-reviewed articles describing outcomes, results, and challenges of your research project.
  - How you will advance the transfer of findings into practice by disseminating findings, reports, and/or project outputs to key target audiences, including scientific, professional, and lay audiences. Recipients will have implemented their plan to advance the transfer of findings into practice by the end of the period of performance, including dissemination to HRSA and other HHS agencies. In terms of communication channels, recipients may distribute research findings and information on project activities and findings through targeted email messages, newsletter articles, conference presentations, webcasts, fact sheets, infographics, policy briefs, and website and social media posts, as appropriate.

## ***E. RESOURCES AND CAPABILITIES -- CORRESPONDS TO SECTION V'S REVIEW CRITERION #5 RESOURCES/CAPABILITIES***

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

### **Organizational Facilities and Other Resources**

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

## **Qualifications of Research Team's Key Personnel**

- The qualifications of the research team's key personnel are assessed as part of Section V's Review Criterion #5 Resources/Capabilities. To assess the qualifications of the research team's key personnel, the following items are used: (a) Preliminary Studies in Section C. Methodology/Research Strategy 2) Work Plan/Approach; (b) Staffing Plan in Budget Narrative; and (c) Biographical Sketches of key personnel.
- Biographical sketches should follow the format described below. When applicable, biographical sketches should include training, language fluency and experience working with the culturally and linguistically diverse populations served by their programs.

**NOTE: The biographical sketch may not exceed five pages per person. Follow the formats and instructions below.**

**Professional Information:** At the top of page 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. 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 active duty military service.

### **B. Positions and Honors**

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

### **C. Contribution to Science**

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



#### **D. Research Support**

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

Do not confuse “Research Support” with “Other Support.” Although they sound similar, these parts of the application are very different. As part of the biosketch section of the application, “Research Support” highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual’s qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, “Other Support” information is required for all applications that are selected to receive 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.

#### **F. FEASIBILITY – CORRESPONDS TO SECTION V’S REVIEW CRITERION #7 PROGRAM ASSURANCES**

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

##### **Proposed Sequence or Timetable**

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

##### **Resolution of Challenges**

- Discuss any challenges that are likely to be encountered in designing and implementing the research activities described in the Work Plan/Approach, and approaches that will be used to resolve such challenges. Examples include staff training, putting culturally/linguistically competent project staff in place quickly, etc.
- Discuss alternative strategies should any of these potential challenges arise.
- Discuss the feasibility of obtaining the dataset or administrative record, including access to most-recent dataset or administrative record(s) if multiple years exist.
- Describe any strategy to establish the feasibility of the proposed work, and to address the management of any high-risk aspects of the proposed work.
- If appropriate, point to any procedures, situations, or materials that may be hazardous to personnel, and precautions to be exercised.

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

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

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

##### **Protection of Human Subjects**

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

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

## 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.

### 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.

<u>Narrative Section</u>	<u>Review Criteria</u>	<u>Points</u>
A. Introduction (for resubmission only)	Not Applicable--For Resubmissions Only	N/A
B. Specific Aims: 1) Needs Assessment	(1) Need	10
B. Specific Aims: 2) Significance	(2) Response	20
B. Specific Aims: 3) Goals and Hypotheses	(2) Response	
C. Methodology/Research Strategy: 1) Work Plan/Approach	(3) Evaluative Measures	20

C. Methodology/Research Strategy: 2) Scientific Innovation	(4) Impact	20
D. Impact and Dissemination	(4) Impact	
E. Resources and Capabilities	(5) Resources/Capabilities	10
Budget and Budget Justification (below)	(6) Support Requested	10
F. Feasibility	(7) Program Assurances	10
G. Evaluation and Technical Support Capacity	(7) Program Assurances	
H. Protection of Human Subjects, Data Availability and Diversity of Database Sample	(7) Program Assurances	
<b>Total Points</b>		<b>100</b>

### iii. **Budget**

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

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

The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (P.L. 115-245), Division B, § 202 states "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." 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 FY, as required by law.

### iv. **Budget Justification Narrative**

See Section 4.1.v of HRSA's [SF-424 R&R Application Guide](#).

In addition, the 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.) Copies of biographical sketches for all senior/key personnel and other significant contributors must also be submitted as an attached file to each SF-424 R&R Senior/Key Person Profile.

**v. Program-Specific Forms**

Program-specific forms are not required for application.

**vi. Attachments**

Provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements (if applicable) will not count toward the page limit. You must 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 80-page limitation, a list of citations only may be included.

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

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

*Attachment 4: 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*

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

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

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

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

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

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

For further details, see Section 3.1 of HRSA's [\*SF-424 R&R Application Guide\*](#).

**UPDATED [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. Read the [updated FAQs](#) to learn more.

[SAM.gov](#) is experiencing high volume and delays. If you have tried to create or update your SAM.gov registration but have not been able to complete the process, you may not be able to apply for a HRSA funding opportunity via Grants.gov in a timely manner prior to the application deadline. If so, please email [DGPwaivers@hrsa.gov](mailto:DGPwaivers@hrsa.gov), per the instructions in Section 3.6 of your HRSA Application Guide.

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

## 4. Submission Dates and Times

### Application Due Date

The due date for applications under this NOFO is *January 22, 2019 at 11:59 p.m. Eastern Time*. HRSA suggests submitting applications to Grants.gov at least **3 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, the total cost (inclusive of direct **and** indirect costs).

The General Provisions in Division B of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (P.L. 115-245) 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 the following FY, as required by law.

You cannot use funds under this notice for the following purposes:

Funds under this notice (HRSA-19-090) may not be used for travel outside of the U.S.

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

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative(s) applied to the award(s) under the program will be addition. 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 of applications 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. See the review criteria outlined below with specific detail and scoring points.

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

Review criteria are used to review and rank applications. The Autism SDAR Program has seven review criteria:

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

TOTAL: 100 points

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

- The extent to which the target population characteristics (i.e., including age ranges of children/youth) are clearly stated;
- The extent to which the proposed project clearly describes the unmet health needs of the targeted population and, if appropriate, the sociocultural determinants of health and health disparities impacting the targeted population;
- The extent to which the relevance to children and adolescents with ASD/DD and their families and rationale for the research problem are clearly described;
- The extent the proposed application of findings to practice and/or the ways that services are organized and delivered are described and are applicable to the ASD/DD population; and
- The extent to which the sociocultural determinants of health and health inequalities impact the population are described.



**Criterion 2: RESPONSE (20 points) -- Corresponds to Program Narrative Sections B. Specific Aims: 2) Significance and 3) Goals and Hypotheses**

**Background Literature and Statement of Problem**

- The extent to which the investigators demonstrate awareness of previous and current work in the area of the project.
- The extent to which the cited literature is pertinent to the research problem and provides a rationale for the research.
- The extent to which the hypotheses are logically derived from the literature, clearly stated, and are related to the defined problem.

**Relevance**

- The extent to which the project addresses a critical problem or barrier to progress the field of ASD/DD.
- The extent to which the proposed project describes a significant issue relevant to the health of children and adolescents with ASD/DD.

**Goals and Objectives**

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

**Hypotheses and Specification of Variables**

- The extent to which the proposal clearly and succinctly presents the specific questions the study will answer, including hypotheses and justifications for the hypotheses.
- The extent to which the application clearly defines variables.
- The extent to which the logic of the study is clearly stated and linked to need.
- The extent to which there is congruence among the associations depicted by a graphic analytic model (if included), the table of variables, the statement of hypotheses, and the plan for data analysis.

**Criterion 3: EVALUATIVE MEASURES (20 points) -- Corresponds to Program Narrative Section C. Methodology/Research Strategy: 1) Work Plan/Approach**

***C. Methodology/Research Strategy: 1) Work Plan/Approach***

**Publications and Study Design (5 points)**

- The extent to which the applicant's plan for producing several peer-reviewed publications is reasonable and feasible within their budget and timeline.

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

#### **Data Collection (5 points)**

- The extent to which instruments were selected or developed and were adequate and appropriate for the data in the selected database.
- The extent to which adequate attention was given to reliability and validity of instruments (psychometric properties).
- The extent to which any self-reported data can provide convincing validity for intended measurements, e.g., self-reported blood pressure, parent-reported anthropometric data.
- The extent to which the data are available to the investigator and are appropriate for this study. **The application must contain written confirmation that the proposed data to be used in the analysis are available to the investigator.** (NOTE: This award program does not support analysis of data previously collected by the applicant PD/PI).

#### **Population Description and Sampling (5 points)**

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

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

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

***CRITERION 4: IMPACT (20 points) -- Corresponds to Program Narrative Sections C. Methodology/Research Strategy: 2) Scientific Innovation; and D. Impact and Dissemination***

- The extent to which the proposed project will advance scientific knowledge, technical capability, and/or clinical practice in one or more broad fields relevant to ASD/DD populations.
- The extent to which successful completion of the aims will change the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field.
- The extent to which the application challenges and seeks to shift current research or clinical practice paradigms by utilizing innovative theoretical concepts, approaches or methodologies, instrumentation, or interventions.
- The extent to which the proposed project generates new evidence to address the needs of underserved populations and contribute to the limited evidence of effective interventions.
- The degree to which the proposed project will have a sustained influence on the research field.

***D. Impact and Dissemination (10 points)*****Public Health Impact**

- The extent to which the expected outcomes are likely to have an impact on health care delivery.
- The extent to which the expected outcomes are likely to help improve the physical and behavioral health of children and adolescents with ASD/DD.
- The extent to which the problem addressed by the proposed research is unique to a community or region or is one of national proportion.
- The extent to which the findings will be generalizable and replicable.
- The extent to which the proposed study specifically addresses challenges with expected broad public health impact.

- The extent to which the number of children and families affected by the problem or who will benefit from the research is significant.

### **Publication and Dissemination Plan**

- The extent to which there is a feasible and appropriate publication and dissemination plan described.
- The degree to which the applicant has a sound plan for how they will meet the expectation to produce several publications for each for each Autism SDAR project.
- The degree to which the PD/PI and other key personnel demonstrate current and/or past success in publishing the findings of their research. In particular, if investigators are past award recipients, the degree to which they demonstrate publication success from their previous award(s).
- The extent to which the proposal clearly demonstrates a plan to advance the transfer of findings into practice by disseminating findings, reports, and/or award project outputs to key target audiences, including researchers, providers, State Title V and children with special health care needs programs and other program(s) serving ASD/DD populations, policymakers, families and the general public.

### ***CRITERION 5: RESOURCES/CAPABILITIES (10 points) -- Corresponds to Program Narrative Section E. Resources/Capabilities; C. Methodology/Research Strategy: Preliminary Studies, and Budget Justification Narrative: Staffing Plan***

#### ***E. Resources/Capabilities***

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

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

#### **Qualifications of Research Team (5 points)**

- The extent to which the Key/Senior Support Personnel Profiles and biographical sketches indicate that the PI, collaborators, staff, and other researchers are well qualified by training and/or expertise to conduct the research.
- If Early Stage Investigators or New Investigators, the appropriateness of their experience and training. If established, the degree to which they have

- demonstrated an ongoing record of accomplishments that have advanced their field(s).
- The extent to which the proposal describes relevant preliminary studies performed by key personnel, indicating the capacity to conduct the work as described.

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

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

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

***F. Feasibility (3 points)***

**Proposed Sequence or Timetable**

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

**Resolution of Challenges**

- The extent to which the application anticipates and addresses potential barriers to project progress.
- The degree to which the applicant provides assurance that they can conduct and complete the research as proposed. (The expectation is that funded projects will demonstrate ongoing progress and completion as proposed and approved).
- The degree to which the applicant demonstrates the feasibility of accessing the database(s) or administrative record(s) including access to most recent database or administrative records if multiple years exist within the timeline provided.

***G. Evaluation and Technical Support Capacity (3 points)***

- The extent to which applicant meets performance metrics specified in the application according to the timeline provided.

## ***H. Protection of Human Subjects, Data Availability and Diversity of Database Sample (4 points)***

### **Protection of Human Subjects**

The extent to which:

- Adequate protections are afforded to human subjects, including children and youth, and the extent to which measures are in place to ensure the security of the research data (data security);
- The 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; and
- The applicant discusses plans to seek IRB approval. IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects.

### **Data Availability and Diversity of Database Sample**

The extent to which:

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

## **2. Review and Selection Process**

The independent review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. 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 below in award selection, (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 and Other Pre-Award Activities**

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

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.

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

#### **4. Anticipated Announcement and Award Dates**

HRSA anticipates issuing/announcing awards prior to the start date of September 1, 2009

## **VI. Award Administration Information**

### **1. Award Notices**

HRSA will issue the Notice of Award prior to the start date of September 1, 2019. See Section 5.4 of HRSA’s [SF-424 R&R Application Guide](#) for additional information.

### **2. Administrative and National Policy Requirements**

See Section 2.1 of HRSA’s [SF-424 R&R Application Guide](#).

#### **Requirements of Subawards**

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

#### **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.

The updated and final reporting package incorporating all OMB-accepted changes can be reviewed at:

<https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection> (OMB Number: 0915-0298 Expiration Date: 06/30/2019).

Award recipients must comply with Section 6 of HRSA's [SF-424 Application Guide](#) and the following reporting and review activities:

- 1) **Progress Report(s).** The recipient must submit a progress report to HRSA on an **annual** basis, which should address progress against program outcomes, including any expected outcomes in the first year of the program. Further information will be available in the award notice.
- 2) **Final Report Narrative.** The recipient must submit a final report narrative to HRSA after the conclusion of the project.
- 3) **Performance Reports.** HRSA has modified its reporting requirements for Special Projects of Regional and National Significance projects, Community Integrated Service Systems projects, and other grant/cooperative agreement programs to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). GPRA requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act.

#### a) Performance Measures and Program Data

To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are at [https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/R41\\_3.HTML](https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/R41_3.HTML) and



below.

Administrative Forms			
<ul style="list-style-type: none"> <li>Form 1, Project Budget Details</li> <li>Form 2, Project Funding Profile</li> <li>Form 4, Project Budget and Expenditures</li> <li>Form 6, Maternal &amp; Child Health Discretionary Grant</li> <li>Form 7, Discretionary Grant Project</li> <li>Form 8, (For Research Projects Only) MCH Discretionary Grant Project Abstract for FY</li> <li>Products, Publications, and Submissions Data Collection Form</li> </ul>			
Updated DGIS Performance Measures, Numbering by Domain (All Performance Measures are revised from the previous OMB package)			
Performance Measure	New/Revised Measure	Prior PM Number (if applicable)	Topic
<b>Core</b>			
Core 1	New	N/A	Grant Impact
<b>Capacity Building</b>			
CB 4	Revised	5	Sustainability
CB 5	Revised	3, 4	Scientific Publications
CB 6	New	N/A	Products

## b) Performance Reporting Timeline

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

Performance reporting is conducted for each year of the period of performance. Recipients will be required, within 120 days of the budget period start date, to enter HRSA's EHBs and complete the program-specific forms. This requirement includes providing expenditure data, finalizing the abstract and grant/cooperative agreement summary data as well as finalizing indicators/scores for the performance measures.

### **c) Period of Performance End Performance Reporting**

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

## **VII. Agency Contacts**

You may request additional information 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, Mailstop 10W10B  
Rockville, MD 20857  
Telephone: (301) 945-3935  
Fax: (301) 443-9320  
Email: [SGordon2@hrsa.gov](mailto: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  
Attn: R41 Autism SDAR Research Program  
Maternal and Child Health Bureau  
Health Resources and Services Administration  
5600 Fishers Lane, Room 18-118N  
Rockville, MD 20857  
Telephone: (301) 443-2259  
Email: [ssosa@hrsa.gov](mailto: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](mailto: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 HRSA's EHBs, contact the HRSA Contact Center, Monday-Friday, 8 a.m. to 8 p.m. ET, excluding federal holidays at:

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

## **VIII. Other Information**

### **Logic Models**

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: Monday, November 5, 2018  
Time: 2:00 pm – 3:30 pm ET  
Call-In Number: 1- 888-566-5772  
Participant Code: 4176887  
Weblink: [https://hrsa.connectsolutions.com/r41\\_autism\\_nofa\\_ta](https://hrsa.connectsolutions.com/r41_autism_nofa_ta)  
Playback Number: 1- 888-562-7630  
Passcode: 2259

### **Tips for Writing a Strong Application**

See Section 4.7 of HRSA's [SF-424 R&R Application Guide](#).

## **Relevant Websites**

### **Bright Futures**

<http://brightfutures.aap.org/>

### **Healthy People 2020 / Developing Healthy People 2030**

<http://www.healthypeople.gov/2020/>

### **Human Subjects Assurances**

<http://www.hhs.gov/ohrp>

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

### **Inclusion of Children - Policy Implementation**

<http://grants.nih.gov/grants/funding/children/children.htm>

### **National Academy of Medicine**

<https://nam.edu/>

### **Making Websites Accessible: Section 508 of the Rehabilitation Act**

<http://www.section508.gov/>

### **MCH Training Website**

<http://www.mchb.hrsa.gov/training>

### **National Center for Cultural Competence**

<http://nccc.georgetown.edu/>

### **National Center for Medical Home Implementation**

<http://www.medicalhomeinfo.org/>

### **Logic Models**

[https://www.cdc.gov/eval/tools/logic\\_models/index.html](https://www.cdc.gov/eval/tools/logic_models/index.html)

## **Tips for Writing a Strong Application**

See Section 4.7 of HRSA's [\*SF-424 R&R Application Guide\*](#).

## **Appendix A: Key Terms for Project Abstracts**

### **(a) Content Terms (maximum of 10):**

#### ***Health Care Systems & Delivery***

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

#### ***Primary Care & Medical Home***

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

#### ***Insurance & Health Care Costs***

- Cost Effectiveness
- Health Care Costs
- Insurance Coverage

#### ***Prenatal/Perinatal Health & Pregnancy Outcomes***

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

***Nutrition & Obesity***

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

***Parenting & Child Development***

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

***School Settings, Outcomes, & Services***

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

***Screening & Health Promotion***

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

***Illness, Injury, & Death***

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

***Mental/Behavioral Health & Well-being***

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

***Special Health Care Needs & Disabilities***

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

***Life Course & Social Determinants***

- Neighborhood
- Life Course
- Social Determinants of Health

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

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

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

- Women's Health & Well-being (Preconception/Interconception/Parental)
- Prenatal (until 28<sup>th</sup> week of gestation)
- Perinatal (28<sup>th</sup> 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 B: Frequently Asked Questions (FAQs) about the R41 Autism Secondary Data Analysis Research (SDAR) Program**

### **1. Where do I find application materials for the R41 Autism SDAR Program?**

*All application materials are available through Workspace on [Grants.gov](https://www.grants.gov).*

### **2. How can I download the complete application package for the HRSA-19-090 NOFO?**

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

*HRSA-19-090 on Grants.gov:*

- 1) Click on the hyperlink for HRSA-19-090*
- 2) Click on the last blue tab entitled "PACKAGE."*
- 3) Scroll down and click on the "Preview" hyperlink under the "Actions" column.*
- 4) Select the "Download Instructions" button in the right-hand corner. This will download the application.*

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

*[Grants.gov](https://www.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](https://www.grants.gov) website.*

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

*Yes, make sure that the Authorized Organization Representative at your university or institution has registered the university/organization and himself/herself in [Grants.gov](https://www.grants.gov). In order to submit your application (new or resubmission), your university and your Authorized Organization Representative MUST be registered in [Grants.gov](https://www.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](https://www.grants.gov).*

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

- 1) Make sure that the Authorized Organization Representative from your university/organization is registered in [Grants.gov](https://www.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](https://www.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](https://www.grants.gov) to access these resources.*

### **6. 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.*

**7. Can I get a copy of the NOFO from the 2015 competition?**

*The past funding announcement will not be distributed to avoid confusion among potential applicants.*

**8. 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*

**9. We are a foreign organization interested in applying for the R41 Autism SDAR Program. Are foreign entities eligible to apply?**

*The R41 Autism SDAR is a domestic grant program and open only to U.S. entities that meet the eligibility criteria as outlined in the NOFO.*

**10. How do I know whether to apply to the R41 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 R41 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?"*

**11. 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.*

**12. If I were to receive an R41 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.*

**13. 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.

**14. 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.

**15. 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.

**16. 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 R41 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.

**17. 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 R41 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 ASD/DD-related research question or specific ASD/DD population, then the best available public data set can be used. In all cases, the NOFO requires that findings will address a significant issue relevant to the health of children and adolescents with ASD/DD. Therefore, you would want to highlight how findings from your proposed project will address a critical problem or barrier to progress the field of ASD/DD. Funding decisions are based on scientific merit as determined by the external review committee and the availability of funds.

**18. 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. Please review Criterion 4 in the NOFO for additional information.*

**19. 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 R41 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.*

**20. Does the HRSA-19-090 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 R41 Competition, a PD/PI on an active MCHB-funded research grant is allowed up to 10 percent effort as a Co-Investigator on an existing HRSA/MCHB research grant. HRSA allows one PD/PI to be named on the face page of the SF-424 R&R application, who will serve as the key point of contact. The application can include Co-Investigators as key personnel on the project. If selected for funding, the new recipient will need to verify that percent effort across all federally funded grants does not exceed 100 percent.*

**21. 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.*

**22. Is it possible for postdoctoral fellows to apply as PI for the R41 Autism SDAR Program if they are affiliated with a university?**

*Postdoctoral fellows are allowed to serve as PD/PI on the R41 Autism SDAR grant. Ultimately, the determination of who may or may not serve as PD/PI depends on the rules of the institution.*

**23. Can someone who is currently a PI on a grant funded by another agency be a PI on an R41 grant?**

*Yes, a PI on another (non-HRSA/MCHB) agency's grant can be a PI on an R41 Autism SDAR grant; however, if selected for funding, the new recipient will need to verify that percent effort across all federally funded grants does not exceed 100 percent.*

**24. 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 R41 program, as long as all other application responsiveness criteria are met.*

**25. Which format should we follow for the biographical sketch?**

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

**26. Are there page limits for the submitted application?**

*Yes, the R41 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.*

**27. What counts towards the page limits?**

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

**28. Are there any page limitations to the narrative?**

- *The current R41 Autism SDAR Program NOFO requires a six-page limit for the research strategy section of the narrative.*
- *The research strategy includes Significance, Innovation, and Approach.*
- *Preliminary studies can be included in the Approach section of the Research Strategy, if applicable, and would be included in the six-page limit as described above.*
- *The other parts of the program narrative, which includes Sections A to B and D to G, do not have page limits. However, the entire application is limited to 80 pages total, excluding the SF 424 R&R form pages. It is important that you consult the NOFO you are responding to for any changes to these guidelines.*
- *If an application exceeds required page limitations, it will not be considered for funding.*

**29. 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.*

**30. 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.*

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

*Please bear in mind that submitting an application as a resubmission does not give the application any advantage over other applications in the review process. All review points and review criteria are listed in the NOFO. Ultimately, you should decide whether to mark the application as a resubmission. There is no cap on the number of resubmissions. Please refer to NOFO guidance in the Project Narrative section A. Introduction*

**32. 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.*

**33. 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.*

## Appendix C: Grant Application Completeness Checklist

Funding Opportunity Number: \_\_\_\_\_

Application Due Date in Grants.gov: \_\_\_\_\_

Requirement	Yes	No	Comments
Are you applying to the <b>correct funding opportunity</b> ?			
Does this application propose a <b>secondary data analysis</b> project?			<i>If no, you are applying to the wrong application.</i>
Do you meet the <b>eligibility criteria</b> ?			
Did you read the <b>R&amp;R Application Guide</b> ?			HRSA's SF-424 R&R Application Guide: <a href="https://www.hrsa.gov/grants/apply/application_guide/sf424rrguidev2.pdf">https://www.hrsa.gov/grants/apply/application_guide/sf424rrguidev2.pdf</a>
Do you have a <b>DUNS number</b> ?			Dun and Bradstreet number: <a href="http://www.dnb.com/duns-number.html">http://www.dnb.com/duns-number.html</a>
Did your Authorized Organization Representative register in <b>SAM and Grants.gov</b> ?			<ul style="list-style-type: none"> <li>This process can take up to 1 month to complete.</li> <li>System for Award Management (SAM:) <a href="https://www.sam.gov/">https://www.sam.gov/</a></li> <li>Grants.gov: <a href="http://www.grants.gov/">http://www.grants.gov/</a></li> </ul>
In the <b>NEED Section</b> , did you fully address how the proposal will address an unmet need?			
In the <b>RESPONSE Section</b> , did you fully address: <ul style="list-style-type: none"> <li>Goals and Hypotheses?</li> <li>Significance of Methodology/Research Strategy?</li> </ul>			
In the <b>EVALUATIVE MEASURES Section</b> , did you fully address your Work Plan Approach?			
In the <b>IMPACT Section</b> , did you fully address: <ul style="list-style-type: none"> <li>Scientific Innovation and Importance?</li> <li>Impact and Dissemination?</li> </ul>			
In the <b>RESOURCES CAPABILITIES Section</b> , did you fully address Organizational Information/ Environment?			
<p>In the <b>SUPPORT REQUESTED Section</b>, did you accurately complete the Budget and Budget Justification?</p> <p>Did you follow the budget instructions in the <b>NOFO and R&amp;R Application Guide</b>?</p> <p>Do you know your institution's <b>indirect cost rate</b>?</p>			<p>The directions offered in the <b>SF-424 R&amp;R Application Guide</b> differ from those offered by Grants.gov. Please follow the instructions included in the R&amp;R Application Guide and, if applicable, the additional budget instructions in the <b>NOFO</b>.</p> <p>Your institution's indirect cost rate is negotiated by the institution with the U.S.</p>

Requirement	Yes	No	Comments
			<i>Department of Health and Human Services (HHS). Check with your sponsored programs office for further information about the indirect cost rate.</i>
In the <b>PROGRAM ASSURANCES Section</b> , did you fully address: <ul style="list-style-type: none"> <li>• Feasibility?</li> <li>• Evaluation and Technical Support Capacity?</li> <li>• Protection of Human Subjects?</li> <li>• Targeted/Planned Enrollment?</li> </ul>			
Is your <b>Project Summary/Abstract</b> one page in length <b>and</b> single-spaced?			
Did you clearly label your <b>attachments</b> ?			
Are your <b>page borders</b> no more than 1 inch wide?			<i>Biosketches can have .5" margins.</i>
Did you include <b>Biosketches</b> ?			
Did you use 12-point <b>font</b> ?			
Are your <b>pages</b> , including attachments and biosketches, within the 80-page limit?			<i>Face page, Standard OMB-approved forms, Indirect Cost Rate Agreement, proof of non-profit status (if applicable), and budget pages <b><u>do not count</u></b> toward the 80-page limit.</i>
Is the <b>RESEARCH STRATEGY Section</b> within the six-page limit?			
Is the <b>budget</b> within the funded limit?			
Did you experience system glitches or a qualified emergency and need to request an <b>exemption/waiver</b> ?			<i>Submit exemption request in writing to: <a href="mailto:DGPWaivers@hrsa.gov">DGPWaivers@hrsa.gov</a></i>