U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Maternal and Child Health Bureau
Office of Epidemiology and Research

Autism Field-Initiated Innovative Research Studies Program (Autism-FIRST)

Funding Opportunity Number: HRSA-21-053
Funding Opportunity Type(s): New
Assistance Listings (CFDA) Number: 93.877

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

Application Due Date: April 15, 2021

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

Issuance Date: January 15, 2021

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), is accepting applications for the fiscal year (FY) 2021 Autism Field-Initiated Innovative Research Studies (Autism-FIRST) Program. The purpose of this program is to support empirical research that advances the evidence on early screening and interventions to improve the health of children, adolescents, and young adults with autism spectrum disorders and other developmental disabilities (ASD/DD) across the lifespan. Research should include a special focus on addressing the needs of underserved populations and, as appropriate, engage families. HRSA supports programs to improve the quality of care for those diagnosed with ASD/DD through education, early detection, and intervention, with the goal of optimizing development and promoting health and well-being for children, adolescents, and young adults with ASD/DD.

Funding Opportunity Title:	Autism Field-Initiated Innovative Research Studies (Autism-FIRST)
Funding Opportunity Number:	HRSA-21-053
Due Date for Applications:	April 15, 2021
Anticipated Total Annual Available FY 2021 Funding:	$600,000
Estimated Number and Type of Award(s):	Up to two (2) grants
Estimated Award Amount:	Up to $300,000 total cost per year subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2021 through August 31, 2024 (3 years)
Eligible Applicants:	Eligible applicants include any domestic public or private entity, including research centers or networks. Domestic faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply. See Section III-1 of this notice of funding opportunity (NOFO) for complete eligibility information.

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. A short video explaining the *Application Guide* is available at http://www.hrsa.gov/grants/apply/applicationguide/.

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Friday, January 22, 2021
Time: 2 – 3 p.m. ET
Call-In Number: 1-888-381-5770
Participant Code: 3734558
Weblink: https://hrsa.connectsolutions.com/autismfirstwebinar/

Instant replay:
Call-In Number: 866-430-4730
Passcode: 42321
Available until: April 23, 2021

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

HRSA will record the webinar and make it available at:
https://mchb.hrsa.gov/fundingopportunities/default.aspx

Table of Contents

I. Program Funding Opportunity Description

1. Purpose

The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB)'s Office of Epidemiology and Research is accepting applications for the fiscal year (FY) 2021 Autism Field-Initiated Innovative Research Studies (Autism-FIRST) Program. The purpose of this program is to support empirical research that advances the evidence base on interventions designed to improve the health of children, adolescents, and young adults with autism spectrum disorders and other developmental disabilities (ASD/DD) across the lifespan. Because racial and ethnic disparities exist in the early screening and diagnosis of ASD/DD, the Autism-FIRST Program has a special focus on addressing the needs of underserved populations, such as low-income, racial/ethnic minorities, individuals living in rural areas and, in the case of ASD/DD populations, girls and young women, who are often under identified with regard to ASD, particularly at the higher functioning end.[1] The Autism-FIRST program supports research studies that address critical issues surrounding the health and well-being of underserved children, adolescents, and young adults with ASD/DD up to the age of 26, and their families, recognizing that the first 25 years of life help lay the foundation for health and well-being across the lifespan.

A focus on underserved populations is consistent with HRSA's mission as an agency that promotes access to equitable and coordinated health and health care delivery services. A focus on children, adolescents, and young adults up to the age of 26 is consistent with the mission of the Maternal and Child Health Bureau (MCHB) and the populations it serves. The Autism-FIRST's program's goals and objectives are to:

- Generate new evidence to address the needs of underserved ASD/DD populations for whom there is limited evidence of the effectiveness of interventions, and limited access to screening, diagnosis, and treatment for ASD/DD;
- Contribute to the broad public health impact to improve health and service delivery services through studies that are generalizable and replicable for underserved ASD/DD populations; and
- Conduct and disseminate findings from applied and/or translational research on critical and emerging ASD/DD issues using a research design focused on collection of primary data among underserved populations, with a special focus on underserved populations and children, adolescents, and young adults up to the age of 26. Examples of autism intervention research topics of interest to HRSA's MCHB include, but are not limited to, developing and testing ways to:
    - Improve access to supports and services among underserved

[1] The Department of Health and Human Services (HHS) characterizes underserved, vulnerable, and special needs populations as communities that include members of minority populations or individuals who have experienced health disparities. For this funding opportunity, under-resourced/underserved populations include low-income, racial/ethnic minorities, immigrants, tribal, geographically remote, and other groups that are not already well-represented in current pediatric research. https://marketplace.cms.gov/technical-assistance-resources/training-materials/vulnerable-and-underserved-populations.pdf, accessed 11/23/2020

populations of children, adolescents, and young adults with ASD/DD and their families;

- Effectively tailor services, supports, and interventions to individual and family strengths, needs, and challenges, recognizing the heterogeneity with which ASD/DD manifests itself across children, adolescents, and young adults with ASD/DD and their families;
- Facilitate the transition into adulthood, including continuity in health care and other supports and services associated with optimal transitions and laying the foundation for improved health and well-being across the lifespan;
- Improve the coordination of care across different aspects of the medical home, and/or across multiple sectors (e.g., health, school) that affect the lives of children, adolescents, and young adults with ASD/DD and their families; and
- Identify services and supports that mediate or moderate relations between family stresses and outcomes for children, adolescents, and young adults with ASD/DD.

2. Background

This program is authorized by 42 U.S.C. § 280i-1(f) (Title III, § 399BB(f) of the Public Health Service Act, as amended by the Autism Collaboration, Accountability, Research, Education, and Support Act of 2019 (Autism CARES Act of 2019) (Pub. L. 116-60)). In carrying out these provisions, HRSA supports various programs to improve the quality of care for those who have, or are at risk for developing ASD/DD through education, early detection, and intervention. Specifically, these programs are designed to:

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

The Autism CARES Act of 2019 emphasizes improving health outcomes and the well-being of individuals with ASD/DD across the lifespan.

A comprehensive picture of ASD among children in the U.S is best understood by examining two key estimates of ASD prevalence[2]. The Centers for Disease Control and Prevention used population-based ASD prevalence estimates for U.S. children reported from the Autism Developmental Disabilities Monitoring Network (ADDM) – a surveillance system in local population-based areas in which ASD cases are identified through education and health records review – to report that approximately one in 54

[2] Kogan, et al. (2018) The Prevalence of Parent-Reported Autism Spectrum Disorder Among US Children. Pediatrics 142(6).

children have ASD.[3] Parent-reported data from the 2016 National Survey of Children's Health, a study published in 2018, documented that one in 40 children aged 3-17 years have a diagnosis of ASD.[4] Estimates from these two systems reflect different years, populations (local U.S. populations versus the entire U.S.), and ages of children (children aged 8 years in ADDM versus 3-17 years in NSCH) and contribute unique information that, when combined, help form a comprehensive picture of ASD among children in the U.S. ASD is a complex neurodevelopmental disorder, and individuals with this condition experience core behavioral challenges with social interactions, communication, as well as restrictive and repetitive behaviors, which can be lifelong and pervasive.[5] Additionally, 83 percent of children with ASD have at least one co-occurring non-ASD condition.[6] Children and adolescents with ASD also have greater health service needs, which can place a significant financial and emotional burden on their families.[7]

Access to adequate health care is a significant problem for children, adolescents, and young adults with special health care needs, and is even more pronounced for those with ASD/DD. Many gaps in research remain regarding effective interventions for their complex needs. Since racial and ethnic disparities exist in the early evaluation and diagnosis of ASD/DD, a particular focus on underserved populations is warranted.

The impact of racial and ethnic disparities in the early evaluation and diagnosis of ASD/DD may be compounded by other social determinants of health (SDOH) across the lifespan. SDOH are conditions in which people are born, grow, live, work, and age.[8] SDOH include factors like socioeconomic status, education, neighborhood and physical environment, community violence, employment, and social support networks, as well as access to health care. Addressing SDOH, which affect a wide range of health, functioning, and quality-of-life outcomes and risks, is in line with HRSA's objective to improve the health and well-being of individuals and the communities in which they reside.

In response to this need, the Autism CARES Act of 2019 reauthorized research, surveillance, and education activities related to ASD/DD. The MCHB Division of Research within the Office of Epidemiology and Research supports applied and translational research and research networks relating to MCH services, including services for children, adolescents, and young adults with ASD/DD. Research projects address critical MCH research questions focused on public health systems and infrastructure, health disparities, quality of care, and promoting the health and well-being of MCH populations -- issues which also support the goals of HRSA. Emphasis is placed on projects that show promise of substantial contribution to the advancement of the current knowledge pool, and improvements in health and health services when applied in states and communities.

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[3] Autism and Developmental Disabilities Monitoring Network (2016 data) (http://www.cdc.gov/ncbddd/autism/data.html)
[4] Kogan, et al. (2018) The Prevalence of Parent-Reported Autism Spectrum Disorder Among US Children. Pediatrics 142(6).
[5] American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders V*. Washington, DC: American Psychiatric Publishing; 2013.
[6] Levy SE, Giarelli E, Li-Ching L, Schieve LA, Kirby RS, Cuniff C, et al. Autism spectrum disorder and co-occurring developmental, psychiatric, and medical conditions among children in multiple populations of the United States. *Journal of Developmental and Behavioral Pediatrics*. 2010;31:267–275.
[7] Vohra, R, Madhavan, S, Sambamoorthi, U, St Peter, C. Access to services, quality of care, and family impact for children with autism, other developmental disabilities, and other mental health conditions. *Autism*, 2014; 18(7):815-26.
[8] Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. https://health.gov/healthypeople/objectives-and-data/social-determinants-health, accessed 11/23/20.

The Autism-FIRST Program supports research on interventions for individuals with ASD/DD. Advancing the health and well-being of underserved children, adolescents, and young adults with ASD/DD and their families requires the application of new knowledge, evidence, and data. There is an additional need to examine how the systems and services to support underserved children, adolescents, and young adults with ASD/DD may fall short with regard to equitable and coordinated access for families. The FY21 Autism-FIRST Program aligns with the Autism CARES Act of 2019 requesting applied and translational research that will develop and test new interventions and effective services in order to help improve the health and well-being of underserved children, adolescents, and young adults with ASD/DD across the lifespan. Funding associated with these awards is intended to support the conduct of empirical research that will result in the following:

- Advancement of the current knowledge base through the development and testing of new and innovative investigator-initiated services and interventions designed to improve health and well-being across the lifespan for underserved children, adolescents, and young adults with ASD/DD and their families, as evidenced by the publication of study findings in peer-reviewed journals; and
- Facilitation of research findings into practice through the dissemination of information, 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 programs serving the populations targeted by the proposed research study, as well as policymakers, families, and the general public.

Autism-FIRST projects have been awarded across a variety of topics related to improving services and care for children, adolescents, and young adults with ASD/DD and their families.

For more information about MCHB's autism programs, please see https://mchb.hrsa.gov/maternal-child-health-initiatives/autism. For more information about the MCH Research Program, visit our website: http://www.mchb.hrsa.gov/research.

A list of Frequently Asked Questions (FAQs) about applying to our programs can be found in Appendix E of this NOFO.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New

HRSA will provide funding in the form of a grant.

2. Summary of Funding

HRSA expects approximately $600,000 to be available annually to fund two (2) recipients. You may apply for a ceiling amount of up to $300,000 per year, which

includes both direct and indirect costs. The period of performance is September 1, 2021 through August 31, 2024 (3 years). Funding beyond the first year is subject to the availability of appropriated funds for the Autism FIRST program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

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 notice.

3. Other

HRSA will consider any application that exceeds the ceiling amount of $300,000 per year total costs to be 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 to be 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.

Please make sure you submit your application to the correct NOFO number: HRSA-21-053 Autism-FIRST program. Applications submitted to the wrong competition will be deemed nonresponsive.

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-FIRST 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) on more than one application to this competition.
- 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 that overlap in period of performance with a currently funded HRSA/MCHB Research project by the same PD/PI will not be considered for funding (i.e., a PD/PI cannot have two (2) HRSA/MCHB Research awards in effect simultaneously). A 1-year no-cost extension counts as part of the total period of performance during which an overlap in period of performance is not allowed.
- A recipient who currently has or in the past has had a HRSA/MCHB Research award cannot apply for a new award to follow longitudinally the population used in their previous HRSA/MCHB award. This limitation applies for a period of 3 years. The following are acceptable, however: Applications that include a longitudinal design within the proposed 3-year period of performance; and applications that involve collecting follow-up data on a population targeted in an award funded by another agency.
- All applications that request funding for this competition must involve the collection of primary data (i.e., original data that will be collected, compiled, and analyzed specifically for the proposed research project). Applications that focus on the analysis of secondary data (i.e., data that were previously collected by you or other investigators, institutions, or agencies) are not eligible for the multi-year HRSA-21-053 Autism-FIRST program, and will not be considered for funding.
- The applicant PD/PI is expected to spend a minimum of 10 percent effort on this project to ensure that sufficient time is allocated and devoted to conducting the proposed study.

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

IV. Application and Submission Information

1. Address to Request Application Package

HRSA ***requires*** you to apply electronically. HRSA encourages you to apply through Grants.gov using the SF-424 Research and Related (R&R) workspace application package associated with this NOFO following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.
The NOFO is also known as "Instructions" on Grants.gov. You must select "Subscribe" and provide your email address for each NOFO you are reviewing or preparing in the workspace application package in order to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. You are ultimately responsible for reviewing the For Applicants page for all information relevant to this NOFO.

2. Content and Form of Application Submission

Section 4 of HRSA's *SF-424 R&R Application Guide* provides instructions for the budget, budget justification, staffing plan and personnel requirements, assurances,

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

See Section 8.5 of the *SF-424 R&R Application Guide* for the Application Completeness Checklist (also Appendix C of this application).

Application Page Limit
The total size of all uploaded files included in the page limit 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.

Biographical sketches for any key employed personnel that will be assigned to work on the proposed project must be attached to RESEARCH & RELATED Senior/Key Person Profile (OMB Number 4040-0001) found in the application package on Grants.gov. Due to the HRSA 80-page limit, it is recommended that all biographical sketches are no more than five pages in length and must follow the HRSA font/margin requirements. For details on how to format the biographical sketch visit: https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-for-Research-Grant-Applicants-Jan2020-2023.docx.

Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. However, biographical sketch OMB forms do count in the page limitation. Please note: If you use an OMB-approved form that is not included in the workspace application package for HRSA-21-053 it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. It is therefore important to take appropriate measures to ensure your application does not exceed the specified page limit.

Please note that the Methodology/Research Strategy of the application narrative is STRICTLY LIMITED TO 12 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.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

1) You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
3) Where you are unable to attest to the statements in this certification, an explanation shall be included in *Attachment 8*: Other Relevant Documents.

See Section 4.1 viii of HRSA's *SF-424 R&R Application Guide* for additional information on this and other 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), please include the following:

i. Project Abstract

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

Include the information requested at the top of the abstract. Because the abstract is often distributed to provide information to the public and Congress, please prepare this to be clear, accurate, concise, and without referring to other parts of the application. Briefly state the principal needs and problem, goals, proposed activities including underserved target population(s), planned coordination, anticipated products, and plans for evaluation.

Abstract content: The following describes the different suggested section headers (capitalized) and content. The abstract should not exceed one page in length.

- FUNDING OPPORTUNITY NUMBER: HRSA-21-053
- FUNDING OPPORTUNITY TITLE: Autism-FIRST program
- PROBLEM: Briefly state the principal needs and problems that are addressed by the project.
- GOAL(S) AND OBJECTIVES: Include the major goal(s) and objectives for the period of performance listed in your proposal. Typically, the goal is stated in a sentence or paragraph, and the objectives are presented in a numbered list.
- PROPOSED ACTIVITIES AND TARGET POPULATION(S): Describe the programs and activities used to attain the objectives, the underserved population(s) addressed, and comment on innovations in the proposed plan.
- COORDINATION: Describe the coordination planned with, and participation of, any appropriate national, regional, state, and/or local health agencies, interdisciplinary professional groups and providers, and/or organizations that function as stakeholders or partners in the proposed project.

- PRODUCTS: Provide a brief description of the anticipated products of this research project, including modes of dissemination of project activities and findings.
- EVALUATION: Briefly describe the evaluation methods you will use to assess program outcomes as well as the effectiveness and efficiency of the project in attaining goals and objectives.
- KEY TERMS: From Appendix B select: (a) significant content terms that describe your project (maximum of 10 content terms), (b) targeted populations (select all that apply), and (c) age ranges (select all that apply), and include at the end of your abstract.

ii. Project Narrative

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

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

A. SPECIFIC AIMS -- Corresponds to Section V's Review Criteria 1 Need and 2 Response

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

1) Needs Assessment *(Corresponds to Section V's Review Criterion 1 Need)*

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

- Briefly describe the underserved population(s) (including age ranges of children/youth) and its unmet health needs that the proposed study targets.
- As appropriate, include sociocultural determinants of health and health disparities impacting the population that the proposed 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 proposed 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 the targeted population, 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)*

- Clearly and succinctly state the specific objectives of the particular research proposed, for example, to test a stated hypothesis, create a novel intervention, solve a specific problem, challenge an existing paradigm or

clinical practice, address a critical barrier to progress in the field, and/or develop new technology.

- Clearly and concisely summarize the expected outcome(s) and how these will address the unmet needs of the targeted population.
- Construct and present a logic model or graphical representation of the set of relationships held to be operative among the variables (see Attachment 3 and Appendix D for more detailed information on how to construct a logic model).
- Make sure that there is congruence among the associations depicted by the logic model or graphic model, the statement of hypotheses, and the plan for data analysis.

Do not use the Specific Aims section to circumvent the 12-page limit of the Methodology/ Research Strategy section.

B. METHODOLOGY/RESEARCH STRATEGY -- Corresponds to Section V's Review Criteria: 3 Evaluative Measures, and 4 Impact

Organize the Methodology/Research Strategy section in order of instructions provided below. Start each section with the appropriate section heading – Work Plan/Approach and Scientific Innovation and Importance. Cite relevant publications 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, Scientific Innovation and Importance) is limited to 12 pages in length. Applications that exceed this 12-page limit in the Methodology/ Research Strategy section will be deemed nonresponsive, and will not be considered for funding under this notice.

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

- Describe the overall study design, strategy, methodology, and analyses to be used to accomplish the specific aims of the proposed project.
- Describe the procedures for data collection and instrumentation as appropriate, including information/citations regarding the established validity of the instruments used if applicable.
- Describe the study population. Include demographic information on the participant population (i.e., targeted ages, expected racial/ethnic background and socioeconomic status, rural/urban, etc.).
- Describe eligibility inclusion/exclusion criteria.
- Address issues regarding sampling design and randomization as appropriate.
- Include expected targeted/planned enrollment number and power analyses as appropriate.
- Include a description of strategies for participant recruitment.
- Include how the data will be collected, analyzed, and interpreted as

well as any resource sharing plans as appropriate.

- Assure cultural competence in the planning and implementation of the proposed research project.

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

- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in the ASD/DD field.
- Describe the impact that the results of the proposed research will have 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, instrumentation, or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, policies, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, policies, or interventions.
- Describe how the concepts, methods, technologies, treatments, services, policies, or preventive interventions that drive the relevant field will be changed if the proposed aims are achieved.

PRELIMINARY STUDIES

Information regarding Preliminary Studies may be placed in Attachment 4. [Note that this attachment counts in the overall 80-page limit.]

BIBLIOGRAPHY AND REFERENCES CITED

The Bibliography/References cited may be placed between Section B, Methodology/Research Strategy, and Section C, Impact and Dissemination. **It does not count in the 12-page limit for Section B, but does count in the overall 80-page limit.**

C. IMPACT AND DISSEMINATION -- Corresponds to Section V's Review Criterion 4 Impact

1) Public Health Impact

- Describe the public health impact that study results are likely to have.
- Describe the impact that the expected outcomes are likely to have on care delivery strategies involved and/or the health and well-being of the target population(s) that the study sample is drawn from.
- Describe the extent to which study results will be generalizable and replicable.
- Describe the extent to which study results will be regional or national in significance.

2) Publication and Dissemination Plan

- Autism-FIRST awardees will produce at least three (3) peer-reviewed publications per study. Describe how the dissemination plan will

include at least three peer-reviewed publications.
- Reference relevant publications from any previous work.
- Describe 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 MCH and ASD/DD populations, policymakers, families and the general public. In terms of communication channels, awardees 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.

D. ORGANIZATIONAL INFORMATION/ENVIRONMENT -- Corresponds to Section V's Review Criterion 5 Resources/Capabilities

This information is used to assess the capability of the organizational resources available to perform the effort proposed. NOTE: The SF-424 R&R Table of Contents in HRSA's *SF-424 R&R Application Guide* 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.

- Identify the facilities to be used (laboratory, clinical setting, computer lab, office, and/or other). If appropriate, indicate capacities available to the proposed study. Describe only those resources that are directly applicable to the proposed work.
- Describe how the scientific environment in which the research will be done, and/or useful collaborative arrangements that enhance the scientific environment in which the project will be conducted, contribute to the probability of its success (e.g., institutional support, physical and other resources, and intellectual environment).
- For Early Stage Investigators (defined as up to 7 years following attainment of the field-relevant doctoral degree), describe institutional investment in the success of the investigator; examples of such investment would be: resources for professional development, travel, training; collegial support such as career enrichment programs and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; 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 Attachment 4; (b) Staffing Plan in Budget Narrative; and (c) Biographical Sketches of key personnel.

- Include biographical sketches for persons occupying key positions. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch. Please use the MCHB biographical sketch form found here: https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-for-Research-Grant-Applicants-Jan2020-2023.docx. Please note that even though the document has an OMB clearance number, it's not a standard form and your response **counts against the page limit**. The biographical sketch **may not exceed five pages per person**. This OMB form can be attached to RESEARCH & RELATED Senior/Key Person Profile (OMB Number 4040-0001) found in the application package on grants.gov.
- Do not confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very different. As part of the biographical sketch 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 funding awards. HRSA staff will request complete and up-to-date "other support" information from you after peer review. This information will be used to check that the proposed research has not already been federally-funded.

E. FEASIBILITY -- Corresponds to Section V's Review Criterion 7 Program Assurances

Proposed Sequence or Timetable

- Provide a sequence or timetable for the project that includes the activities or 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 recruitment of study sites and study participants, staff training and standardization of research protocols across multiple sites, putting culturally/linguistically competent project staff in place quickly, recruiting participants from specific populations, etc.

- Discuss alternative strategies should any of these potential challenges arise.
- Discuss the feasibility of reaching targeted/planned enrollment levels.
- Establish feasibility by describing any strategies that will be used to address the **management of any high-risk aspects of the proposed work.**

F.EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criterion 7 Program Assurances

- Describe a plan for performance evaluation (evaluating project progress towards 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 collection begun by month 6, etc.). The purpose is to monitor ongoing processes and the progress towards the aims and objectives of the project.

G.HUMAN SUBJECTS Protections -- Corresponds to Section V's Review Criterion 7 Program Assurances

- 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 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.
- This section is required for applicants answering "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 human specimens and/or data from subjects, you must provide a justification in this section for the claim that no human subjects are involved.
- Discuss plans to seek Institutional Review Board (IRB) approval. IRB approval is not required at the time of application submission, but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.

If appropriate, describe any procedures, situations, or materials that may be hazardous to personnel, and precautions to be exercised.

H. TARGETED/PLANNED ENROLLMENT -- Corresponds to Section V's Review Criterion 7

Program Assurances

Provide details about the targeted/planned enrollment for the proposed study. Information should include targeted/planned enrollment totals by:

- Ethnic Category (Hispanic Heritage): "Hispanic or Latino" or "Not Hispanic or Latino"
    - Gender distribution within each Ethnic Category (Hispanic Heritage)
    - Total planned enrollment by Ethnic Category (Hispanic Heritage)
- Racial Categories
    - American Indian/Alaska Native
    - Asian
    - Native Hawaiian or Other Pacific Islander
    - Black or African American
    - White
    - More than One Race
    - Gender distribution within each racial category
    - Total planned enrollment by racial category
- The "Ethnic Category (Hispanic Heritage): Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects". Also list any proposed racial/ethnic subpopulations, if applicable.
- The "Total Planned Enrollment" means the number of subjects that are expected to be enrolled during the entire period of the proposed study and are needed to evaluate the research question. The "Total Planned Enrollment" 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 project will assure cultural competence in terms of including individuals from the study population in the planning and implementation of the research project and in adapting the research methodology to reflect an understanding of, and valuing the culture of, the study population(s).

iii. Budget

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

The maximum number of budget periods allowed is three. A budget period represents 12 months of project effort.

In addition, the HRSA-21-053 Autism-FIRST program requires the following:

The budget should reflect the travel expenses associated with participating in the HRSA MCHB Autism CARES recipients' meeting, which is expected to be held in person in the Washington, D.C. metropolitan area in 2023. Sufficient funds must be set aside for the PI to attend this meeting. [Note: meeting may be virtual depending on COVID or other restrictions.]

NOTE: Travel outside of the United States is not supported.

The Consolidated Appropriations Act, 2021(P.L. 116-260), Division H, § 2.02 states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II. . . ." See Section 4.1.iv Budget – Salary Limitation of HRSA's *SF-424 R&R Application Guide* for additional information. Note that these or other salary limitations may apply in the following fiscal years, as required by law.

iv. Budget Narrative

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

In addition, the Autism FIRST program requires the position descriptions (roles, responsibilities, and qualifications of proposed project staff) in the Budget Justification under Personnel costs. The budget justification is uploaded into the Budget Narrative Attachment Form. Biographical sketches for any key personnel must be attached to RESEARCH & RELATED Senior/Key Person Profile (OMB Number 4040-0001) found in the application package on Grants.gov. *NOTE: Each biographical sketch must follow the HRSA font/margin requirements and may not exceed 5 pages per person. This OMB form does count against your page limit and can be attached to RESEARCH & RELATED Senior/Key Person Profile (OMB Number 4040-0001) found in the application package on Grants.gov.* For details on how to format the biographical sketch visit: https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-for-Research-Grant-Applicants-Jan2020-2023.docx. Please note that even though the document has an OMB clearance number, it's not a standard form and your response counts against the page limit.

NARRATIVE GUIDANCE

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

Narrative Section	**Review Criteria**
A. Specific Aims: 1) Needs Assessment	(1) Need

A. Specific Aims: 2) Significance	(2) Response
A. Specific Aims: 3) Goals and Hypotheses	
B. Methodology/Research Strategy: 1) Work Plan/Approach	(3) Evaluative Measures
B. Methodology/Research Strategy: 2) Scientific Innovation and Importance	(4) Impact
C. Impact and Dissemination	
D. Organizational Information/ Environment	(5) Resources/Capabilities
Budget and Budget Justification	(6) Support Requested
E. Feasibility	(7) Program Assurances
F. Evaluation and Technical Support Capacity	
G. Human Subjects Protections	
H. Targeted/Planned Enrollment	

v. Program-Specific Forms

1) *Performance Standards for Special Projects of Regional or National Significance (SPRANS) and Other MCHB Discretionary Projects*

   HRSA has modified its reporting requirements for SPRANS projects, Community Integrated Service Systems (CISS) projects, and other grant/cooperative agreement programs administered by MCHB 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). This Act 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, which authorizes several maternal and child health programs administered by MCHB. Performance measures for other MCHB-funded grant/cooperative agreement programs have been approved by OMB and are primarily based on existing or administrative data that projects should easily be able to access or collect. An electronic system for reporting these data elements has been developed and is now available.

2) *Performance Measures for the MCH Autism Field-Initiated Innovative Research Program*

To inform successful applicants of their reporting requirements, the listing of MCHB administrative forms and performance measures for this program can be found in Section "VI. Award Administration Information" of this NOFO.

NOTE: The performance measures and data collection information is for your PLANNING USE ONLY. These forms are not to be included as part of this application.

vi. Attachments

Please provide the following items in the order specified below to complete the content of the application. Unless otherwise noted, attachments count toward the application page limit. Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the 80-page limit. Each attachment must be clearly labeled.

Attachment 1: Letters of Agreement/Letters of Support

Provide any documents that describe working relationships between your agency and other agencies and programs cited in the proposal, including letters of agreement for use of datasets. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the subcontractors and any deliverable(s). Include only letters of support, which 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: Surveys, Questionnaires, Data Collection Instruments, Clinical Protocols

Surveys, questionnaires, and other data collection instruments, clinical protocols and informed consent documents may be submitted as an attachment. **Keep in mind that this attachment counts in the overall 80-page limit.**

Attachment 3: Logic Model

Submit a logic model for designing and managing the project. A logic model is a diagram that presents the conceptual framework for a proposed project and explains the links among program elements.

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 publicly available website: https://www.cdc.gov/obesity/downloads/CDC-Evaluation-Workbook-508.pdf.

While HRSA does not endorse any organization/website, the following reference may be helpful when developing a logic model: http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf.

Appendix D contains an example of a logic model. There are many versions of logic models; however, for the purpose of this NOFO, the logic model should, at a minimum, address the following areas:

1. Identify the Problem(s), Target Population(s), and Program Purpose:
   - What problem does the program address?
   - Target population(s):
     - o Who does the program target?
     - o Who gets the intervention, and (if different) who is the intervention eventually supposed to impact?
     - o Are there primary and secondary target populations?
   - Program Purpose:
     - o How does the program offer a solution?
     - o What does the program do to address the problem?

2. Identify Activities and Clarify Outputs:
   - Activities:
     - o What does the program do?
     - o What services does the program deliver?
   - Products:
     - o What does the program create?
     - o What are the outputs of the program?

3. Identify Program Outcomes:
   - Short-Term and Intermediate Outcome(s):
     - o May include changes in skills, attitudes, knowledge or changes in behaviors and decision-making.
     - o Should directly result from program outputs.
   - Long-Term Outcome(s):
     - o May include changes related to health status, health conditions, or systems changes.
     - o Should directly result from short-term/intermediate outcomes.

Attachment 4: Preliminary Studies

Use this section to provide an account of the PD/PI's preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the targeted population(s). This information will also help to establish the scientific research experience and competence of the investigator to pursue the proposed research project. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed research.

This attachment is carefully considered during the review process and will be evaluated as part of Review Criterion 5: Resources and Capabilities.

Attachment 5: Explanation on Delinquent Federal Debt, if applicable.

Attachment 6: Proof of Nonprofit Status (Not counted in the page limit).

Attachment 7: Indirect Cost Rate Agreements (Not counted in the page limit)

Check with your sponsored program office for further information about the indirect cost rate. Your institution's indirect cost rate is negotiated by the institution with HHS. Limitations on indirect cost rates are discussed earlier in this NOFO.

Attachments 8–15: Other Relevant Documents

Unless otherwise noted, attachments count toward the application page limit. Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. Each attachment must be clearly labeled.

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

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

You must also register with 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)).

If you are chosen as a recipient, HRSA would not make an award until you have complied with all applicable DUNS (or UEI) and SAM requirements and, if you have not fully complied with the requirements by the time HRSA is ready to make an award, you may be deemed not qualified to receive an award and use that determination as the basis for making an award to another applicant.

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

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

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

- Grants.gov (http://www.grants.gov/)

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

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

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

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

4. Submission Dates and Times

Application Due Date
The due date for applications under this NOFO is *April 15, 2021 at 11:59 p.m.ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadline** to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's *SF-424 R&R Application Guide* for additional information.

5. Intergovernmental Review

The MCH Research 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 3 years, at no more than $300,000 per year (inclusive of direct **and** indirect costs. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

Funds awarded under HRSA-21-053 may not be used for travel outside of the U.S.

The General Provisions in Division H of the Consolidated Appropriations Act, 2021 (P.L. 116-260) apply to this program. Please see Section 4.1 of HRSA's *SF-424 R&R*

Application Guide for additional information. Note that these or other restrictions will apply in the following fiscal year, as required by law.

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

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

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

V. Application Review Information

1. Review Criteria

Procedures for assessing the technical and scientific merit of applications have been instituted to provide for an objective review of applications and to assist you in understanding the standards against which each application will be judged. Critical indicators have been developed 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. Review criteria are outlined below with specific detail and scoring points. These criteria are the basis upon which the reviewers will evaluate the application. The entire proposal will be considered during objective review.

NOTE: The terms *project, research project,* and *study* are used interchangeably. Review criteria are used to review and rank applications. The R41 MCH Autism Field-Initiated Innovative Research Program has seven (7) review criteria:

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

CRITERION 1: NEED (10 points) -- Corresponds to Program Narrative Section A Specific Aims: 1) Needs Assessment

A. Specific Aims

Needs Assessment

The extent to which:

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

CRITERION 2: RESPONSE (20 points) -- Corresponds to Program Narrative Section A Specific Aims: 2) Significance and 3) Goals and Hypotheses

Significance

The extent to which:

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

Goals and Hypotheses

The extent to which:

- The project's goals and hypotheses are clear, concise, appropriate, and well-justified;
- The expected outcomes are clearly and succinctly summarized, with attention to how these outcomes will address the unmet needs of the targeted population;
- The hypotheses are logically derived from the research literature, clearly stated, and are related to the defined problem;
- Variables are clearly defined; and
- There is congruence among the associations depicted by the graphic model (if included), the variables, the statement of hypotheses, and the plan for data analysis.

CRITERION 3: EVALUATIVE MEASURES (30 points) -- Corresponds to Program Narrative Section B Methodology/Research Strategy: Work Plan/Approach

B. Methodology/Research Strategy: Work Plan/Approach

Study Design

The extent to which:

- The overall strategy, methodology, and analyses are well reasoned and appropriate to accomplish the specific aims of the project;
- The description of the design is clear enough to permit replication;
- Significant threats to internal and external validity of the design have been adequately acknowledged and addressed;
- The scientific activities described in the proposal are capable of addressing the problem and attaining the project objectives;
- Proper controls are included;
- The method of randomization, if used, is clearly described;
- The project assures cultural competence in the planning and implementation of the research project.

Data Collection

The extent to which:

- The instruments that have been selected or developed are adequate and appropriate;
- Adequate attention is given to reliability and validity (psychometric properties); and
- Any self-reported data can provide convincing validity for intended measurements (e.g., self-reported blood pressure, parent-reported anthropometric data).

Population Description, Sampling, and Recruitment

The extent to which:

- The study population is described (i.e., targeted age(s) or age ranges, expected racial/ethnic background and socioeconomic status, urban/rural, etc.);
- The sampling design is appropriate and includes an adequate and justified sample size;
- The expected differences between groups are defined in terms of statistical as well as clinical significance;
- The eligibility criteria for entering the study are well defined;
- The recruitment plan is clearly described;
- The letters of agreement from study sites supporting recruitment are in place;
- Participant recruitment is feasible; and
- Targeted enrollment is feasible to complete with the period of performance, given recruitment methods.

Plan for Data Analysis

The extent to which:

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

CRITERION 4: IMPACT (10 points) -- Corresponds to Program Narrative Sections B Methodology/Research Strategy: Scientific Innovation and Importance; and C Impact and Dissemination

B. Methodology/Research Strategy: Scientific Innovation and Importance

The extent to which:

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

C. Impact and Dissemination

Public Health Impact

The extent to which:

- The expected outcomes are likely to help improve the health and/or well-being of children, adolescents, and young adults with ASD/DD in underserved populations; and
- The findings will be generalizable and are of regional or national significance and/or scope.

Publication and Dissemination Plan

The extent to which:

- The applicant presents a sound plan for how they will produce the expected minimum number of peer-reviewed publications (i.e., three (3) publications).
- The PI and other key personnel demonstrate current and/or past success in publishing the findings of their research;
- 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 the targeted population, as well as policymakers, families, and the general public.

CRITERION 5 RESOURCES/ CAPABILITIES (15 POINTS). Corresponds to Program Narrative Section D Organizational Information/ Environment

Key Personnel

The extent to which:

- The Key/Senior Support Personnel Profiles and Biographical Sketches indicate that the PD/PI, collaborators, staff, and other researchers are well-qualified by training and/or expertise to conduct the research;
- If Early Stage Investigators, the appropriateness of their experience and training; if established investigators, the degree to which they have demonstrated an ongoing record of research accomplishments that have served to advance the field; and
- The proposal describes relevant preliminary studies performed by key personnel, indicating the capacity to conduct the research as described.

Organizational Capacities

The extent to which:

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

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

The extent to which:

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

Criterion 7: Program Assurances (10 points). Corresponds to E. Feasibility; F. Evaluation and Technical Support Capacity; G. Human Subjects Protections; H. Targeted/Planned Enrollment

E. Feasibility

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

Proposed Sequence or Timetable

The extent to which:

- The proposed project provides a clear timeline and is feasible to conduct within the proposed time frame;
- The timeline presents clear, detailed, and feasible goals throughout the duration of the project; and
- The application anticipates and addresses potential barriers to project progress.

F. Evaluation and Technical Support Capacity

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

G. Human Subjects Protections

The extent to which:

- The proposal is in compliance with the Department of Health and Human Services (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 Human Subjects Section of the Research Plan;
- Adequate measures are in place to ensure the security of the research data (data security); and
- The application discusses plans to seek Institutional Review Board (IRB) approval (IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects).

H. Targeted/Planned Enrollment

The extent to which:

- The plan is achievable in terms of meeting targeted participant enrollment, given recruitment methods and frequent difficulties of recruiting hard-to-reach populations;
- Details are provided regarding the Targeted/Planned Enrollment for the proposed studies, including information on anticipated sociocultural group categories (e.g., race, ethnicity, language, rural versus urban, socioeconomic, gender); and
- Assurances are provided regarding cultural competence as appropriate. (See Appendix A for additional resources and definitions).

2. Review and Selection Process

The objective review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. See Section 5.3 of HRSA's *SF-424 R&R Application Guide* for more details.

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

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

VI. Award Administration Information

1. Award Notices

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

2. Administrative and National Policy Requirements

See Section 2 of HRSA's *SF-424 R&R Application Guide*.

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

regulations and policies in effect at the time of the award, and applicable statutory provisions.

Requirements of Subawards

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

Data Rights

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

Human Subjects Protection

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

- 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 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 Methods portion of the Project Narrative Section.

3. Reporting

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

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

1) **Discretionary Grant Information System (DGIS) Performance Reports.** Available through the Electronic Handbooks (EHBs), the Discretionary Grant Information System (DGIS) is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report annually, by the specified deadline. To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are available at https://grants4.hrsa.gov/DGISReview/FormAssignmentList/R41_2.html.

   The type of report required is determined by the project year of the award's period of performance.

Type of Report	Reporting Period	`	Report Due Date
New Competing Performance Report	September 1, 2021 - August 31, 2024 *(administrative data and performance measure projections, as applicable)*	Period of performance start date	120 days from the available date
Non-Competing Performance Report	September 1, 2021- August 31, 2022 September 1, 2022- August 31, 2023	Beginning of each budget period (Years 2–3, as applicable)	120 days from the available date
Project Period End Performance Report	September 1, 2023- August 31, 2024	Period of performance end date	90 days from the available date

The full OMB-approved reporting package is accessible at

https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection (OMB Number: 0915-0298 | Expiration Date: 06/30/2022).

2) **Progress Report(s)**. The recipient must submit a progress report narrative to HRSA **annually** via the Non-Competing Continuation Renewal in the EHBs,

which should address progress against program outcomes (e.g., accomplishments, barriers, significant changes, plans for the upcoming budget year), and include annual data on performance measures identified in the Project Narrative, if not captured by DGIS. Submission and HRSA approval of a progress report will trigger the budget period renewal and release of each subsequent year of funding. Further information will be available in the Notice of Award (NOA).

3) **Final Report Narrative.** The recipient must submit a final report narrative to HRSA after the conclusion of the project.

4) **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.

5) **Web-based Project Presentation.** Award recipients will be asked to give a web-based presentation on their project's progress and preliminary findings to MCHB staff towards the end of the project's third year of funding.

6) **Dissemination.** Recipients for this competition will be required to notify their MCHB project officer as soon as they are aware their research is being or has been published. Recipients must report back to HRSA regarding the execution of their dissemination plans as part of the non-competing continuation (NCC) application and the final comprehensive report.

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

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

VII. Agency Contacts

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

Stanley Gordon
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane

Rockville, MD 20857
Telephone: (301) 945-3935
Email: SGordon2@hrsa.gov

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

Sylvia Sosa, MSc
Program Officer
Division of Research
Office of Epidemiology and Research
Health Resources and Services Administration
Telephone: (301) 443-2259
Email: ssosa@hrsa.gov

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

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

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

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

VIII. Other Information

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Friday, January 22, 2021
Time: 2 p.m. – 3 p.m. ET
Call-In Number: 1-888-381-5770
Participant Code: 3734558
Weblink: https://hrsa.connectsolutions.com/autismfirstwebinar/

Instant replay:
Call-In Number: 866-430-4730
Passcode: 42321
Available until: April 23, 2021

HRSA will record the webinar and make it available at: https://mchb.hrsa.gov/fundingopportunities/default.aspx.

Tips for Writing a Strong Application

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

Appendix A: Relevant Publicly Available Websites

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

Bright Futures

http://brightfutures.aap.org/

Healthy People 2020 / Developing Healthy People 2030

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

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

HRSA/MCHB Division of Workforce Development Website

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

Human Subjects Protections Assurances

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

Inclusion Across the Lifespan - Policy Implementation

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

Logic Models

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

Making Websites Accessible: Section 508 of the Rehabilitation Act

http://www.section508.gov/

National Academy of Medicine

https://nam.edu/

National Center for Cultural Competence

http://nccc.georgetown.edu/

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

Appendix B: Key Terms for Project Abstracts

a) Content Terms (maximum of 10)

Health Care Systems & Delivery

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

Primary Care & Medical Home

- Adolescent Health
- Coordination of Services
- Community-Based Approaches
- Integration of Care
- Medical Home
- Oral Health
- Preconception/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
- Smoking
- Stress
- Substance Use
- Violence & Abuse

Special Health Care Needs & Disabilities

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

Lifespan & Social Determinants

- Neighborhood
- Lifespan
- Social Determinants of Health

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

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

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

- Women's Health & Well-being (Preconception/Interconception/Parental)
- Prenatal (until 28th week of gestation)

- Perinatal (28th week of gestation to 4 weeks after birth)
- Infancy (1–12 months)
- Toddlerhood (13–35 months)
- Early Childhood (3–5 years)
- Middle Childhood (6–11 years)
- Adolescence (12–18 years)
- Young Adulthood (19–26 years)

Appendix C: Application Completeness Checklist

Funding Opportunity Number: HRSA-21-053 **Application Due Date in Grants.gov:** April 15, 2021	
Requirement	**Yes**
Do you meet the eligibility criteria?	
Did you read the R&R Application Guide? (https://www.hrsa.gov/sites/default/files/hrsa/grants/apply/applicationguide/sf-424-rr-app-guide.pdf)?	
Do you have a DUNS number (https://www.dnb.com/duns-number.html)?	
Did your Authorized Organization Representative (AOR) register in SAM (https://www.sam.gov/)?	
Did your AOR register in Grants.gov (https://www.grants.gov/)?	
Is your Abstract no more than one page in length and single spaced?	
Does the Narrative Section of your application fully address: • Background and Significance? • Specific Goals and Objectives? • Project Design, Methods, and Evaluation? • Plan/Schedule of Implementation and Capability of Applicant? • Feasibility? • Evaluation and Technical Support Capacity? • Human Subjects Protections? • Targeted/Planned Enrollment?	
Did you confirm that your application addressed all of the NOFO Review Criteria?	
Is your Methods Section within the 12-page limit?	
Are your budget and budget justification narrative completed accurately and in the yearly funding limit? **NOTE:** The directions offered in the HRSA SF-424 R&R Application Guide differ from those offered by Grants.gov. Please follow the instructions included in the R&R Application Guide and, *if applicable*, the additional budget instructions in the **NOFO**.	
Did you clearly label all of your attachments?	
Did you include the Biographical Sketches of Key Personnel in the Application?	
Do you know your institution's indirect cost rate?	
Did you use no less than 12-point font and are your page margins at least 1 inch wide in the Narrative and Attachment Sections of the Application? **NOTE:** The Biographical Sketches of Key Personnel can have .5" margins.	

Are your pages, including attachments, within the 80-page limit? **NOTE:** Pages which do not count toward the 80-page limit include: Cover Page, Indirect Cost Rate Agreement, Proof of Non-Profit Status (if appropriate), Budget, and Standard OMB-approved forms.	

Appendix D: Logic Models

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

The following logic model illustrates HRSA's expectations and goals for the HRSA-21-053 Autism-FIRST.

Step 1: Identify Activities and Clarify Outputs

PROGRAM PROCESS What is the planned work for the program?		PROGRAM OUTCOMES What are the program's intended results?	
ACTIVITIES (What will program inputs do?)	**OUTPUTS / PRODUCTS** (What will be created as a result of the activity?)	**SHORT-TERM / INTERMEDIATE** (What will change as a result of the product/system implemented?)	**LONG-TERM / IMPACT** (What will change if short-term / intermediate outcomes are achieved?)
Design and conduct innovative applied or translational intervention research using rigorous scientific methodology.	Complete applied intervention studies within 3 years of award.	Increase the number of innovative, applied intervention studies addressing current and emerging issues relevant to children with ASD/DD and their families.	Advance and contribute to the Autism evidence base to inform the work of health care providers, other practitioners, public health systems, and Title V Block Grant programs.
Recruit, track, and report data on Autism FIRST study participants from diverse backgrounds (including ethnicity, race, gender/sex, geographic location, and socioeconomic status).	Enrollment information and demographic data of Autism populations enrolled in intervention studies.	Understand the diversity of children with ASD/DD and their families represented in HRSA-supported research.	Increased efforts to support the diversity of children with ASD/DD and their families represented in HRSA-supported research.
Train/mentor junior/new investigators in applied research and critical issues affecting Autism populations.	Junior/new investigators trained/mentored.	Increase the number of junior/new investigators trained/mentored in applied research and critical issues affecting Autism populations.	Increase the use/translation of study findings into practices and/or policies in the public health system or related settings.
Prepare and submit grant applications for external funding opportunities outside of HRSA/MCHB's Autism research grant program.	Grant applications completed and submitted for external funding opportunities.	Increase the capacity of grantees to expand/sustain research initiated by the Autism FIRST program.	Support the sustainability of Autism research.
Develop and implement a dissemination plan for communicating research findings to diverse stakeholders.	• Dissemination plan with a timeline and list of proposed products. • Manuscripts published in peer-reviewed journals. • Non-peer-reviewed products aimed at	Increase the accessibility of HRSA funded Autism research to the scientific and lay community.	Advance and contribute to the Autism evidence base to inform the work of health care providers, other practitioners, public health systems,

PROGRAM PROCESS What is the planned work for the program?		PROGRAM OUTCOMES What are the program's intended results?	
ACTIVITIES **(What will program inputs do?)**	**OUTPUTS / PRODUCTS** **(What will be created as a result of the activity?)**	**SHORT-TERM / INTERMEDIATE** **(What will change as a result of the product/system implemented?)**	**LONG-TERM / IMPACT** **(What will change if short-term / intermediate outcomes are achieved?)**
	stakeholders beyond the scientific research community (e.g., reports, blogs, web postings, videos, infographics, and lay summaries of research publications).		

Specify Performance Measures

Measure/Indicator *List each measure/indicator in its own row* *For DGIS Measures, list the overall measure and the selected Tier expected*	**Data** *For each measure, list:* *1) where the data come from;* *2) how often it is reported, and* *3) where it is reported*	**Does this measure link to any of the Outcomes listed in Step 3?** *If yes, list the program outcome from Step 3*	**Type of Measure/Indicator**	
			Process	**Outcome / Impact**
DGIS Core 1 Specific Objectives • Conduct innovative applied or translational intervention ASD/DD research using rigorous scientific methodology; • Recruit, track, and report study participants from diverse backgrounds to include diversity with regards to race/ethnicity, gender/sex, disability, geographic location, and socioeconomic status; and • Develop and submit a dissemination plan for the distribution of research findings and products to scientific, professional, and lay audiences. Dissemination activities include, but are not limited to, peer-reviewed articles, manuscripts, conference presentations, newsletter articles, webcasts, fact sheets, infographics,	DGIS annual reports	No		**x**

Measure/Indicator *List each measure/indicator in its own row* *For DGIS Measures, list the overall measure and the selected Tier expected*	Data *For each measure, list:* *1) where the data come from;* *2) how often it is reported, and* *3) where it is reported*	Does this measure link to any of the Outcomes listed in Step 3? *If yes, list the program outcome from Step 3*	Type of Measure/Indicator	
			Process	**Outcome / Impact**
policy briefs, websites, and social media posts, as appropriate.				
DGIS Core 2	DGIS annual reports	No	**X**	
DGIS Core 3	DGIS annual reports	No	**X**	
# of participants enrolled (including demographic data) in Autism FIRST studies (Form 7)	DGIS annual reports; annually in program reports	Increase the diversity of Autism populations represented in HRSA-supported research.	**X**	
# of research sites	DGIS annual reports; annually in program reports		**X**	
# of peer-reviewed publications produced (CB5 and Products, Publications, and Submissions Data Collection Form)	DGIS annual reports; annually in program reports	Advance and contribute to the Autism evidence base to inform the work of health care providers, other practitioners, public health systems, and Title V Block Grant programs.		**X**
# of non-peer-reviewed publications produced (CB5 and Products, Publications, and Submissions Data Collection Form)	DGIS annual reports; annually in program reports	Advance and contribute to the Autism evidence base to inform the work of health care providers, other practitioners, public health systems, and Title V Block Grant programs.		**X**
# of total researchers involved in the Autism FIRST studies	Annually in program reports	Increase the capacity of grantees to expand/sustain research initiated by the Autism FIRST program.	**X**	
# of junior/new investigators being trained or mentored through Autism FIRST studies	Annually in program reports	Increase the number of junior/new investigators trained/mentored in applied research and	**X**	

Measure/Indicator *List each measure/indicator in its own row* *For DGIS Measures, list the overall measure and the selected Tier expected*	**Data** *For each measure, list:* *1) where the data come from;* *2) how often it is reported, and* *3) where it is reported*	**Does this measure link to any of the Outcomes listed in Step 3?** *If yes, list the program outcome from Step 3*	**Type of Measure/Indicator**	
			Process	**Outcome / Impact**
		critical issues affecting Autism populations.		
# of grant applications for external funding	Annually in program reports	Increase the capacity of grantees to expand/sustain research initiated by the Autism FIRST program.		**X**
# of successful grant applications for external funding	Annually in program reports	• Increase the capacity of grantees to expand/sustain research initiated by the Autism FIRST program. • Increase Autism applied research sustainability.		**X**
# of tools and toolkits	Annually in program reports	• Increase the use/translation of study findings into practices and/or policies in the public. • Increase the number of resources (e.g., tools, toolkits, and/or clinical guidelines) on Autism issues available to help clinicians and other researchers.		**X**
# of clinical guidelines	Annually in program reports	• Increase the use/translation of study findings into practices and/or policies in the public. • Increase the number of resources (e.g., tools, toolkits, and/or clinical guidelines) on Autism issues available to help clinicians and other researchers.		**X**

Appendix E: Frequently Asked Questions (FAQs)

1. **Where do I find application materials?**

   All application materials are available through Grants.gov.

2. **How can I download the complete application package for the Research NOFO?**

   You can download the application from Grants.gov.

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

   Grants.gov is the website that the U.S. Government uses to inform citizens of grant opportunities; it provides a portal for submitting applications to U.S. Government agencies. More information can be found on the Grants.gov website.

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

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

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

   1) *Make sure that the AOR from your university/organization is registered in Grants.gov NOW. This process can take up to 1 month and it is better to complete it and have it out of the way before starting any grant application.*

   2) *Read the instructions on Grants.gov carefully and allow time for corrections. Enter information in fields even if it is 0 or the form will remain incomplete. Required fields are highlighted in yellow.*

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

   4) *Some business practices will change with the introduction of the new SF-424 R&R Form.*

      - *With the HRSA SF-424 R&R, you will be reporting faculty and staff time in calendar month equivalents.*
      - *Budget details about subcontracts will now be described in a section of the SF- 424 R&R called sub-awards.*
      - *New applications will now fill out detailed budgets for each of the years in the period of performance. Therefore, submit detailed budgets for each of the 5 years.*

6. **What types of institutions can apply?**

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

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

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

According to the HRSA SF-424 R&R Application Guide (as aligned with the Uniform Administrative Requirements at 45 CFR part 75), "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 Application Guide also contains information on how to negotiate the indirect cost rate.

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

The applicant institution's indirect cost rate is negotiated by the institution with HHS. Your sponsored programs office will be able to provide further information about the indirect cost rate.

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

In the past, there has not been a minimum percent effort required for Autism-FIRST projects. Beginning with this NOFO, however, the applicant PD/PI is expected to spend a minimum of 10 percent effort on this project to ensure that applicant PDs/PIs allocate and devote sufficient time to justify their commitments to the project. Under Review Criteria 6 of the NOFO, it states that applications will be assessed regarding whether:

- *Time allocated by key personnel is realistic and appropriate to achieve project objectives.*

10. **Can someone who is currently a PI on another agency's grant be a PI of the Autism FIRST?**

Yes, 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.

11. **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.

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

Include biographical sketches for persons occupying key positions. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch. Given the 80-page limit, it is recommended that biographical sketches be no more than five pages in length per person. Please use the MCHB biographical sketch form found here: https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-for-Research-Grant-Applicants-Jan2020-2023.docx. Note that the biographical sketches count against the 80-page limit.

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

The total size of all uploaded files included in the page limit 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. Please note: If you use an OMB-approved form that is not included in the workspace application package for HRSA-21-053, it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect

Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. It is therefore important to take appropriate measures to ensure your application does not exceed the specified page limit.

14. Are there any page limitations to the narrative?

Section B Methodology/Research Strategy of the narrative has a 12-page limit for Section III - Project Design: Methods and Evaluation. Please consult the NOFO and/or the HRSA R&R Application Guide, referenced throughout the NOFO, for more specific information.

15. Are there font/margin requirements?

Follow HRSA guidelines, which call for 1" margins and 12-point font. More information on specifications regarding fonts and margins can be found in the HRSA R&R Application Guide.

16. 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.

17. 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.

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

Please contact:

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

19. Does HRSA offer extensions for submitting applications?

If you experience system glitches or a qualified emergency you can request an exemption/waiver for your application which is subject to HRSA's discretion. Please submit your exemption request in writing to DGPWaivers@hrsa.gov.