Department of Health and Human Services



Health Resources & Services Administration

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2024

Maternal and Child Health Bureau

Office of Epidemiology and Research

Division of Research

Autism Field-Initiated Innovative Research Studies (Autism FIRST)

Funding Opportunity Number: HRSA-24-048

Funding Opportunity Type(s): New

Assistance Listing Number: 93.877

Application Due Date: April 3, 2024

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

Issuance Date: January 4, 2024

Emmie Perchak, MPH, MCD & Sibil Varghese, MPH Project Officers, Office of Epidemiology and Research, Division of Research Call: 301-443-0714 & 224-448-9950 Email: AutismFirst@hrsa.gov

See <u>Section VII</u> for a complete list of agency contacts.

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

508 COMPLIANCE DISCLAIMER

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

SUMMARY

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Funding Opportunity Title:	Autism Field-Initiated Innovative Research Studies (Autism FIRST)			
Funding Opportunity Number:	HRSA-24-048			
Assistance Listing Number:	93.877			
Due Date for Applications:	April 3, 2024			
Purpose:	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 and other developmental disabilities (DD) ¹ across the lifespan. Research for this program includes a special focus on addressing the needs of underserved populations and, as appropriate, engaging families.			
Program Objective(s):	 Generate new evidence to address the needs of underserved autistic and DD populations for whom there is limited evidence of the effectiveness of interventions, and limited access to screening, diagnosis, and treatment for autism and DD; 			

HRSA-24-048 Autism FIRST

¹ The word 'disorder' is not used in this NOFO when referring to persons with autism or other developmental disabilities. HRSA MCHB intends for the abbreviated terminology of 'autism' used herein to refer to the population of individuals which meet the diagnostic criteria for autism spectrum disorder and autistic disorder, as formally recognized by the American Psychological Association (APA) in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-V-TR) and the World Health Organization (WHO) in the International Classification of Diseases 11th Revision (ICD-11), respectively.

	 Conduct and disseminate findings from applied and/or translational research on critical and emerging autism/DD issues using a research design including collection of primary data among underserved populations, with a special focus on children, adolescents, and young adults up to the age of 26; Inform public health efforts to improve delivery of health and related services that are generalizable and replicable for underserved autism/DD populations; and Align research with MCHB's <u>Blueprint for Change</u>, with an emphasis on promoting health equity, family and child well-being and quality of life, and access to services. 		
Eligible Applicants:	 Public or private entities, including research centers or networks 		
	 Community-based organizations 		
	Tribal (governments, organizations)		
	You are required to submit proof of non-profit status as Attachment 5. A foreign applicant will need to be affiliated with a U.S. entity (i.e., university, institution) with a U.S. EIN established and recognized by HRSA to be considered a public or nonprofit institution of higher learning or a public or private nonprofit agency. See <u>Section III.1</u> of this notice of funding opportunity (NOFO) for complete eligibility information.		
Anticipated FY 2024 Total Available Funding:	\$600,000, subject to the availability of appropriated funds		
	We're issuing this notice to ensure that, should funds become available for this purpose, we can process applications and award funds appropriately. You should note that we may cance this program notice before award if funds are not appropriated.		

Estimated Number and Type of Award(s):	Up to 2 new grants	
Estimated Annual Award Amount:	Up to \$300,000 per award	
Cost Sharing or Matching Required:	No	
Period of Performance:	September 1, 2024, through August 31, 2027 (3 years)	
Agency Contacts:	Business, administrative, or fiscal issues: David Colwander Grants Management Specialist Division of Grants Management Operations, OFAM Email: <u>DColwander@hrsa.gov</u>	
	Program issues or technical assistance: Emmie Perchak, MPH, MCD & Sibil Varghese, MPH Project Officers, Office of Epidemiology and Research, Division of Research Maternal and Child Health Bureau Email: <u>AutismFirst@hrsa.gov</u>	

Application Guide

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

Technical Assistance

We have scheduled the following webinar:

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Thursday, January 18, 2024
2 – 3 p.m. ET
Weblink: <u>https://hrsa-</u>
gov.zoomgov.com/j/1613538211?pwd=cHc4ZnZQa1c3UG9zOG90c2xKUCtiQT09
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Passcode: kwd0pS1c

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

Dial-in: 833 568 8864 Meeting ID: 161 353 8211 Participant Code: 07356472

We will record the webinar. https://mchb.hrsa.gov/research/pre-app-ta-webinars.asp

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the FY 2024 Autism Field-Initiated Innovative Research Studies (Autism FIRST) program. The purpose of the Autism FIRST program is to support empirical research that advances the evidence on early screening and interventions to improve the health and well-being of children, adolescents, and young adults with autism and other developmental disabilities (DD) across the lifespan. The Autism FIRST program aims to achieve this goal by testing the implementation of new and/or innovative strategies that address critical issues affecting the health and receipt of related health services among children, adolescents, and young adults with a special focus on addressing the needs of underserved populations.

The Autism FIRST program objectives to be accomplished during the period of performance are to:

- Generate new evidence to address the needs of underserved autistic/DD populations for whom there is limited evidence of the effectiveness of interventions, and limited access to screening, diagnosis, and treatment for autism/DD;
- Conduct and disseminate findings from applied and/or translational research on critical and emerging autism/DD issues using a research design including collection of primary data among underserved populations, with a special focus on children, adolescents, and young adults up to the age of 26.
- Inform public health efforts to improve delivery of health and related services through studies that are generalizable and replicable for underserved autism/DD populations; and
- Align research with MCHB's <u>Strategic Research Issues</u> and <u>Blueprint for</u> <u>Change</u>, with an emphasis on promoting health equity, family and child wellbeing and quality of life, and access to services;

For more details, see Program Requirements and Expectations

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)).

1

A comprehensive picture of autism among children in the U.S is best understood by examining two key estimates of autism prevalence.² The Centers for Disease Control and Prevention used population-based autism 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 autism cases are identified through education and health records review - to report that approximately 2.76% children have autism.³ Parent-reported data from the 2022 National Survey of Children's Health (NSCH), documented that 3.6% of children ages 3-17 years had a current diagnosis of autism, representing nearly 2.2 million children and adolescents.⁴ Estimates from these two systems reflect different data collection periods, 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 autism among children in the U.S. Autism is a complex neurodevelopmental disorder, and individuals with this condition experience a range of behavioral challenges with social interactions and communication, as well as restrictive and repetitive behaviors, which can be lifelong and pervasive.⁵

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 autism/DD.⁶ Many gaps in research remain regarding effective interventions for their complex needs. Furthermore, the impact of racial and ethnic disparities in the early evaluation and diagnosis of autism/DD may be compounded by social determinants of health (SDOH) across the lifespan. SDOH are conditions in which people are born, live, work, learn, play, worship, and age.⁷ SDOH include factors like socioeconomic status,

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

³ Autism and Developmental Disabilities Monitoring Network (2020 data). Accessed 08/01/2023. (<u>http://www.cdc.gov/ncbddd/autism/data.html)</u>

⁴ Child and Adolescent Health Measurement Initiative. 2022 National Survey of Children's Health (NSCH) data query. Data Resource Center for Child and Adolescent Health supported by the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB). Retrieved 10/3/2023 from <u>NSCH 2022: NOM 17.3: Percent of children diagnosed</u> with an autism spectrum disorder, Nationwide (childhealthdata.org).

⁵ American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders V. Washington, DC: American Psychiatric Publishing; 2022.

⁶ Bishop-Fitzpatrick L, Kind AJH. A Scoping Review of Health Disparities in Autism Spectrum Disorder. J Autism Dev Disord. 2017 Nov;47(11):3380-3391. doi: 10.1007/s10803-017-3251-9. PMID: 28756549; PMCID: PMC5693721.

⁷ 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. Accessed 08/02/23. <u>https://health.gov/healthypeople/objectives-and-data/social-determinants-health</u>.

education, neighborhood and physical environment, community violence, employment, and social support networks, as well as access to health care. Addressing SDOH, which affect a wide range of health, functioning, and quality-of-life outcomes and risks, is in line with HRSA's objective to improve the health and well-being of individuals and the communities in which they reside.

The Autism FIRST program aims to improve the quality of care for those who have or are at risk for developing autism/DD through education, early detection, and intervention. For FY 2024, the Maternal and Child Health Bureau will solicit studies addressing HHS/HRSA's priorities and the MCHB strategic plan goals, as well as studies that align with the Title V Block Grant National <u>Performance</u> and <u>Outcome</u> Measures, and focus on underserved populations.

About MCHB and its Strategic Plan

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

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

Goal 2: Achieve health equity for MCH populations

Goal 3: Strengthen public health capacity and workforce for MCH

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

To learn more about MCHB and the Bureau's strategic plan, visit <u>Mission, Vision, and</u> <u>Work | MCHB</u>.

The Autism FIRST program addresses MCHB's Goal 1 and Goal 2 to assure access to high quality and equitable health services to optimize health and well-being for all children, adolescents, and young adults with autism/DD and their families and achieve health equity for MCH populations. This program advances Goal 3 by supporting innovative interventions that build the evidence base in MCH. Goal 4 is addressed through the broad dissemination of research findings to health care providers, other practitioners, researchers, policy makers, public health systems, Title V Block Grant programs, and the MCH community.

Promoting Health Equity

Promoting equity is essential to the Department's mission of protecting the health of Americans and providing essential human services. This view is reflected in <u>Executive</u> Order (E.O.) 13985 entitled, "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government" issued on January 20, 2021, and E.O.

<u>14094 entitled, "Further Advancing Racial Equity and Support for Underserved</u> <u>Communities Through the Federal Government" issued on February 16, 2023</u>.

II. Award Information

1. Type of Application and Award

Application type(s): New

We will fund you via a grant. You must follow all relevant federal regulations and public policy requirements.

2. Summary of Funding

We estimate \$600,000 will be available each year to fund 2 recipients. You may apply for a ceiling amount of up to \$300,000 annually (reflecting direct and indirect costs).

The period of performance is September 1, 2024, through August 31, 2027 (3 years).

This program notice depends on the appropriation of funds. If funds are appropriated for this purpose, we will proceed with the application and award process.

Support beyond the first budget year will depend on:

- Appropriation
- Satisfactory progress in meeting the project's objectives
- A decision that continued funding is in the government's best interest

<u>45 CFR part 75 - Uniform Administrative Requirements, Cost Principles, and Audit</u> <u>Requirements for HHS Awards</u> applies to all HRSA awards.

If you have never received a negotiated indirect cost rate, you may elect to charge a *de minimis* rate of 10 percent of modified total direct costs (MTDC)*. You may use this for the life of the award. If you choose this method, you must use it for all federal awards until you choose to negotiate for a rate. You may apply to do so at any time. See Section 4.1.v. Budget Justification Narrative in the *R&R Application Guide*.

**Note*: One exception is a governmental department or agency unit that receives more than \$35 million in direct federal funding.

III. Eligibility Information

1. Eligible Applicants

You can apply if your organization is a:

- Public or private entity, including research centers or networks
- Community-based organization
- Tribal (governments, organizations)

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

2. Cost Sharing or Matching

Cost sharing or matching is not required for this program.

3. Other

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

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

Due to funding limitations and to diversify the MCHB research portfolio the following are additional application responsiveness criteria. All applications that do not comply with these criteria will be deemed nonresponsive and will not be considered for funding under this notice.

- An individual cannot be named as the project director (PD) or principal investigator (PI)⁸ on more than one application for the Autism FIRST Program;
- The current PD/PI of an active HRSA/MCHB/Office of Epidemiology and Research (OER)/Division of Research (DOR) award can serve for no more than 10 percent time on a new proposal;
- A PD/PI cannot have two (2) active HRSA/MCHB/OER/DOR awards at the same time. An award in a no-cost extension year is considered active and the PD/PI is not allowed to receive another award;

⁸ HRSA allows one PD/PI to be named on the face page of the SF-424 R&R application, who will serve as the key point of contact, yet multiple co-PI/co-PDs are allowed. This application responsiveness criterion only applies to current MCHB PI/PDs, not co-PI/PDs.

- Longitudinal follow-up studies for previously funded MCH or Autism FIRST studies will **NOT** be considered for funding;
- Projects that focus primarily on secondary data analysis will **not** be considered for funding under this award as there are separate competitions that focus on secondary data analyses, the MCH and Autism Secondary Data Analysis Research competitions;
- Projects which include the collection of biological specimens will **not** be considered for the award competition as this program funds translational intervention research on ASD/DD populations.

Multiple Applications

You may submit multiple applications under the same <u>Unique Entity Identifier</u> (UEI), if each proposes distinct projects. We will only review your **last** validated application for each distinct project before the Grants.gov <u>due date.</u>

For example, different investigators (or research teams) from the same institution can apply for the same funding opportunity.

IV. Application and Submission Information

1. Address to Request Application Package

We **require** you to apply online through <u>Grants.gov</u>. Use the SF-424 Research and Related (R&R) workspace application package associated with this notice of funding opportunity (NOFO). Follow these directions: <u>How to Apply for Grants</u>. If you choose to submit using an alternative online method, see <u>Applicant System-to-System</u>.

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

Note: Grants.gov calls the NOFO "Instructions."

Select "Subscribe" and enter your email address for HRSA-24-048 to receive emails about changes, clarifications, or instances where we republish the NOFO. You will also be notified by email of documents we place in the RELATED DOCUMENTS tab that may affect the NOFO and your application. *You're responsible for reviewing all information that relates to this NOFO.*

2. Content and Form of Application Submission

Application Format Requirements

Submit your information as the *R*&*R* Application Guide and this program-specific NOFO state. **Do so in English and budget figures expressed in U.S. dollars.** There's an Application Completeness Checklist in the *R*&*R* Application Guide to help you.

Application Page Limit

The total number of pages that count toward the page limit shall be no more than 60 **pages** when we print them. We will not review any pages that exceed the page limit. Using the pages within the page limit, HRSA will determine eligibility using <u>Section III.</u> <u>Eligibility Information</u> of the NOFO.

These items do not count toward the page limit:

- Standard OMB-approved forms you find in the NOFO's workspace application package
- Abstract (standard form (SF) "Project_Abstract Summary")
- Indirect Cost Rate Agreement
- Letters of Agreement/Letters of Support
- Biographical sketches of key personnel

If there are other items that do not count toward the page limit, we'll make this clear in Section IV.2.vi <u>Attachments</u>.

If you use an OMB-approved form that is not in the HRSA-24-048 workspace application package, it may count toward the page limit.

Applications must be complete and validated by Grants.gov under HRSA-24-048 before the <u>deadline</u>.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- When you submit your application, you certify that you and your principals⁹ (for example, program director, principal investigator) can participate in receiving award funds to carry out a proposed project. That is, no federal department or agency has debarred, suspended, proposed for debarment, claimed you ineligible, or you have voluntarily excluded yourself from participating.
- If you fail to make mandatory disclosures, we may take an action like those in <u>45</u> <u>CFR § 75.371</u>. This includes suspending or debarring you.¹⁰
- If you cannot certify this, you must include an explanation in *Attachments* 6-15: *Other Relevant Documents*.

⁹ See definitions at <u>eCFR :: 2 CFR 180.995 -- Principal.</u> and <u>eCFR :: 2 CFR 376.995 -- Principal (HHS supplement to government-wide definition at 2 CFR 180.995).</u>

¹⁰ See also 2 CFR parts <u>180</u> and <u>376</u>, <u>31 U.S.C. § 3354</u>, and <u>45 CFR § 75.113</u>.

(See Section 4.1 viii "Certifications" of the R&R Application Guide)

Program Requirements and Expectations

We expect each Autism FIRST award recipient to complete the following major activities:

- Conduct and complete the innovative applied or translational autism intervention research studies using rigorous scientific methodology as described in the application; Recruit, enroll, track, and report study participants using methods that encourage participation in the study by individuals from diverse backgrounds with regard to race/ethnicity, gender/sex, disability, geographic location, and socioeconomic status;
- Submit and carry out a dissemination plan for the distribution of research findings and products to study participants, scientific, professional, and lay audiences; including a timeline for implementation. Dissemination activities include, but are not limited to, peer-reviewed articles, manuscripts, conference presentations, newsletter articles, webcasts, fact sheets, infographics, policy briefs, websites, and social media posts, as appropriate;
- Produce at least **three** peer-reviewed publications;
- Present findings at the End of Project Presentation (Research Festival) to MCHB staff; and
- Measure and track program performance on key activities and program objectives. This includes Discretionary Grants Information System (DGIS) measures on Health Equity, Research, and Products and Publications. For more information on these measures, please see the <u>Reporting</u> section.

Program-Specific Instructions

Include application requirements and instructions from Section 4 of the *R&R Application Guide* (budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract).

i. Project Abstract

Use the Standard OMB-approved Project Abstract Summary Form that you'll find in the workspace application package. Do not upload the abstract as an attachment or it may count toward the page limit. See Form Alert in Section IV.1 Application Package. For information you must include in the Project Abstract Summary Form, see Section 4.1.ix of the *R&R Application Guide*.

Include the information requested at the top of the abstract. Because the abstract is often distributed to provide information to the public and Congress, be clear, accurate, concise, and do not refer to other parts of the application. Briefly state the principal

needs and problem, goals, proposed data sets including study population(s), planned coordination, anticipated products, and plans for evaluation.

Provide the information below in the Project Abstract field:

- PROBLEM: Briefly state the needs and problems that are addressed by the project, including the project's relationship to <u>MCHB Strategic Research</u> <u>Issues</u>.
- GOAL(S) AND OBJECTIVES: Identify the major goal(s) and objectives for the period of performance. Typically, the goal is stated in a sentence or paragraph, and the objectives are presented in a numbered list.
- PROPOSED DATA SETS AND PLANNED POPULATION(S): Briefly describe the research design and methods within the abstract and include data collection methods and participant information (i.e., age range and demographic background of planned population) for the project that you propose.
- PRODUCTS: Provide a brief description of the anticipated products of this project, including how project activities and findings will be distributed.
- EVALUATION: Briefly describe the evaluation methods used to assess program outcomes as well as the effectiveness and efficiency of the project in attaining goals and objectives.
- KEY TERMS: At the end of your abstract, include the following **key terms** found in <u>Appendix D</u> to describe: (a) your project (maximum of 10 content terms), (b) planned populations (select all that apply), and (c) age ranges (select all that apply).

NARRATIVE GUIDANCE

The following table provides a crosswalk between the narrative language and where each section falls within the review criteria. Make sure you've addressed everything. We may consider any forms or attachments you reference in a narrative section during the merit review.

Narrative Section	Review Criteria
I. Specific Aims:	Criterion 1: Need
1) Need	Criterion 2: Response
2) Significance	
3) Goals and Hypotheses	

Narrative Section	Review Criteria
II. Methodology/Research Strategy:1) Study Design/Approach	Criterion 3: Study Design/Approach Criterion 4: Impact
2) Scientific Innovation and Importance	
III. Impact and Dissemination	Criterion 4: Impact
1) Public Health Impact	
2) Publication and Dissemination Plan	
IV. Organizational Information/Environment	Criterion 5: Resources/Capabilities
1) Organizational Facilities and Other Resources	
2) Qualifications of Research Team's Key Personnel	
Budget and Budget Justification	Criterion 6: Support Requested
V. Feasibility	Criterion 7 Program Assurances
1) Proposed Sequence or Timetable	
2) Resolution of Challenges	
VI. Evaluation and Technical Support Capacity	Criterion 7 Program Assurances
VII. Protection of Human Subjects	Criterion 7 Program Assurances
VIII. Planned Enrollment	Criterion 7 Program Assurances

ii. Project Narrative

This section must describe all aspects of the proposed project. Make it brief and clear.

Provide the following information in the following order. Please use the section headers.

I. Specific Aims – Corresponds to Section V's Review Criteria #1 <u>Need</u> and #2 <u>Response</u>

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

1) Need -- Corresponds to Section V's Review Criterion #1 Need

- Briefly describe your study population's unmet health needs and identify health disparities facing the study population;
- If relevant, include the social determinants of health (SDOH) and health inequities of the population that your project will address;
- Explain the problems and research gaps that your study will address; and
- Briefly outline how your project aligns with MCHB's <u>Blueprint for Change</u>, with an emphasis on promoting health equity, family and child well-being and quality of life, and access to services.

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

- Provide an overview of the existing literature that demonstrates the importance of your study's research objectives;
- Identify how your results may improve care and/or the ways that services are organized and delivered; and/or
- Describe how your study will advance health equity in ASD/DD populations.

3) Goals and Hypotheses -- Corresponds to Section V's Review Criterion #2 Response

a) Goals and Objectives

• Briefly state the goals and objectives of your research study and what you will accomplish during the grant cycle that address the problems, barriers, and gaps identified. The study objectives should be specific, measurable, achievable, relevant, time bound, inclusive, and equitable (SMARTIE).

b) Hypotheses and Specification of Variables

- Briefly state the specific questions that your study will answer. These should include predictions of findings (hypotheses), as well as the reasoning behind your predictions; and
- Include a summary table of the relevant variables. You should define your variables, including the type of variables (e.g., independent, dependent, mediating, and moderating).
 - You can create a graphic describing the theoretical model, conceptual framework, or the variables' relationships;
 - o Make sure that any relationships shown in graphics are consistent with your variable table, the statement of hypotheses, and the plan for data analysis.

II. Methodology/Research Strategy – Corresponds to Section V's Review Criteria #3 <u>Study Design/Approach</u> and #4 <u>Impact</u>

Organize the Methodology section in the specified order using the instructions provided below. Start each section with the appropriate section heading – Study Design/Approach, and Scientific Innovation and Importance. Cite relevant publications in the Methodology section and provide the full reference in the Bibliography and References Cited section.

The Methodology section is recommended to be no more than 12 pages in length.

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

- Describe the proposed interventions, overall study design, methodology, and analyses you will use to accomplish the specific aims of the project;
- Describe the procedures for data collection and instrumentation, as appropriate;
- Include how you will collect, analyze, and interpret the data, as well as any plans to coordinate data collection and analysis for multi-sites, as appropriate;
- Describe your enrollment and recruitment plan for your planned study participant population, including:
 - Demographic information on the planned population (e.g., race/ethnicity, gender/sex, disability, geographic location, and socioeconomic status;
 - A description of strategies for encouraging enrollment from a wide range of people from various backgrounds and communities.

Address issues regarding sampling design and randomization, as appropriate. Include expected enrollment number and power analyses, as appropriate;

- Letters of Agreement from study sites supporting recruitment must be included in Attachment 1, if applicable; and
- Describe your plan to partner with at least one program or institution that works with underserved populations to ensure cultural competency, recruit study participants, and disseminate research findings.
- Preliminary Studies: Include information on preliminary studies as part of the Section (1) Study Design section. Provide a description of the PD/PI's preliminary studies pertinent to this application. This information will also help to establish the experience and competence of the investigator to pursue the proposed project. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.

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

- Explain how your project will add scientific knowledge, expand the evidence base, improve technical capability and/or clinical practice in the ASD/DD field; and
- Describe any novel, including refined or improved, theoretical concepts, approaches or methodologies, policies, instrumentation, or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, policies, or interventions.

III. Impact and Dissemination–Corresponds to Section V's Review Criterion # 4 Impact

1) Public Health Impact

- Describe the public health impact that study results may have, e.g., how the study can affect care delivery and/or the health and well-being of ASD/DD populations;
- Describe how the study results will be of regional and national significance, including their generalizability; and
- Discuss the potential scalability/sustainability of this project.

2) Publication and Dissemination Plan

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

- Provide an action plan that describes:
 - The number and foci of your proposed peer-reviewed publications, as well as the names and impact factor of the journals where you plan to submit your papers;
 - How you will distribute findings, reports, and/or project results broadly; and
 - How you will inform study participants of the results of your research.
- *IV.* Organizational Information/ Environment– Corresponds to Section V's Review Criterion # 5 <u>Resources/Capabilities</u>

This information is used to judge the ability of your organization, your organization's resources, and staff to complete your study. NOTE: The SF-424 R&R Table of Contents Page refers to Environment as "Facilities & Other Resources." This section on "Environment" can be included as an attachment in the Other Project Information Form, box 10, or included as part of the research narrative.

1) Organizational Facilities and Other Resources

- Identify the facilities you will use (laboratory, clinical setting, computer lab, office, and/or other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work;
- Discuss ways in which the study will benefit from your organization's scientific environment; For Early-Stage Investigators,¹¹ describe institutional investment in the success of the investigator. Examples may include computer and software support, collegial support, such as the availability of organized peer groups, logistical support, such as administrative management and oversight, and financial support, such as protected time for

¹¹ An Early Stage Investigator is a program director / principal investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a federal independent research award. (https://grants.nih.gov/policy/early-investigators/index.htm)

research with salary support; and if there are multiple sites, describe each site's resources.

2) Qualifications of Research Team's Key Personnel

- The merit review panel will use the following to evaluate the research team's qualifications and research strategy: (a) Preliminary Studies in Section II; Methodology/Research Strategy 2) Study Design; (b) Staffing Plan in Budget Narrative; and (c) Biographical Sketches of key personnel.
- Please use the MCHB biographical sketch form found here: <u>MCHB</u> <u>Research Applicants Bio sketch 2023</u> NOTE: While the biographical sketch form does not count against your total page limitation it should not exceed **five** pages per person. This information allows MCHB to determine to what extent individuals of different backgrounds are expected to be enrolled in the proposed study. This information, in addition to other information including career stage, geographic location of the institution, and educational level, assists MCHB in ensuring that federal grant and cooperative agreement funding opportunities are available to a wide range of people from various backgrounds and communities. A detailed description of information that should be included in the biographical sketches is available in <u>Appendix E.</u>

V. Feasibility – Corresponds to Section V's Review Criterion #7 <u>Program Assurances</u> This section addresses questions around project feasibility. If funded, it is important that the recipient implements and completes the study as proposed and approved.

- 1) Proposed Sequence or Timetable
 - Provide a sequence or timetable for the project that includes the steps that you will take to achieve each of the activities proposed during the entire period of performance. Use a timeline that includes each activity and identifies responsible staff.
- 2) Resolution of Challenges
 - Discuss any challenges that you might encounter in designing and implementing the research activities described in the Study Design/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 your strategy to reach planned enrollment levels and how you will address the management of any high-risk aspects or anticipated challenges of the proposed goals; and
- If appropriate, point to any procedures, situations, or materials that may be harmful to the study participants, and precautions you would exercise.
- VI. Evaluation and Technical Support Capacity Corresponds to Section V's Review Criterion #7, <u>Program Assurances</u>
 - Describe the systems and processes that will support your organization's performance management tracking and how the organization will collect and manage data;
 - As appropriate, describe the strategy to collect, analyze, and track data to measure process and impact/outcomes, and explain how the data will be used to inform program development and service delivery;
 - Describe the research team's current experience, skills, and knowledge that will contribute to the success of your project; and
 - Describe any potential obstacles that may affect implementing the program performance evaluation, and your plan to address those obstacles.

VII. Protection of Human Subjects – Corresponds to Section V's Review Criterion #7 <u>Program Assurances</u>

- Discuss plans to seek Institutional Review Board (IRB) approval or exemption. IRB approval is not required at the time of submission but must be received prior to the study;
- If awarded, nonexempt human subjects research must comply with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR part 46) (<u>http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html</u>). Refer to instructions provided in HRSA's <u>R&R Application Guide</u>, <u>Appendix:</u> <u>Supplemental Instructions for Preparing the Protection of Human Subjects</u> <u>Section of the Research Plan and Human Subjects Research Policy</u> for specific instructions on preparing the human subjects section of the application; and
- All institutions that are engaged in nonexempt human subjects research as part of the project, including foreign applicants, must be covered by a Federalwide Assurance (FWA) approved by the Office for Human Research Protections (OHRP). Instructions on how to submit an FWA application, if awarded, can be found on OHRP's website at <u>https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index.html</u>.

VIII. Planned Enrollment – Corresponds to Section V's Review Criterion #7 <u>Program</u> <u>Assurances</u>

Provide details about the range of backgrounds and communities of the planned study enrollees. As applicable, information should include study sample totals by:

1) Racial Categories

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

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

- Gender/sex distribution within each Ethnic Category (Hispanic Heritage);
- Total distribution by Ethnic Category (Hispanic Heritage);
- The "Ethnic Category (Hispanic Heritage): Total Sample" must be equal to the "Racial Categories: Total Sample." List any proposed racial/ethnic subpopulations; and
- The "Total Sample" means the number of subjects in the dataset that will be used in your analysis. They will be reported in two ways in the table: by self-reported "Ethnic Category (Hispanic Heritage)" and by self-reported "Racial Categories."

3) Disability Status

4) Geographic Location

- Urban
- Rural

5) Socioeconomic status

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

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 *R&R Application Guide* directions may differ from those on Grants.gov.

Follow the instructions in Section 4.1.iv Budget of the *R&R Application Guide* and any specific instructions listed in this section. Your budget should show a well-organized plan.

Reminder: The total project or program costs are all allowable (direct and indirect) costs used for the HRSA activity or project. This includes costs charged to the award and non-federal funds used to satisfy a matching or cost-sharing requirement (which may include Maintenance of Effort (MOE), if applicable).

Program Income

You must use any program income you generate from awarded funds for approved project-related activities. Use program income under the addition alternative (45 CFR § 75.307(e)(2)). Find post-award requirements for program income at <u>45 CFR § 75.307</u>.

Specific Instructions

As required by the <u>Consolidated Appropriations Act, 2023 (P.L. 117-328)</u>, Division H, § 202, "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." Effective January 2024, the salary rate limitation is \$221,900. As required by law, salary rate limitations may apply in future years and will be updated.

iv. Budget Justification Narrative

See Section 4.1.v. of the R&R Application Guide.

In addition, the Autism FIRST program requires the following:

Within Personnel Costs, include the staffing plan by providing position descriptions (roles, responsibilities, and qualifications of proposed project staff) in the "Budget Justification" section that you will add to SF-424 R&R Budget Period – Section F – K Form, Box K. This staffing plan should describe the complementary and integrated expertise of the investigators and show that the leadership approach, governance and organizational structure are appropriate for the project. The staffing plan should reflect the commitment of the research team in conducting and completing the study. (NOTE: A current PI of an MCH Research grant can serve for no more than 10 percent time on a new proposal in a capacity other than as PD/PI). Copies of biographical sketches for all senior/key personnel and other significant contributors must also be submitted as an attached file to each SF-424 R&R Senior/Key Person Profile.

The budget justification should be 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. It is recommended that the biographical sketches should be no more than five pages in length and follow the HRSA font/margin requirements. This OMB form **does not** count against your page limit.

v. Attachments

Provide the following attachments in the order we list them.

Most attachments count toward the <u>application page limit.</u> Indirect cost rate agreement, proof of non-profit status and letters of support are the exceptions. They will not count toward the page limit.

Clearly label each attachment. Upload attachments into the application. Reviewers will not open any attachments you link to.

- 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. Documents
 that confirm actual or pending contractual agreements should clearly describe
 the roles of the subcontractors and any deliverables. Include only letters of
 support that specifically indicate a commitment to the project/program (in-kind
 services, dollars, staff, space, equipment, etc.). Letters of agreement and
 letters of support must be recently signed and dated.
- Attachment 2: List of Citations for Key Publications.
 A list of citations for key publications by the key personnel that are relevant to the proposal can be included. Do not include unpublished theses, or abstracts/ manuscripts submitted (but not yet accepted) for publication. In consideration of the 60-page limitation, a list of select citations only may be included.
- Attachment 3: Surveys, Questionnaires, Data Collection Instruments, Clinical Protocols.
 Surveys, questionnaires, other data collection instruments, clinical protocols, and informed consent documents may be submitted as an attachment as necessary, keeping in mind that these count in the 60-page limitation.
- Attachment 4: Explanation on Delinquent Federal Debt, if applicable.
- Attachment 5: Proof of Non-profit status
- Attachments 6–15: Other Relevant Documents

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

A UEI is required to apply for this funding. You must register in the <u>SAM.gov</u> to receive your UEI.

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You cannot use a DUNS number to apply. For more details, visit the following webpage: <u>General Service Administration's UEI Update</u>

After you register with SAM, maintain it. Keep your information updated when you have: an active federal award, application, or plan that an agency is considering.¹²

When you register, you must submit a notarized letter naming the authorized Entity Administrator.

We will not make an award until you comply with all relevant SAM requirements. If you have not met the requirements by the time we're ready to make an award, we will deem you unqualified and award another applicant.

If you already registered on Grants.gov, confirm that the registration is active and that the Authorized Organization Representative (AOR) has been approved.

To register in Grants.gov, submit information in two systems:

- System for Award Management (SAM) (SAM Knowledge Base)
- Grants.gov

Effective March 3, 2023, individuals assigned a SAM.gov <u>Entity Administrator</u> role must be an employee, officer, or board member, and cannot be a non-employee. This change is to ensure entities are in control of who has permission to control roles within their entity.

Here's what this means:

- Entity Administrators assigning roles to non-employees will only be able to assign a Data Entry role or lower.
- Any entities assigning Entity Administrator roles using an Entity Administrator Role Request Letter (formerly called "notarized letter") will no longer be able to assign the Entity Administrator role to a non-employee.
- Entity Administrator roles assigned to non-employees will be converted to Data Entry roles. With a Data Entry role, non-employees can still create and manage entity registration data entry but cannot manage roles.

If you are an entity using a non-employee or if you are a non-employee working with an entity to manage registrations, please read (and share) <u>more about this change on the BUY.GSA.gov blog</u> to know what to expect.

For more details, see Section 3.1 of the *R&R Application Guide*.

¹² Unless 2 CFR § 25.110(b) or (c) exempts you from those requirements or the agency approved an exemption for you under 2 CFR § 25.110(d)).

Note: Allow enough time to register with SAM and Grants.gov. We do not grant application extensions or waivers if you fail to register in time.

4. Submission Dates and Times

Application Due Date

Your application is due on *April 3, 2024, at 11:59 p.m. ET*. We suggest you submit your application to Grants.gov at least 3 calendar days before the deadline to allow for any unexpected events. See the *R&R Application Guide's* Section 8.2.5 – Summary of emails from Grants.gov.

5. Intergovernmental Review

Autism FIRST does not need to follow the terms of <u>Executive Order 12372</u> in 45 CFR part 100.

See Section 4.1 ii of the *R&R Application Guide* for more information.

6. Funding Restrictions

The General Provisions in Division H of the <u>Consolidated Appropriations Act, 2023 (P.L.</u> <u>117-328</u>) apply to this program. See Section 4.1 of the *R&R Application Guide* for information. Note that these and other restrictions will apply in fiscal years that follow, as the law requires.

Program-specific Restrictions

You must have policies, procedures, and financial controls in place. Anyone who receives federal funding must comply with legal requirements and restrictions, including those that limit specific uses of funding.

- Follow the list of statutory restrictions on the use of funds in Section 4.1 (**Funding Restrictions**) of the *R&R Application Guide.* We may audit the effectiveness of these policies, procedures, and controls.
- 2 CFR § 200.216 prohibits certain telecommunications and video surveillance services or equipment. For details, see the <u>HRSA Grants Policy Bulletin Number:</u> <u>2021-01E</u>.

If funded, for-profit organizations are prohibited from earning profit from the federal award (45 CFR § 75.216(b)).

V. Application Review Information

1. Review Criteria

We review your application on its technical merit. We have measures for each review criterion to help you present information and to help reviewers evaluate the applications.

We use seven review criteria to review and rank Autism FIRST applications. Here are descriptions of the review criteria and their scoring points.

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

Criterion 1: NEED (10 points) – Corresponds to Section IV's Specific Aims 1)Need

The extent to which the application:

- Describes the gap in autism/DD-related research that the proposed study will address;
- States clearly the scientific rationale for this project;
- Describes the health disparities and unmet health needs of the study population; and
- Aligns with MCHB's <u>Blueprint for Change</u>, with an emphasis on promoting health equity, family and child well-being and quality of life, and access to services.

Criterion 2: RESPONSE (20 points) – Corresponds to Section IV's <u>Specific Aims</u>: 2) <u>Significance</u> and 3) <u>Goals and Hypotheses</u>

Significance (10 points)

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

• The application adequately addresses health inequities faced by underserved populations with ASD/DD, and the study has the potential to advance health equity among children, adolescents, and young adults with ASD/DD.

Goals and Hypotheses (10 points)

The extent to which:

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

Criterion 3: Study Design/Approach (30 points) – Corresponds to Section IV's II. <u>Methodology/Research Strategy</u> 1) <u>Study Design/Approach</u>.

Study Design/Approach (10 points)

The extent to which:

- The overall research strategy, study design, statistical methodology, and analyses are clearly described, well-reasoned, and suitable to complete the project's specific aims;
- The method of randomization, if used, is clearly described, and proper controls are included;
- Major threats to the design's internal and external validity have been adequately acknowledged and addressed; and
- The project assures cultural competence in the planning and implementation of the research project.

Population Description, Sampling, and Recruitment (10 points)

- The study population is clearly described (e.g., race/ethnicity, gender/sex, disability, geographic location, socioeconomic status);
- The eligibility criteria for entering the study are well defined;

- The sampling design is appropriate and includes an adequate and justified sample size. The expected differences between groups are defined by statistical and clinical significance;
- The recruitment plan is clearly described and feasible to complete within the period of performance, given recruitment methods; and the letters of agreement adequately demonstrate the support of recruitment at the study sites.

Data Collection (5 points)

The extent to which:

- The instruments that have been selected or developed are appropriate, reliable, and valid (i.e., psychometric properties have been tested); and
- Any self-reported data can provide convincing validity for intended measurements (e.g., self-reported blood pressure, parent-reported anthropometric data).

Plan for Data Analysis (5 points)

The extent to which:

- Plans for data analysis are adequately described including the rationale for the sequence of steps to be taken;
- The plans are appropriate given the nature of the data, design, and sampling; and
- Sufficient time is allocated for data cleaning, management, and analysis.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's Methodology: <u>Scientific</u> <u>Innovation and Importance</u> and <u>Impact</u>

1) Scientific Innovation and Importance (5 points)

- 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 and their families as appropriate, if the aims of the project are achieved;
- The application challenges and seeks to shift current research or clinical practice paradigms by enhancing existing or applying new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions; and
- The findings will be generalizable and are of regional or national significance and/or scope, and likely to exert a sustained influence on the research and practice field(s) involved.

2) Public Health Impact and Dissemination (5 points)

The extent to which:

- The findings will be generalizable and are of regional or national significance and/or scope, and likely to exert a sustained influence on the research and practice field(s) involved;
- The expected outcomes are likely to help improve the health and/or wellbeing of children, adolescents, and young adults with ASD/DD, particularly those in underserved populations;
- There is a feasible and appropriate publication and dissemination plan described including a plan for publishing at least three peer-reviewed publications; and
- The application clearly describes a plan to advance the transfer of findings into practice by disseminating findings and reports to key audiences, including study participants, researchers, providers, State Title V, and children with special health care needs programs and other program(s) serving MCH populations, policymakers, families, and the general public.

Criterion 5: RESOURCES/CAPABILITIES (15 points) – Corresponds to Section IV's <u>Organizations Information/Environment</u> <u>Resources/Capabilities</u>

1) Organizational Capacities (5 points)

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, the collaborative arrangements, and available populations.

2) Qualifications of Key Personnel (10 points)

- The Key/Senior Support Personnel Profiles and Biographical sketches indicate that the Principal Investigator (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.

Criterion 6: SUPPORT REQUESTED (5 points) – Corresponds to Section IV's <u>Budget</u> <u>and Budget Justification</u>

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 and budget line items are well described and supported in the budget justification;
- The time allocated to key personnel is realistic and appropriate to achieve project objectives; and
- Other current and pending support is clearly described, as applicable. (Note: A current PI of an Office of Epidemiology and Research/Division of Research, Research award (including a No Cost Extension (NCE) year) can serve for no more than 10 percent time on a new MCH Research proposal).

Criterion 7: PROGRAM Assurances (10 points) - Corresponds <u>V Feasibility; VI.</u> <u>Evaluation and Technical Support Capacity, VII. Protection of Human Subjects and VIII.</u> <u>Planned Enrollment</u>

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.

1) **Proposed timeline and evaluation (6 points)**

The extent to which:

- The proposed project provides a clear, detailed, and feasible timeline to be conducted within the proposed timeframe;
- Plans are in place to determine if the project objectives are being met according to the timeline; and
- The application anticipates and addresses potential barriers to project progress.

2) Human Subjects Protections (4 points)

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

2. Review and Selection Process

Subject matter experts provide an impartial evaluation of your application. Then, they pass along the evaluations to us, and we decide who receives awards. See Section 5.3 of the *R&R Application Guide* for details. We consider the following when selecting applications for award:

- How high your application ranks
- Funding availability
- Risk assessments
- Other pre-award activities, as described in Section V.3 of this NOFO

3. Assessment of Risk

If you have management or financial instability that directly relates to your ability to carry out statutory, regulatory, or other requirements, we may decide not to fund your high-risk application (<u>45 CFR § 75.205</u>).

First, your application must get a favorable merit review. Then we:

- Review past performance (if it applies)
- Review audit reports and findings
- Analyze the cost of the project/program budget
- Assess your management systems
- Ensure you continue to be eligible
- Make sure you comply with any public policies.

We may ask you to submit additional information (for example, an updated budget) or to begin activities (for example, negotiating an indirect cost rate) as you prepare for an award.

However, even at this point, we do not guarantee that you will receive an award. After a full review, we will decide whether to make an award, and if so, if special conditions are required, and what level of funding is appropriate.

Award decisions are discretionary and final. You cannot appeal them to any HRSA or HHS official or board.

As part of this review, we use SAM.gov Entity Information <u>Responsibility / Qualification</u> (formerly named FAPIIS) to check your history for all awards likely to be over \$250,000. You can comment on your organization's information in SAM.gov. We'll consider your comments before making a decision about your level of risk.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NOA) is issued on or around the <u>start date</u> listed in the NOFO. See Section 5.4 of the *R&R Application Guide* for more information.

2. Administrative and National Policy Requirements

See Section 2.1 of the R&R Application Guide.

If you receive an NOA and accept the award, you agree to conduct the award activities in compliance/accordance with:

- All provisions of <u>45 CFR part 75</u>, currently in effect.
- The termination provisions in <u>45 CFR 75.372</u>. No other specific termination provisions apply.
- Other federal regulations and HHS policies in effect at the time of the award. In particular, the following provision of 2 CFR part 200, which became effective on or after August 13, 2020, is incorporated into this NOFO: <u>2 CFR § 200.301</u>
 <u>Performance measurement.</u>
- Any statutory provisions that apply
- The <u>Assurances</u> (standard certification and representations) included in the annual SAM registration.

Accessibility Provisions and Non-Discrimination Requirements

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to this when you register in SAM.gov. You must also submit an Assurance of Compliance (<u>HHS-690</u>). To learn more, see the <u>HHS Office for Civil Rights website</u>.

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

The HRSA Office of Civil Rights, Diversity, and Inclusion (OCRDI) offers technical assistance, individual consultations, trainings, and plain language materials to supplement OCR guidance and assist HRSA recipients in meeting their civil rights obligations. Visit <u>OCRDI's website</u> to learn more about how federal civil rights laws and accessibility requirements apply to your programs, or contact OCRDI directly at <u>HRSACivilRights@hrsa.gov</u>.

Executive Order on Worker Organizing and Empowerment

<u>Executive Order on Worker Organizing and Empowerment (E.O. 14025)</u> encourages you to support worker organizing and collective bargaining. Bargaining power should be equal between employers and employees.

This may include developing policies and practices that you could use to promote worker power. Describe your plans and activities to promote this in the application narrative.

Subaward Requirements

If you receive an award, you must follow the terms and conditions in the NOA. You'll also be responsible for how the project, program, or activity performs; how you and others spend award funds; and all other duties.

In general, subrecipients must comply with the award requirements (including public policy requirements) that apply to you. You must make sure your subrecipients comply with these requirements. <u>45 CFR § 75.101 Applicability</u> gives details.

Data Rights

All publications you develop or purchase with award funds must meet program requirements.

You may copyright any work that's subject to copyright and was developed, or for which ownership was acquired, under an award.

However, we reserve a royalty-free, nonexclusive, and irrevocable right to your copyright-protected work. We can reproduce, publish, or otherwise use the work for federal purposes and allow others to do so. We can obtain, reproduce, publish, or otherwise use any data you produce under the award and allow others to do so for federal purposes. These rights also apply to works that a subrecipient develops.

Human Subjects Protection

All research that was commenced or ongoing on or after December 13, 2016, and is within the scope of subsection 301(d) of the Public Health Service Act is deemed to be issued a Certificate of Confidentiality (Certificate) through and is therefore required to protect the privacy of individuals who are subjects of such research. As of March 31, 2022, HRSA will no longer issue Certificates as separate documents. More information

about HRSA's policy about Certificates can be found via this link to HRSA's website.

3. Reporting

Award recipients must comply with Section 6 of the *R&R Application Guide* and the following reporting and review activities:

 DGIS Performance Reports Available through the Electronic Handbooks (EHBs), the Discretionary Grant Information System (DGIS) is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report annually, by the specified deadline.

Please be advised the administrative forms and performance measures for MCHB discretionary grants have been updated and are currently undergoing OMB approval. The new performance measures are intended to align data collection forms more closely with current program activities and include common process and outcome measures as well as program-specific measures that highlight the unique characteristics of discretionary grant/cooperative agreement projects that are not already captured. Recipients will only complete forms in this package that are applicable to their activities, to be confirmed by MCHB after OMB approval. The proposed updated forms are accessible at <u>https://mchb.hrsa.gov/data-research/discretionary-grants-information-system-dgis</u>.

Type of Report	Reporting Period	Available Date	Report Due Date
a) New Competing Performance Report	9/1/2024-8/31/2027 (administrative data and performance measure projections, as applicable)	Period of performance start date	120 days from the available date
b) Non-Competing Performance Report	9/1/2024-8/31/2025 9/1/2025-8/31/2026	Beginning of each budget period (Years 2– 5, as applicable)	120 days from the available date
c) Project Period End Performance Report	9/1/2026-8/31/2027	Period of performance end date	90 days from the available date

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- Federal Financial Report. The Federal Financial Report (SF-425) is required. The report is an accounting of expenditures under the project that year. Financial reports must be submitted electronically. Visit <u>Reporting Requirements</u> <u>| HRSA</u>. More specific information will be included in the NOA.
- 3) Progress Report(s). The recipient must submit a progress report to us annually via the Non-Competing Continuation (NCC) 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. The NOA will provide details.
- 4) **Other Required Reports and Products:** The recipient must submit a comprehensive final report narrative after the end of the project.
- 5) Integrity and Performance Reporting. The NOA will contain a provision for integrity and performance reporting in SAM.gov Entity Information <u>Responsibility</u> / <u>Qualification</u> (formerly named FAPIIS), as <u>45 CFR part 75 Appendix I, F.3.</u> and <u>45 CFR part 75 Appendix XII</u> require.

VII. Agency Contacts

Business, administrative, or fiscal issues:

David Colwander Grants Management Specialist Division of Grants Management Operations, OFAM Health Resources and Services Administration Call: 301-443-7858 Email: <u>DColwander@hrsa.gov</u>

Program issues or technical assistance:

Emmie Perchak, MPH, MCD & Sibil Varghese, MPH Public Health Analysts, Office of Epidemiology and Research Attn: Autism FIRST HRSA-24-048 Maternal and Child Health Bureau Health Resources and Services Administration Call: 301-443-0714 & 224-448-9950 Email: <u>AutismFirst@hrsa.gov</u>

You may need help applying through Grants.gov. Always get a case number when you call.

Grants.gov Contact Center (24 hours a day, 7 days a week, excluding federal holidays) Call: 1-800-518-4726 (International callers: 606-545-5035) Email: <u>support@grants.gov</u> <u>Search the Grants.gov Knowledge Base</u>

Once you apply or become an award recipient, you may need help submitting information and reports through <u>HRSA's Electronic Handbooks (EHBs</u>). Always get a case number when you call.

HRSA Contact Center (Monday – Friday, 7 a.m. – 8 p.m. ET, excluding federal holidays) Call: 877-464-4772 / 877-Go4-HRSA TTY: 877-897-9910 Electronic Handbooks Contact Center

The EHBs login process changed on May 26, 2023, for applicants, recipients, service providers, consultants, and technical analysts. To enhance EHBs' security, the EHBs now uses **Login.gov** and **two-factor authentication**. Applicants, recipients, service providers, consultants, and technical analysts must have a Login.gov account for the new login process. For step-by-step instructions on creating a Login.gov account refer to the <u>EHBs Wiki Help page</u>.

VIII. Other Information

Technical Assistance

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

Tips for Writing a Strong Application

See Section 4.7 of the R&R Application Guide.

Appendix A: Strategic Research Issues

Strategic Research Issues (SRI)

Full SRI Guidance

Guiding Principles

These are themes that inform MCHB's research goals. When conducting research, all funded research projects should keep the following in mind:

Principle 1: Incorporate social determinants of health and health equity frameworks into MCH research.

Principle 2: Improve the quality and accessibility of health and community resources and services for mothers, children, and families, especially those of underserved MCH populations.

Principle 3: Strengthen the evidence base for the field of MCH.

Principle 4: Accelerate the coordination, translation, and implementation of evidence-based/evidence-informed research.

Goals

The ways that our funded research aim to create change:

1. Improve the Health System for Mothers and Children

a. Find gaps in the health care system and improve them by changing the system. Changes include using technology, public health data, and the medical home model of care delivery.

2. Promote the Health and Well-Being of Mothers

a. Prevent death and serious injury, and support the well-being of women, before, during and after pregnancy and childbirth.

3. Promote the Health and Well-Being of Children

a. Improve the health of children and youth across the life course, including those with special health care needs, and children with autism and developmental disabilities.

4. Promote the Health and Well-Being of Families

a. Learn about what factors impact family health and how to engage the community.

5. Increase Evidence for Maternal and Child Health Practice

a. Find the strategies, programs, and interventions that work best and how to best measure their impact.

6. Support Innovation and Collaboration in Research

a. Study new technology, methods, and ideas in research, including supporting new researchers with different backgrounds.

Appendix B: Research Program Application Completeness Checklist

Requirement	Yes
Do you meet the <u>eligibility criteria</u> ?	
Did you read the <u>R&R Application Guide?</u>	
Do you have a <u>Unique Entity Identifier (UEI)</u> that's been assigned by System for Award Management (SAM)?	
Did your Authorized Organization Representative (AOR) register in <u>SAM?</u>	
Is your <u>Abstract</u> in plain language, no more than 4,000 characters, and single spaced?	
 Does the <u>Narrative</u> of your application fully address: Background and Significance? Specific Goals and Objectives? Project Design, Methods, and Evaluation? 	
 Plan/Schedule of Implementation and Capability of Applicant? Feasibility? Evaluation and Technical Support Capacity? 	
Protection of Human Subjects?Planned Enrollment?	_
Did you confirm that your application addressed all of the NOFO <u>Review Criteria</u> ?	
Are your <u>budget</u> and <u>budget justification narrative</u> completed accurately and in the yearly funding limit?	
NOTE: The directions offered in the HRSA <u><i>R&R Application Guide</i></u> differ from those offered by <u><i>Grants.gov</i></u> . Please follow the instructions included in the	
<u><i>R&R Application Guide</i></u> and, <i>if applicable</i> , the additional budget instructions in the NOFO	e
Did you clearly label all of your <u>Attachments</u> ?	
Did you include the <u>Biographical Sketches</u> in the Application?	
Do you know your institution's indirect cost rate?	
Did you use no less than 12-point font and are your page margins at least 1 inch wide in the Narrative and Attachment Sections of the Application?	
NOTE: The Biographical Sketches of Key Personnel can have .5" margins.	
Are your pages, including attachments, within the 60-page limit?	
NOTE: Pages which do not count toward the 60-page limit include: Cover Page,	

Letters of Support, Biographical sketches of key personnel and Standard OMB approved forms.

Appendix C: Frequently Asked Questions (FAQs)

1) Where do I find application materials for the Autism Field-Initiated Innovative Research Studies (FIRST) Program?

All application materials are available through Grants.gov.

- 2) **How can I download the complete application package for the NOFO?** You can download the application by searching for the application number HRSA-24-048 on <u>Grants.gov:</u>
 - Click on the hyperlink for HRSA-24-048
 - Click on the last blue tab entitled "PACKAGE."
 - Scroll down and click on the "Preview" hyperlink under the "Actions" column.
 - Select the "Download Instructions" button in the right-hand corner. This will download the application.

3) What is Grants.gov?

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

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

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

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

- 1) Make sure that the Authorized Organization Representative from your university/organization is registered in <u>Grants.gov</u> NOW. This process can take up to 1 month and it is better to complete it and have it out of the way before starting any grant application.
- 2) Read the instructions on <u>Grants.gov</u> carefully and allow time for corrections. Enter information in fields even if it is "0" or the form will remain incomplete. Required fields are highlighted in yellow.
- 3) There are resources available on the Grants.gov website to help you navigate this new system. Please visit <u>Grants.gov</u> to access these resources.
- 4) Key information for <u>budget</u> preparation:
 - With the HRSA SF-424 R&R, report faculty and staff time in calendar month equivalents.

- Budget details about subcontracts are described in a section of the SF-424 R&R called sub-awards.
- Detailed budgets are required for each of the 3 years in the period of performance.

6) Can I get a copy of the NOFO from last year's competition?

 Past funding announcements are not shared in order to avoid confusion among potential applicants. You can find past NOFOs on <u>Grants.gov</u> but the criteria for the Autism FIRST program has changed. Follow instructions provided in this NOFO (HRSA-24-048). All applications for this competition will be reviewed and scored based on the instructions and evaluation criteria outlined in this_NOFO (HRSA-24-048).

7) What types of institutions can apply?

You can apply if your organization is a:

- Public or private entity, including research centers or networks
- Community-based organization
- Tribal (governments, organizations)

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

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

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

9) We are interested in applying for the AUTISM FIRST program. We are wondering if our ideas would be a good fit for the program.

. The purpose of the Autism FIRST Program is to support empirical research that advances the evidence on early screening and interventions to improve the health and well-being of children, adolescents, and young adults with autism and other developmental disabilities across the lifespan. *Applications are expected to demonstrate alignment with:* <u>MCHB strategic research issues</u>; <u>HRSA MCHB Strategic Plan</u>; ; or the Title V performance priority areas. You should highlight how your proposal aligns with the aforementioned priorities listed in this paragraph. All funding decisions are based on scientific merit as determined by an external review committee, and on availability of funds.

10) 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 R&R Application Guide, "any non-federal entity that has never received a negotiated indirect cost rate, (except a governmental department or agency unit that receives more than \$35 million in direct federal funding) may elect to charge a de minimis rate of 10 percent of modified total direct costs (MTDC) which may be used indefinitely." The HRSA R&R Application Guide also contains information on how to negotiate the indirect cost rate.

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

Your institution's indirect cost rate is negotiated by the institution with the U.S. Department of Health and Human Services (HHS). Your sponsored program office will be able to provide further information about the indirect cost rate.

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

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

• The current PD/PI of an active HRSA/MCHB/Office of Epidemiology and Research (OER)/Division of Research (DOR) award can serve for **no more** *than 10 percent time* on a new proposal.

13) Is it possible for postdoctoral fellows to apply as PI for the Autism FIRST Research program if they are affiliated with a university?

The NOFO does not contain language that excludes postdoctoral fellows from serving as PI on the Autism FIRST Research grants. Ultimately, the determination of who may or may not serve as PI depends on the rules of the institution.

14) Can someone who is currently a PI on a grant funded by another agency be a PI on an Autism FIRST Research grant?

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

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

Yes, multiple applications from an organization with the same <u>Unique Entity Identifier</u> (UEI) are allowable if the applications propose separate and distinct projects. For example, different investigators (or research teams) from the same institution can apply for the same funding opportunity.

16) Which format should we follow for the biographical sketch?

Please use the MCHB biographical sketch form found here: <u>MCHB Biographical sketch</u> for Research Applicants 2023.

17) Are there page limits for the submitted application?

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

18) What counts towards the page limits?

The page limit applies to the:

- Project and budget narratives
- Attachments

The page limit does not apply to the following:

- Standard OMB-approved forms (including the new Project Abstract Summary) that are included in the application package
- Indirect Cost Rate Agreement
- Proof of Non-Profit Status
- Letters of commitment and support required in application guide and the NOFO
- Biographical sketches
- Preliminary studies can be included in the Approach section of the Research Strategy, if applicable, and would be included in the recommended 12-page limit for the Methodology Section as described in the narrative. If an application exceeds required page limitations, the pages over the limit will be deleted.

19) Are there any page limitations to the narrative?

There is no page limitation to the narrative. However, MCHB/OER highly recommends the methodology section be no more than 12 pages. Methodology includes: Significance, Innovation, and Approach.

20) Does the Specific Aims section have a page limitation?

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

21) 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.

22) Where can I find information on previous awards for the Autism Research Program?

Information on current and past funded Autism Field-Initiated Research projects can be found on our website. Feel free to search our funded projects at: <u>https://mchb.hrsa.gov/research/projects.asp</u>

23) Who should I talk to if I have further questions?

Please contact:

- For programmatic questions, the Project Officers listed in the NOFO via email.
- For budget questions, the <u>Grants Management Specialist</u> listed in the NOFO via email.

24) Can I ask the program officer listed in the NOFO to read my proposal for their comments and suggestions?

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

Appendix D: Key Terms for Project Abstracts

a) Content Terms (maximum of 10)

Health Care Systems & Delivery

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

Primary Care & Medical Home

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

Insurance & Health Care Costs

- Cost Effectiveness
- Health Care Costs
- Insurance Coverage

Prenatal/Perinatal Health & Pregnancy Outcomes

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

HRSA-24-048 Autism FIRST

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

Behavioral Health & Well-being

- Bullying & Peer Relationships
- Depression

- Behavioral Health & Well-being
- Risk Behaviors
- Smoking
- Stress
- Mental health and 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) Underserved Communities (as many as apply):

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

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

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

- Adolescence (12–18 years)Young Adulthood (19–25 years)

Appendix E: Guidance on Biographical Sketches

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

The following information should be included on all biographical sketches for the PI (required) and all key personnel (optional) according to the chart on the <u>MCHB</u> <u>Biographical sketch form</u>

- Education and Training: List your institution(s), degree(s), start date(s), completion date(s) and the field of study.
- **Race/Ethnicity Data:** Provide race and ethnicity data. The race/ethnicity chart can be modified to include only the relevant rows and columns. This information helps MCHB ensure that federal grant and cooperative agreement funding opportunities are available to diverse populations.
- **Personal Statement**: Briefly describe why you are well suited for your role(s) in this network. The relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise. You may also list up to four peer-reviewed publications that highlight your experience and qualifications for this project.
- **Positions and Honors:** List in chronological order previous positions, ending with your current position. List relevant honors. Include current membership on any federal government public advisory committee.
- **Contribution to Science:** Briefly describe one to three of your most important contributions to science. For each contribution, detail the background that frames the scientific problem, the central finding(s), and the impact of the findings to the field or the how the findings apply to health or technology, and your specific role in the work. For each of contribution, list up to **four** peer-reviewed publications or other relevant products. The description of each contribution should be no longer than half a page, including figures and citations.

Appendix F: Relevant Websites

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

Bright Futures

http://brightfutures.aap.org/

Developing Healthy People 2030 https://health.gov/our-work/national-health-initiatives/healthy-people/healthy-people-2030

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

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

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

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

Making Websites Accessible: Section 508 of the Rehabilitation Act http://www.section508.gov/

National Academy of Medicine https://nam.edu/

National Center for Cultural Competence http://nccc.georgetown.edu/

National Resource Center for Patient/Family-Centered Medical Home (formerly the National Center for Medical Home Implementation) <u>https://medicalhomeinfo.aap.org/Pages/default.aspx</u>

Appendix G: Page Limit Worksheet

The purpose of this worksheet is to give you a tool to ensure the number of pages uploaded into your application is within the specified <u>page limit. (Do not submit this</u> worksheet as part of your application.)

The Standard Forms listed in column 1 do not count against the page limit; however, attachments to the Standard Forms listed in column 2 do count toward the page limit. For example, the Budget Narrative Attachment Form does not count, however the attachment uploaded in that form does count against the page limit.

Standard Form Name (Forms themselves do not count against the page limit)	Attachment File Name (Unless otherwise noted, attachments count against the page limit)	# of Pages Applicant Instruction – enter the number of pages of the attachment to the Standard Form
SF-424 (R&R)	Box 18 SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation (<i>If</i> <i>applicable</i>)	My attachment = pages
R&R Senior/Key Person Profile (Expanded)	Biographical Sketch Attachment (Does not count against the page limit)	Does not count against the page limit
R&R Subaward Budget Attachment(s) Form	Attach up to 10 R&R subaward budget <i>(as</i> <i>applicable)</i>	My attachment = pages
Attachments Form	Attachment 1: Letters of Agreement/Letters of Support (Does not count against the page limit)	Does not count against the page limit
Attachments Form	Attachment 2: List of Citations for Key Publications	My attachment = pages
Attachments Form	Attachment 3: Surveys, Questionnaires, Data Collection Instruments, Clinical Protocols	My attachment = pages

Standard Form Name (Forms themselves do not count against the page limit)	Attachment File Name (Unless otherwise noted, attachments count against the page limit)	# of Pages Applicant Instruction – enter the number of pages of the attachment to the Standard Form
Attachments Form	Attachment 4: Explanation on Deliquent Federal Debt, if applicable	Does not count against the page limit
Attachments Form	Attachment 5: Proof of Non-profit Status (Does not count against the page limit)	Does not count against the page limit
Attachments Form	Attachment 6 Other Relevant Documents	My attachment = pages
Attachments Form	Attachment 7 Other Relevant Documents	My attachment = pages
Attachments Form	Attachment 8 Other Relevant Documents	My attachment = pages
Attachments Form	Attachment 9 Other Relevant Documents	My attachment = pages
Attachments Form	Attachment 10 Other Relevant Documents	My attachment = pages
Attachments Form	Attachment 11 Other Relevant Documents	My attachment = pages
Attachments Form	Attachment 12 Other Relevant Documents	My attachment = pages
Attachments Form	Attachment 13 Other Relevant Documents	My attachment = pages
Attachments Form	Attachment 14 Other Relevant Documents	My attachment = pages
Attachments Form	Attachment 15 Other Relevant Documents	My attachment = pages
Project/Performance Site Location Form	Additional Performance Site Location(s) (<i>as</i> <i>applicable)</i>	My attachment = pages

Standard Form Name (Forms themselves do not count against the page limit)	Attachment File Name (Unless otherwise noted, attachments count against the page limit)	# of Pages Applicant Instruction – enter the number of pages of the attachment to the Standard Form
R&R Other Project Information Form	Box 7 – Project Summary/Abstract – Attach Blank document Box 8 - Project Narrative Box 9 - Bibliography/References Cited Box 10 - Facilities and Other Resources Box 11 - Equipment Box 12 - Other attachments	My attachment = pages
R&R Budget Form	Additional Senior Key Persons (as applicable) Box L - Budget Justification	My attachment = pages
# of Pages Attached to S	Standard Forms	Applicant Instruction: Total the number of pages in the boxes above.
Page Limit for HRSA-24-048 is 60 pages		My total = pages