U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Maternal and Child Health Bureau
Office of Epidemiology and Research
Maternal and Child Health Research Network Program

UT2 Autism Intervention Research Network on Physical Health (AIR-P)

Funding Opportunity Number: HRSA-20-054
Funding Opportunity Type(s): New
Assistance Listings (CFDA) Number: 93.877

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2020

Application Due Date: April 30, 2020

MODIFIED on April 3, 2020: Due to the COVID-19 pandemic, HRSA is extending the application due date from April 13, 2020 to April 30, 2020.

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

Issuance Date: January 13, 2020

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2020 UT2 Autism Intervention Research Network on Physical Health (AIR-P) Program. The purpose of this program is to establish and maintain an interdisciplinary, multicenter research forum for scientific collaboration and infrastructure building. This Research Network will provide national leadership in research to advance the evidence base on effective interventions for children and adolescents with autism spectrum disorder and other developmental disabilities (ASD/DD) as they transition to adulthood across the lifespan, with a focus on addressing physical health and well-being.

Funding Opportunity Title:	UT2 Autism Intervention Research Network on Physical Health (AIR-P)
Funding Opportunity Number:	HRSA-20-054
Due Date for Applications:	April 30, 2020
Anticipated Total Annual Available FY 2020 Funding:	$3,000,000
Estimated Number and Type of Award(s):	Up to one cooperative agreement
Estimated Award Amount:	Up to $3,000,000 total cost per year dependent on the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2020 through August 31, 2025 (5 years)
Eligible Applicants:	Eligible applicants include any domestic public or private entity, including research centers or networks. Domestic faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply. See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.

Application Guide

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

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Thursday, January 23, 2020
Time: 1–2 p.m. ET
Call-In Number: 1-800-369-1830
Participant Code: 4796126
Weblink: https://hrsa.connectsolutions.com/autism_intervention_research/

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

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

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the UT2 Autism Intervention Research Network on Physical Health (AIR-P) Program. The purpose of this program is to establish and maintain an interdisciplinary, multicenter research platform for scientific collaboration and infrastructure building. The Research Network will provide national leadership in research to advance the evidence base on effective interventions[1] for children and adolescents with autism spectrum disorder and other developmental disabilities (ASD/DD), with a focus on addressing physical health and well-being across the lifespan. Physical health may include, but is not limited to, medical, dental, visual, nutrition, and speech/hearing components.

The Research Network will determine the evidence-based practices for interventions to improve the physical health of individuals with ASD/DD across the lifespan, develop guidelines for those interventions, and disseminate information related to such research and guidelines as authorized by the Autism Collaboration, Accountability, Research, Education, and Support Act of 2019 (Autism CARES Act).

ASD/DD initiatives focused on behavioral health will not be considered for this notice of funding opportunity (NOFO). A separate NOFO is available for the Autism Intervention Research Network on Behavioral Health (AIR-B) Program (Funding opportunity number HRSA-20-055).

The Research Network will:

- Lead, promote, and coordinate national research activities to improve the physical health and well-being of children and adolescents with ASD/DD as they transition to adulthood across the lifespan, especially those from underserved populations with limited access to effective ASD/DD treatments;[2,3]
- Develop and maintain an infrastructure to support the design of a portfolio of an interdisciplinary research focuses on fostering the implementation of multi-site intervention research studies, translating research to policy and practice;
- Provide an environment for mentoring and training the next generation of diverse clinical and non-clinical researchers in applied and translational autism research and practice;[4]

[1] For the purpose of this NOFO, an "intervention" is defined as a manipulation of the subject or subject's environment to modify one or more health-related biomedical or behavioral processes and/or endpoints or outcomes for children and adolescents with ASD/DD. Examples include, but are not limited to, delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior(s) (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and diagnostic strategies. A manipulation or task would be regarded as an intervention if it is used to modify a health-related biomedical or behavioral outcome. A manipulation or task used expressly for measurement, and not modification, would not be considered as an intervention. National Institutes of Health, Office of Extramural Research. Frequently Asked Questions: NIH clinical trial definition. Available at: https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5226. Accessed August 27, 2019.

[2] In this NOFO, underserved populations include low-income, racial/ethnic minorities, immigrant, female, tribal, geographically remote and other groups that are not already well-represented in current research on children and adolescents with ASD/DD.

[3] The Health Resources and Services Administration's Maternal and Child Health Bureau also funds the Autism Transitions Research Project, please see https://mchb.hrsa.gov/research/project_info.asp?ID=318.

[4] Consistent with HRSA's mission, training and mentoring of diverse emerging investigators fosters the development of a pipeline of ASD/DD researchers who are critical in promoting the sustainability of autism research and the work of the network.

- Address, where applicable, the U.S. Department of Health and Human Services' (HHS) and Health Resources and Services Administration (HRSA) priorities, namely, mental health, opioid use disorder, prescription drug pricing, maternal health, and telehealth; and
- Indicate how study findings will further develop the evidence base, where relevant for this program and in alignment with the research and surveillance activities identified in the Autism CARES Act.

For cooperative agreement activities please see **Project Narrative Section IV.**

2. Background

This program is authorized by the Public Health Service Act, § 399BB(f) (42 U.S.C. § 280i-1(f)), as amended. The Research Network is a national multi-site, Research Network focused on building the evidence base for physical health intervention research for children and adolescents with ASD/DD. The Research Network provides national leadership by engaging researchers, practitioners, policymakers and consumers in collaborative, innovative, and multidisciplinary research projects.

Approximately 1 in 40 children in the United States is diagnosed with ASD.[5] ASD is a complex neurodevelopmental disorder.[6] Additionally, 83 percent of children with ASD have at least one co-occurring non-ASD DD.[5] Children and adolescents with ASD experience more physical health problems than those who are typically developing, including seizures, sleep problems, gastrointestinal disorders, nutritional deficiencies, and metabolic conditions.[7,8,9] Consequently, these children and adolescents have greater health services needs which can place a significant financial and emotional burden on their families.[5] Children and adolescents with ASD/DD (including those transitioning to adulthood) from underserved populations encounter persistent disparities in screening, diagnosis, and health service access increasing their vulnerability to adverse health outcomes across the lifespan.[10,11] Given the limited number of evidence-based interventions for improving the physical health of children and adolescents with ASD/DD as they transition to adulthood across the lifespan, especially those from underserved populations, Research Networks are needed to coordinate and provide infrastructure for national autism research activities.[10,12]

[5] Kogan, MD, Vladutiu, CJ, Schieve, LA, et al. The prevalence of parent-reported autism spectrum disorder among US children. 2018, *Pediatrics*, 142(6), e20174161.
[6] American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders V*. Washington, DC: American Psychiatric Publishing; 2013.
[7] Coury D. Medical treatment of autism spectrum disorders. *Curr Opin Neurol*. 2010;23(2):131-136.
[8] Lavelle TA, Weinstein MC, Newhouse JP, Munir K, Kuhlthau KA, Prosser LA. Economic burden of childhood autism spectrum disorders. *Pediatrics*. 2014;133(3):e520-9.
[9] Doshi-Velez F, Ge Y, Kohane I. Comorbidity clusters in autism spectrum disorders: an electronic health record time-series analysis. *Pediatrics.* 2014;133(1):e54–e63. doi:10.1542/peds.2013-0819
[10] Zuckerman KE, Lindly OJ, Reyes NM, Chavez AE, Macias K, Smith KN, Reynolds A. Disparities in diagnosis and treatment of autism in Latino and non-Latino white families. *Pediatrics*. 2017; 139(5):e20163010.
[11] Bishop-Fitzpatrick L, Kind AJH. A scoping review of health disparities in autism spectrum disorder. *J Autism Dev Disord.* 2017;47(11):3380-3391.
[12] 2017 Report to Congress. Young Adults and Transitioning Youth with Autism Spectrum Disorder. Available at: https://iacc.hhs.gov/publications/report-to-congress/2017/report_to_congress_2017.pdf. Accessed on November 8, 2019.

Autism CARES Act

In carrying out the provisions of the Autism CARES Act, HRSA supports programs to improve the quality of care for those diagnosed with ASD/DD through education, early detection, and intervention**.** Specifically, these activities are designed to:

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

HRSA supports four program areas in accordance with the above activities:

- Training for Professionals,
- Autism Research Programs,
- Autism Policy Programs, and
- National Evaluation.

For additional details, please see https://mchb.hrsa.gov/maternal-child-health-initiatives/autism.

The HRSA Maternal and Child Health Research Network Program

The HRSA Maternal and Child Health (MCH) Research Network Program administered by the Division of Research in MCHB's Office of Epidemiology and Research supports the establishment and maintenance of interdisciplinary, multi-site, collaborative, national Research Networks that lead, promote, and coordinate national research activities on both broad and specific MCH topics. As of June 2019, HRSA MCH Research Networks have contributed to improving the lives and health of MCH populations by:

- Enrolling and serving approximately 3.9 million participants in research studies;
- Publishing 837 peer-reviewed articles in leading scholarly journals; and
- Developing and placing 84 clinical guidelines, tools, and toolkits collectively in the hands of over 260,000 practitioners and families.

Functions

The following describes multiple aspects of the Research Network that you should consider in the development of your application:

Organization and Functions

The Research Network will consist of a Network Coordinating Center (NCC) and multiple Collaborating Research Entities/Sites (CREs). [13] The NCC is the administrative center of the Research Network, providing leadership and maintaining a partnership, with its CREs. An example of this structure is depicted in the following diagram:



Research Network Organizational Structure with the NCC

The NCC will be located at the principal investigator's (PI) institution, which is the recipient of the cooperative agreement. The NCC provides the core administrative and operational functions that include the following:

1) Support the Research Network infrastructure for partnership among CREs;
2) Facilitate the process for the development, selection, implementation, and oversight of scientific research studies;

[13] This structure ensures that all Research Network activities encompass a general approach to address population needs to accelerate, upstream, together. **Accelerate:** An acknowledgement that although progress has been made in a variety of areas, much remains to be done. Research Networks must continue to innovate, grow the evidence base, and strive to address health disparities in maternal and child health by considering ways to reduce the gap between populations—whether those are defined by race, place, age, or gender. **Upstream:** A consideration of the social determinants of health—a broader and expansive way of looking at contributors to health beyond health care. Research Networks must think about primary prevention, but recognize the importance of secondary and tertiary prevention for some MCH populations. **Together:** A need to strategically engage stakeholders who understand the needs and priorities of the maternal and child health population. Research Networks must collaboratively develop solutions to the current and emerging health and development challenges. Available at: http://familyvoices.org/wp-content/uploads/2019/05/Warren-2019.05.09-MCHB-Presentation-to-Family-Voices_c.pdf. [14] The recipient is expected to participate in the national evaluation of HRSA/MCHB's Autism CARES Act programs and will receive more information at the time of award.

3) Coordinate a plan to enhance the research training and mentorship of diverse emerging investigators through the use of innovative mentorship/research experiences and manuscript development;
4) Coordinate the dissemination of findings to health professionals, researchers, policymakers, family members, and the greater public;
5) Establish and foster partnerships with programs and organizations serving underserved populations, and recruit study participants from these populations;
6) Establish a plan to ensure parent, family and/or consumer involvement and input in Research Network activities; and
7) Collaborate with pertinent partners, including the other HRSA-supported Autism CARES Act Programs (available here: https://mchb.hrsa.gov/maternal-child-health-initiatives/autism) and MCH Research Network recipients which are available here: https://mchb.hrsa.gov/research.

Research Network Advisory Board or Committee

The Research Network Advisory Board or Steering Committee will be comprised of representatives of the CREs and HRSA/MCHB. The PI will serve as Chair of the Research Network Advisory Board or Steering Committee. All major scientific decisions (e.g., study designs and policies) are determined by majority vote of the Research Network Advisory Board or Steering Committee. All participating CREs must agree to abide by these approved decisions. The Research Network Advisory Board or Steering Committee will meet monthly by telephone or other online platforms, and in person at least once a year in the Washington, D.C. area. The PI will meet annually with HRSA/MCHB leadership and other key stakeholders including, but not limited to: Title V directors, clinical interest groups, state and local education districts, Centers for Medicare and Medicaid Services, and Department of Education agencies, as applicable, to brief them on the existence and progress of the Research Network and to leverage their networks for translating Research Network findings into practice and policy.

Data Collection and Management

The NCC will facilitate data gathering, data management training, and data quality assurance according to developed protocol. CREs must follow the Research Network policies and procedures to (1) monitor adverse events; (2) report data and other information to the NCC; (3) ensure good clinical practice or other applicable regulatory requirements; and (4) participate in the national evaluation of HRSA/MCHB's Autism CARES Act programs. [14]

[14] The recipient is expected to participate in the national evaluation of HRSA/MCHB's Autism CARES Act programs and will receive more information at the time of award.

II. Award Information

1. Type of Application and Award

Types of applications sought: New

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement, as opposed to a grant, is an award instrument of financial assistance in which substantial involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

In addition to the usual monitoring and technical assistance provided under the cooperative agreement, **HRSA Program responsibilities shall include**:

1) Assurance of the availability of HRSA/MCHB personnel or designees to participate in the planning and development of all phases of this activity;
2) Review of policies and procedures established for carrying out project activities;
3) Participation in meetings and regular communications with the award recipient to review mutually agreed upon goals and objectives and to assess progress;
4) Facilitation of effective communication and accountability to HRSA/MCHB regarding the project, with special attention to new program initiatives and policy developments that have the potential to advance the utility of the Research Network;
5) Assistance in establishing and maintaining federal interagency and inter-organizational contacts necessary to carry out the project;
6) Review of all documents and products prior to submission for publication or public dissemination;
7) Identification of emerging research issues or agency priority topics that warrant new Research Network research studies; and
8) Participation in project activities such as meetings, webinars, presentations, publications, and other forms of disseminating information regarding project results and activities.

The cooperative agreement recipient's responsibilities shall include:

1) Establishing and maintaining an interdisciplinary, multicenter Research Network to determine evidence-based practices for interventions to improve the physical health of children and adolescents with ASD/DD as they transition to adulthood across the lifespan;
2) Designing and implementing multi-site research protocols to develop evidence-based practices for interventions (including innovative models for reaching underserved populations), address disparities in physical health interventions, and treatment of individuals with ASD/DD;
3) Establishing partnerships with programs serving underserved populations and recruiting study participants from these populations, such as HRSA's Health Center Program or the MIECHV Program;

4) Providing a research environment that supports the professional development and mentorship of diverse emerging investigators in the field of physical health intervention research for ASD/DD;
5) Developing and instituting a plan to ensure dissemination of Research Network findings via peer-reviewed publications, and other formats (e.g., presentations, tools, guidelines) to diverse stakeholders in order to increase the evidence base and accelerate the adoption of effective interventions into practice and care;
6) Developing and implementing procedures to store and share, after a 3-year embargo period, de-identified data with interested members of the research community in a manner that protects the privacy of participants and providers while enabling the full utilization of those data to improve the health and well-being of the population;
7) Leveraging Research Network capacity to compete for grant opportunities from other federal and private sources to bolster support and more strongly extend implementation of Research Network research protocols;
8) Providing an electronic copy of any products supported by award funds (including guidelines, assessment tools, publications, books, pamphlets, PowerPoint presentations, curricula, videos, etc.) to be made available to the general public and to the MCH Research Program; and
9) Collaborating with the other HRSA-supported Autism CARES Act Programs to ensure synergy, sharing of information, avoidance of duplication, and to promote the translation of findings into practice.

2. Summary of Funding

HRSA estimates approximately $3,000,000 to be available annually to fund one recipient. The actual amount available will not be determined until enactment of the final FY 2020 federal appropriation. You may apply for a ceiling amount of up to $3,000,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is September 1, 2020 through August 31, 2025 (5 years). Funding beyond the first year is subject to the availability of appropriated funds for the Research Network in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

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

Please note that if indirect costs are requested, the applicant must submit a copy of the latest negotiated rate agreement. This project supports an infrastructure from which to conduct research, but is not a research project in and of itself, therefore, it is not eligible for research indirect rates. The indirect costs rate refers to the "Other Sponsored Program/Activities" rate and to neither the research rate, nor the education/training program rate. Those applicants without an established indirect cost rate for “other sponsored programs” may only request 10 percent of salaries and wages, and must request an “other sponsored programs” rate from Cost Allocation Services (CAS).

Direct cost amounts for equipment (capital expenditures), tuition and fees, and contracts in excess of $25,000 are excluded from the actual direct cost base for purposes of this calculation.

III. Eligibility Information

1. Eligible Applicants

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

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

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

HRSA will consider any application that fails to satisfy the deadline requirements referenced in Section IV.4 non-responsive and will not consider it for funding under this notice.

The **Methods section of the Project Narrative is limited to 12 pages in length.** Applications that exceed this 12-page limit for the Methods section will be deemed nonresponsive, and will **not** be considered for funding under this notice.

NOTE: Multiple applications from an organization are allowable. In order to diversify the HRSA/MCHB research grant portfolio, an individual cannot serve as the project director (PD) or PI on more than one active HRSA MCH Research Network. To foster interdisciplinary collaboration and increase opportunities for mentorship for emerging MCH researchers, a PD/PI on an active HRSA MCH research grant is expected to serve for no more than 10 percent effort as a co-investigator on an existing HRSA MCH research grant. HRSA allows one PD/PI to be named on the cover page of the SF-424 R&R application, who will serve as the key point of contact. The application can include co-investigators as key personnel on the project. It does not apply to being a PI on grants from other agencies. However, if selected for funding, the new recipient will need to verify that percent effort across all federally-funded grants does not exceed 100 percent.

Please make sure you submit your application to the correct NOFO number: HRSA-20-054, the UT2 AIR-P Research competition. Applications submitted to the wrong competition will be deemed nonresponsive and will not be considered for funding under this notice.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates) an application is submitted more than once prior to the application due date, HRSA will only accept your **last** validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

IV. Application and Submission Information

1. Address to Request Application Package

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

The NOFO is also known as "Instructions" on Grants.gov. You must provide your email address when reviewing or preparing the workspace application package in order to receive notifications including modifications and/or republications of the NOFO on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are ultimately responsible for reviewing the For Applicants page for all information relevant to desired opportunities.*

2. Content and Form of Application Submission

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

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

Application Page Limit

The total size of all uploaded files may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments including biographical sketches, and letters of commitment and support required in HRSA's *SF-424 R&R Application Guide* and this NOFO. Standard Office of Management and Budget (OMB)-approved forms that are included in the workspace application package do not count in the page limit. Biographical sketches **do** count in the page limitation. Indirect Cost Rate Agreement and proof of non-profit status do not

count in the page limit. **We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.**

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

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

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

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

Program-Specific Instructions

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

i. *Project Abstract*

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

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

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

- FUNDING OPPORTUNITY NUMBER: HRSA-20-054
- FUNDING OPPORTUNITY TITLE: UT2 Autism Intervention Research Network on Physical Health (AIR-P)
- PROBLEM: Briefly state the principal needs and problems that are addressed by the project.

- 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 ACTIVITIES AND TARGET POPULATION(S): Describe the programs and activities used to attain the objectives, the target population(s) addressed, and comment on innovations and other characteristics of the proposed plan.
- COORDINATION: Describe the coordination planned with, and participation of, appropriate national, regional, state, and/or local health agencies, interdisciplinary professional groups and providers, and/or organizations that function as stakeholders or partners in the proposed project.
- PRODUCTS: Provide a brief description of the anticipated products of this Research Network, including modes of dissemination of project activities and findings.
- 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: From Appendix B select: (a) significant content terms that describe your project (maximum of 10 content terms), (b) targeted populations (select all that apply), and (c) age ranges (select all that apply), and include at the end of your abstract.

ii. *Project Narrative*

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

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

> ***SECTION I – BACKGROUND AND SIGNIFICANCE*** *-- CORRESPONDS TO SECTION V'S REVIEW CRITERIA #1 NEED, #2 RESPONSE, AND #4 IMPACT*
>
> Demonstrate/Include the following:
>
> - A thorough knowledge and understanding of the gaps in evidence-based practices for interventions to improve the physical health of individuals with ASD/DD;
> - Critical evaluation of the national significance of this Research Network;
> - Knowledge and identification of the physical health needs and issues for children and adolescents with ASD/DD as they transition to adulthood across the lifespan, especially those from underserved

populations;
- How proposed interdisciplinary research studies may fill gaps in research and advance the field of physical health of children with ASD/DD; and
- How the interdisciplinary, national, multi-site Research Network may address the identified needs of children and adolescents (including those transitioning to adulthood) with ASD/DD from underserved populations.

SECTION II – SPECIFIC GOALS AND OBJECTIVES -- *CORRESPONDS TO SECTION V'S REVIEW CRITERIA #2 RESPONSE, #4 IMPACT, AND #5 RESOURCES/CAPABILITIES*

Include the following:

- A numbered list of objectives and goals that address the major Research Network activities listed in the Purpose section of this notice to be accomplished during the period of performance. Specific objectives should be succinctly stated and innovative, and direct attention to the scope of expected activities listed. Objectives should be specific, measurable, achievable, realistic, time-bound (SMART), and tied to a distinct project goal;
- A detailed plan for completing several intervention studies, including studies on emerging physical health topics affecting children and adolescents with ASD/DD as they transition to adulthood across the lifespan, especially those from underserved populations, in consultation with HRSA/MCHB stakeholders;
- The process for developing an integrated Research Network and a plan of proposed activities showing progressive implementation to ensure national reach during the 5-year period of performance;
- A description of the activities or steps that will be used to achieve each of the project goals. Please provide a timeline that includes each activity and identifies responsible staff;
- A description of how proposed activities will build upon ongoing efforts, and not be duplicative of existing funded efforts (including HRSA/MCHB and Autism CARES Act projects). As appropriate, identification of meaningful support and collaboration with key stakeholders and partners in planning, designing, and implementing all activities; and
- A logic model utilized for designing and managing the project in this section of the narrative. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements. The creation of a logic model is a requirement of the Research Network Application, as described in the Attachments Section of this NOFO ***(Attachment 5)***.

HRSA's expectations and goals for the Research Network logic model is further illustrated in Appendix D of this NOFO.

Provide documentation (letters of agreement) of participation of CREs that will collaborate to fulfill the goals and objectives of the Research Network, with descriptions of each CRE's characteristics that include patient population characteristics for individuals with ASD/DD, average patient numbers, types of ASD/DD-related treatments, interventions or services currently delivered, as well as characteristics and structure of staff. **Include letters of agreement from CRE sites in *Attachment 2*.** It is expected that at least six CREs will work in collaboration with partnering programs and should demonstrate success in recruiting from underserved population(s) with limited access to services, and/or other underserved populations as defined by your organization.

To assist you in demonstrating a plan for collaboration with programs serving underserved populations, this section describes the expected documentation that would demonstrate commitment of both your organization and the partnering programs. Examples of collaboration with HRSA's Health Center Program and the MIECHV Program are given. For collaboration with other non-federal programs, you should provide similar documentation.

- **The HRSA Health Center Program:** Submit a letter of agreement from a Primary Care Association (PCA) that will serve as the mediator for research involving recruitment from Health Centers. The PCA will document a commitment to working with your organization in identifying Health Centers that demonstrate the patient population needed to support Research Network research endeavors. They will support staff leadership and commitment to the project and collaboration with your organization to fulfill the purpose of the Research Network program. The PCA will facilitate the arrangements between your organization and the Health Centers.

- Link to find Primary Care Associations: https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/ncapca/associations.html

- Establish subcontract arrangements between your organization and Health Centers identified by the PCA for Research Network participation that will provide funding for Health Center Program liaison(s), such as a research project coordinator. The Health Center Program liaison will facilitate the research coordination and recruitment of Health Center patients for Research Network research studies.

- **The HRSA MIECHV Program:** Submit a letter of agreement from a MIECHV State Program that will facilitate connections with MIECHV local implementing agencies (LIAs). The MIECHV State Program must document a commitment to

working with your organization in the identification of LIAs that demonstrate the patient population needed to support Research Network research endeavors. They will support staff leadership and commitment to the project and collaboration with your organization to fulfill the purpose of the Research Network program. The MIECHV State Program will facilitate arrangements between your organization and the MIECHV LIAs.

- Link to find MIECHV State Programs: https://mchb.hrsa.gov/maternal-child-health-initiatives/home-visiting/fy18-home-visiting-awards

- Establish subcontract arrangements between your organization and the MIECHV LIAs that will provide funding for a LIA liaison. The LIA liaison will facilitate the research coordination and recruitment of participants served by the MIECHV LIAs for Research Network research studies.

  Responsibility of the NCC overseeing the CREs: Address how the Research Network will manage CRE or sites. The Research Network provides the CREs with guidance to ensure:

  - Staff and training needed for the CREs to implement a study protocol and participate in Research Network activities;
  - A data acquisition system to collect intake, treatment, and outcome data for all study participants, according to protocol-specific requirements; and
  - Additional support such as quality control to ensure the successful completion of the scientific goals of a research project and other Research Network activities. You should include budgets for CRE travel support to Research Network meetings in your applications.

  Responsibility of Each CRE Site: Each CRE should, as appropriate, in conducting studies and participating in Research Network activities:

  - Describe a plan to establish and sustain the CREs;
  - Participate in Research Network subcommittees and agree to attend Research Network monthly teleconferences and in-person meetings;
  - Participate in the development of concept and protocol of observational and clinical trial studies to be conducted by the Research Network;
  - Agree to participate in observational studies and clinical trials, including subject enrollment, data collection, patient record maintenance, adherence to good clinical practice, compliance with protocol requirements, randomization methods for assignment of patients to experimental or control groups or randomization of care delivered to different conditions;
  - Participate in Research Network activities that enhance the research training and mentorship of junior/new investigators; and,

- Participate in the translation of critical Research Network findings to practice settings and educational training that will result in advancing and strengthening the evidence base on ASD/DD physical health research and other related outcomes.

SECTION III – PROJECT DESIGN: METHODS AND EVALUATION -- *CORRESPONDS TO SECTION V'S REVIEW CRITERIA #2 RESPONSE, #3 EVALUATIVE MEASURES, #4 IMPACT, #5 RESOURCES/CAPABILITIES, AND #7 PROGRAM ASSURANCES*

A. Methods:

This section has a strict 12-page limit.

Provide detailed descriptions of the methodology for accomplishing the work of the Research Network and each of its distinct objectives. Include sufficient technical detail to demonstrate the necessary steps to accomplish each objective and to convey to reviewers adequate information to assess the methodology.

Indicate the specific methods that will be used to evaluate progress in each activity area. List and discuss anticipated obstacles that may be encountered and indicate how these will be overcome.

It is important that you describe how the interdisciplinary team will function in true partnership/collaboration within the Research Network to accomplish their objectives and meet their goals. Anticipate potential problems and challenges that may arise in this process, and propose mechanisms for collaborative resolution.

Successful participation in the Research Network includes the ability to work collaboratively to achieve the goals of the Research Network, address challenges, and fulfill commitments to the project as indicated in the proposal and Letters of Agreement.

In addition, describe plans to disseminate findings to stakeholders, including health professionals, policymakers, family members, and the greater public. These include:

- Peer-reviewed publications: It is expected that the Research Network will produce at least four peer-reviewed publications per year. In addition, it is expected that a new or updated national research agenda for the Research Network will be published in a peer-reviewed journal;
- Research Network website: Maintain a public Research Network website to disseminate research findings, generate interest in the Research Network, and expand Research Network membership;

- Research acceleration: Disseminate findings to help accelerate the synthesis, analysis, and translation of existing and future knowledge so that it can be applied to practice and policy at the state and national levels;
- Stakeholder engagement: Showcasing informational products and educational opportunities, including webinars, website material, plenary sessions, abstracts, conference presentations, annual Research Network meetings, and consumer materials, etc.

B. Evaluation:

Describe a plan for program performance evaluation that will contribute to continuous quality improvement. The program performance evaluation should monitor ongoing processes and progress towards the goals and objectives of the project.

Indicate the specific methods that will be used to evaluate progress in each activity area. List and discuss anticipated obstacles to implementing the program performance evaluation that may be encountered and describe plans to overcome these obstacles.

Describe the systems, processes, and staff that will support the organization's performance management requirements through effective tracking of performance outcomes, including a description of how the organization will collect and manage data (e.g., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes. As appropriate, describe the data collection strategies that will be used to collect, analyze, and track data to measure progress and impact/outcomes with different sociocultural groups (e.g., race, ethnicity, language, rural versus urban, socioeconomic, gender), and explain how the data will be used to inform program development and service delivery. Describe a plan to recruit diverse participants in research with the target of including at least 60 percent of Research Network study participants from underserved populations.

For each described objective, include an evaluation measure. The evaluation measure should be SMART with a timeline for evaluation and should be presented consistent with the plan and schedule of implementation of the goals and objectives.

C. Cooperative Agreement Activities:

Infrastructure Development:

- Develop and maintain a national Research Network of research entities from across the country that will collaborate to advance and strengthen the evidence base for improving the physical health of children and

adolescents with ASD/DD as they transition to adulthood across the lifespan, in accordance with the objectives and functions outlined in this NOFO; and

- Establish an interdisciplinary Research Network Advisory Board or Steering Committee comprised of a broad representation of diverse key stakeholders, including but not limited to, health professionals, national experts, research entities, and family members, including those from underserved populations, in accordance with the guidance outlined in this NOFO.

Research Network Activities:

- Create an interdisciplinary Research Network for autism intervention research on physical health of children and adolescents with ASD/DD as they transition to adulthood across the lifespan;
- Engage family members in the planning, design, and implementation of Research Network studies;
- Conceptualize or update and publish, in a peer-reviewed journal, a national research agenda for ASD/DD intervention research on physical health;
- Design, implement, and complete several multi-site intervention research studies, clearly identifying the number of studies and how they address disparities in screening, diagnosis, and access to services for children and adolescents with ASD/DD, including innovative models serving underserved populations;
- Develop a plan for the design and implementation of multi-site intervention research studies addressing emerging issues affecting the physical health of children and adolescents with ASD/DD as they transition to adulthood across the lifespan especially those from underserved populations, in consultation with HRSA/Maternal and Child Health Bureau (MCHB) leadership;
- Plan and recruit diverse participants in research with the target of including at least 60 percent of Research Network study participants from underserved populations, in order to address gaps in the field and provide regular updates on progress to HRSA/MCHB;
- Develop and foster partnerships with several programs serving underserved populations (e.g., HRSA Health Center Program; Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV));
- Develop and implement a dissemination plan for communicating research findings to diverse stakeholders;
- Engage key audiences that serve children and adolescents with ASD/DD as they transition to adulthood across the lifespan, especially those from underserved populations, to advance the translation of Research Network research into practice such as policymakers, researchers, school systems, health professionals, families, community members, and state, tribal, territorial, and local agencies;

- Develop and evaluate resources such as guidelines, tools, or toolkits for use in clinical practice or intervention-based research in communities;
- Develop and implement strategies to sustain the Research Network infrastructure;
- Train and mentor diverse emerging investigators in autism intervention research; and;
- Develop and maintain a public website for engaging multiple stakeholders.

Communications:

Translate research findings into formats that are beneficial for the constituents/research community for policy and practice.

Dissemination:

Disseminate information on Research Network activities and research findings to a broad audience including researchers, health professionals, policymakers, educators, community members, and families.

Consistent with HRSA's mission to improve access to quality services for underserved populations, the Research Network should ensure that research activities will be responsive to the cultural and linguistic needs of underserved populations such as partnering with programs that serve these populations in Research Network activities. These services should be family-centered, accessible to consumers, and reflect the needs of the populations described above.

SECTION IV – PLAN AND SCHEDULE OF IMPLEMENTATION, AND CAPABILITY OF THE APPLICANT -- *CORRESPONDS TO SECTION V'S REVIEW CRITERIA #3 EVALUATIVE MEASURES, #4 IMPACT, #5 RESOURCES/CAPABILITIES, #6 SUPPORT REQUESTED, AND #7 PROGAM ASSURANCES*

Provide a description of the organizational plan for management of the project, including an explanation of the roles and responsibilities of interdisciplinary project personnel and collaborators. Provide a draft organizational chart as ***Attachment 4*** describing the leadership structure of the Research Network demonstrating collaboration between the PI, co-investigators, and CREs.

In addition, provide an implementation schedule for each activity described in previous sections. The material should be presented in a succinct manner, with a brief listing of specific milestones and expected outcomes.

In demonstrating capability to fulfill the goals of the Research Network program, describe your organization's significant experience and the publication record of key personnel in carrying out interdisciplinary collaborative research and

related projects relating to the goals and objectives of the Research Network. Describe experience in working with underserved populations and key stakeholders groups, as available.

Include reference citations for publications and works cited following the end of the Project Narrative, not as an attachment.

NARRATIVE GUIDANCE

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

Narrative Section	**Review Criteria**
Background and Significance	(1) Need (2) Response (4) Impact
Specific Goals and Objectives	(2) Response (4) Impact (5) Resources/Capabilities
Project Design: Methods and Evaluation	(2) Response (3) Evaluative Measures (4) Impact (5) Resources/Capabilities (7) Program Assurances
Plan and Schedule of Implementation, and Capability of Applicant	(3) Evaluative Measures (4) Impact (5) Resources/Capabilities (6) Support Requested (7) Program Assurances
Biographical Sketches	(5) Resources/Capabilities
Budget and Budget Justification Narrative (below)	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

The Research Network has seven review criteria. A summary of the points is below. See Section V. Application Review Information for details.

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

Criterion 7.	Program Assurances	10 points
TOTAL		100 points

iii. *Budget*

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

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

In addition, the maximum number of budget periods allowed is five. A budget period represents 12 months of project effort.

Use the following guidelines to allocate project funding:

- At least 60 percent of yearly total project funds are expected to directly support the conduct of multi-site protocol research;
- It is expected that your institution be prepared to provide infrastructural support for the maintenance of Research Network activities. It is expected that no more than 10 percent of these funds will be used to support the Research Network infrastructure;

The budget should reflect travel expenses associated with participating in meetings that address MCH research efforts and other proposed trainings or workshops. The following meetings are required for the Research Network:

- Annual in-person Research Network leadership meeting in the Washington, D.C. metropolitan area.
- Annual in-person meeting of the PI and/or co-PIs with HRSA/MCHB leadership to provide updates on the Research Network.
- Annual in-person attendance for up to two people (the PI and one key personnel) for 2 days at the HRSA MCH Research Network and Single Investigator Innovation Programs Grantee Meeting in the Washington, D.C. metropolitan area.
- An in-person or virtual attendance MCHB Autism CARES Act Grantee Meetings, held in the Washington, D.C. metropolitan area. For planning, it is recommended that the PI attend during Year 2 and Year 4 (in-person meeting

occurs every 2 years). Budgets should include travel costs associated with this 1½ day grantee meeting.

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

The Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, § 202 states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II. . . ." See Section 4.1.iv Budget – Salary Limitation of HRSA's *SF-424 R&R Application Guide* for additional information. Note that these or other salary limitations may apply in the following fiscal years, as required by law.

iv. *Budget Justification Narrative*

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

In addition, the Research Network program requires the position descriptions (roles, responsibilities, and qualifications of proposed project staff) in the Budget Justification under Personnel costs. The budget justification is uploaded into the Budget Narrative Attachment Form. Biographical sketches for any key employed personnel that will be assigned to work on the proposed project must be included as ***Attachment 1***. Due to the HRSA 80-page limit, it is recommended that all biographical sketches are no more than two pages in length and must follow the HRSA font/margin requirements. Biographical sketches should document education, skills, and experience that are relevant, necessary, and demonstrate capability to fulfill the assigned roles for the proposed project.

v. *Program-Specific Forms*

Program-specific forms are not required for application.

vi. *Attachments*

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

Attachment 1: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying key positions. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch. Given the 80-page limit, it is recommended that biographical sketches be no more than two pages in length per person. Biographical sketches should document education, skills, and experience that are relevant, necessary, and demonstrate capability to fulfill the

assigned roles for the proposed project. Please follow the system prompts to upload biographical sketches.

Attachment 2: 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 collaborators and any deliverables. Include only letters that specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.). Letters of agreement and letters of support must be dated.

Attachment 3: List of Citations for Key Publications

A list of citations for key publications by your key personnel that are relevant to the proposal can be included. Do not list unpublished theses or abstracts/manuscripts submitted (but not yet accepted) for publication. In consideration of the 80-page limitation, a list of citations only may be included.

Attachment 4: Project Organizational Chart, Including Partners and Collaborators

Provide a project organizational chart that describes the functional structure of the Research Network. The chart should provide the following information for key personnel: Institution, Responsibilities/Activities.

Attachment 5: Logic Model

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

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

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

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

- Program Purpose:
  - How does the program offer a solution?
  - What does the program do to address the problem?

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

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

Attachment 6: Proof of Non-Profit Status (Not counted in the page limit)

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

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

Attachments 8–15: Other Relevant Documents, As Necessary

Include here any other documents that are relevant to the application. All documents are included in the page limit.

3. Dun and Bradstreet Data Universal Numbering System Number and System for Award Management

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

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

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

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

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

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

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

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

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

4. Submission Dates and Times

Application Due Date

The due date for applications under this NOFO is *April 30, 2020 at 11:59 p.m. ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadline** to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's *SF-424 R&R Application Guide* for additional information.

5. Intergovernmental Review

The Research Network is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR 100.

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

6. Funding Restrictions

You may request funding for a period of performance of up to 5 years, at no more than $3,000,000 per year (inclusive of direct **and** indirect costs). Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

Travel outside of the United States is not supported under this notice.

The General Provisions in Division A of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) apply to this program. Please see Section 4.1 of HRSA's *SF-424 R&R Application Guide* for additional information. Note that these or other restrictions will apply in the following fiscal years, as required by law.

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

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

V. Application Review Information

1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation.

These criteria are the basis upon which the reviewers will evaluate and score the merit of the application. The entire proposal will be considered during objective review. The Research Network has seven review criteria. See the review criteria outlined below with specific detail and scoring points.

Criterion 1: NEED (10 points) *-- Corresponds to Section IV's* ***Background and Significance***

The extent or degree to which the application describes:

- The current research gaps in evidence-based practices for interventions to improve the physical health of children and adolescents with ASD/DD, addressing disparities in effective interventions, treatment, and access to care, especially for underserved populations;
- An approach using interdisciplinary collaborative multi-site research to address the identified needs of children and adolescents with ASD/DD; and
- The national significance and impact of the Research Network and how the coordination of multi-site research can advance the field by developing guidelines, fostering the adoption of innovative treatment models, and disseminating findings.

Criterion 2: RESPONSE (20 points) *-- Corresponds to Section IV's Background and Significance; Specific Goals and Objectives; Project Design: Methods and Evaluation*

Intervention Studies (10 points)

The degree to which the application:

- Proposes intervention studies and discusses how these studies will address physical health outcomes in ASD/DD populations.

Other Response Areas (10 points)

- Responds to, and describes its abilities to implement all activities described in the "Purpose" section for this competition;
- Demonstrates awareness of previous work in the area of this project, including citation of relevant literature and justification of the need for the Research Network;
- Describes clear, concise, and appropriate goals and objectives and their relationship to the identified project;
- Aligns its activities (scientific or other) with addressing the identified problem(s) and attaining the project objectives;
- Includes project aims that will advance scientific knowledge, technical capability, and/or clinical practice or other services and act as a catalyst in developing methodology, treatments, practice, services, or preventive interventions that advance the field;
- Describes critical research and methodology that challenge and seek to shift

current research, practice, or service paradigms by utilizing innovative theoretical concepts, approaches or methodologies, instrumentation, or interventions;
- Proposes refining, improving, or applying new theoretical concepts, approaches or methodologies, instrumentation, or interventions;
- Describes a plan to ensure successful collaboration with all key partners identified in the proposal;
- Clearly articulates the project in a logic model; and
- Describes collaboration with several partnering programs serving underserved populations, such as HRSA's Health Center Program or the MIECHV Program and includes documentation of agreement from the partnering programs.

Criterion 3: EVALUATIVE MEASURES (20 points) *– Corresponds to Section IV's Project Design: Methods and Evaluation; Plan and Schedule of Implementation, and Capability of Applicant*

The strength and effectiveness of the methods proposed to monitor and evaluate project results. Evidence that the evaluative measures will be able to assess: (1) how well the program objectives have been met, and (2) the degree to which these can be attributed to the project. The effectiveness of the application plan to ensure that:

- Proposed activities are capable of attaining project goals and objectives;
- The plan and methodology for establishing and managing the Research Network described in the proposal are appropriate, feasible, and of high quality;
- A clear, articulated implementation plan for the proposed intervention studies;
- Experience and familiarity with data gathering procedures as they relate to collaborative multi-site research are well described; and
- Scalable evaluation measures are included for each described objective, including intervention research studies, with a timeline for evaluation consistent with the plan and schedule of implementation.

The extent to which the description in the application methods section includes:

- An effective and robust dissemination plan that includes, four peer-reviewed publications a year, disseminating information to scientific and professional audiences, Research Network website; and
- Other dissemination strategies to research and practice communities, as well as families and communities that will promote the transfer of findings to improve care.

Criterion 4: IMPACT (20 points) *– Corresponds to Section IV's Background and Significance; Specific Goals and Objectives; Project Design: Methods and Evaluation; Plan and Schedule of Implementation, and Capability of Applicant*

- The quality of the applicant's plan for establishing a Research Network, and the nature and technical quality of the activities proposed.
- The significance of the project in terms of its potential impact in creating a multi-

site, collaborative, interdisciplinary Research Network that will advance and strengthen the evidence base related to physical health outcomes for ASD/DD populations.
- The potential impact of project results in advancing and strengthening the evidence base for physical health interventions and treatments and access to care for children and adolescents with ASD/DD, especially underserved populations.
- The effectiveness of the dissemination plan to facilitate the translation of Research Network findings to a broad audience of researchers, health professionals, policymakers, educators, and families.
- The feasibility of the applicant's plan for delivering at least four peer-reviewed publications each year resulting from the award.
- An effective plan for engaging other funded Autism CARES Act and MCH programs (e.g., Research Networks) and cooperative agreements pertinent to the Research Network.

Criterion 5: RESOURCES/CAPABILITIES (10 points) *– Corresponds to Section IV's Specific Goals and Objectives; Project Design: Methods and Evaluation; Plan and Schedule of Implementation, and Capability of Applicant; Biographical Sketches*

The strength of the application's plan in regards to project personnel and collaborators' training qualifications and/or experience to implement and carry out the project. This includes evaluation of the capabilities of the applicant organization and collaborators, the quality and availability of facilities, and personnel to fulfill the needs and requirements of the proposed project.

The strength of the PI and project team's documented history of leadership in the conduct of multi-site, national, interdisciplinary, collaborative research and publication record on advancing the field of ASD/DD physical health.

Implementation of a National Research Network (5 points)

The extent to which the applicant proposes:

- Key personnel such as co-investigators, study coordinator, data manager, NCC staff and other key personnel for the successful implementation of a national Research Network.

Other Resource/Capabilities Areas (5 points)

The extent to which:

- The PI, staff, and collaborators are well-qualified by training and/or expertise to develop the infrastructure of the Research Network and to accomplish the activities of the Research Network as described in this NOFO;
- The PI and other key personnel demonstrate current and/or past success in publishing the findings of their research;

- The applicant has the existing resources/facilities to achieve project objectives and to successfully support the proposed Research Network described; and
- The partnering programs, such as HRSA's Health Center Program or the MIECHV Program, demonstrate the ability and commitment to collaborate with the applicant organization and ability to recruit from their patient population for Research Network research studies.

Criterion 6: SUPPORT REQUESTED (10 points) *– Corresponds to Section IV's Budget and Budget Justification Narrative*

The reasonableness of the proposed budget for each year of the period of performance in relation to the objectives, the complexity of the research and related activities, and the anticipated results. A sufficient description, which includes:

- Costs, as outlined in the budget and required resources sections, are reasonable given the scope of work;
- Budget line items that are well described and justified in the budget justification; and
- Time allocated by key personnel is appropriate to achieve project objectives.

Criteria 7: PROGRAM ASSURANCES (10 points) *-- Corresponds to Section III's Project Design: Methods and Evaluation and Section IV's Plan and Schedule of Implementation and Capability of Applicant*

Feasibility

The applicant should demonstrate the feasibility of its proposal to establish the Research Network. This should include a documented strategy to indicate that the project can be completed as proposed and approved, sharing key timelines, and strategies to address challenges.

Proposed Sequence or Timetable

The extent to which the application includes:

- A clear and feasible timeline;
- A proposed project that is feasible to conduct within the project time frame;
- A project that is achievable in terms of meeting targeted participant enrollment, given recruitment methods and frequent difficulties of recruiting among hard-to-reach populations; and
- A project that demonstrates the feasibility of reaching targeted/planned enrollment levels within the timeline provided.

Resolution of Challenges

The reasonableness of the application's plan to:

- Anticipate and address potential barriers to project progress;

- Provide assurance that the Research Network platform can be sustained as proposed; and
- Demonstrate the feasibility of reaching targeted/planned enrollment levels within the timeline provided.

Evaluation and Technical Support Capacity

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

Protection of Human Subjects

The extent to which the application description includes:

- Adequate protections afforded to human subjects, including children and youth, and the adequacy of measures in place to ensure the security of the research data (data security);
- Compliance with the HHS regulations for protection of human subjects (45 CFR Part 46). See the instructions in HRSA's SF-424 R&R Application Guide, Appendix B: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan; and
- Plans to seek Institutional Review Board (IRB) approval (IRB approval is not required at the time of application submission, but must be received prior to initiation of any activities involving human subjects).

Targeted/Planned Enrollment

The quality of the plan to:

- Provide details regarding the Targeted/Planned Enrollment for their proposed studies, including information on anticipated sociocultural groups categories (e.g., race, ethnicity, language, rural versus urban, socioeconomic, gender);
- Plan and meet recruitment targets of 60 percent of participants from underserved populations; and
- Provide assurance regarding cultural competence as appropriate.

2. Review and Selection Process

The objective review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

See Section 5.3 of HRSA's *SF-424 R&R Application Guide* for more details.

3. Assessment of Risk

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

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

Award decisions are discretionary and are not subject to appeal to any HRSA or HHS official or board.

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider any of your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

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

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of September 1, 2020. See Section 5.4 of HRSA's *SF-424 R&R Application Guide* for additional information.

2. Administrative and National Policy Requirements

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

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

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

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

- Please refer to instructions provided in HRSA's *SF-424 R&R Application Guide*, Appendix Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy for specific instructions on preparing the human subjects section of the application.
- Discuss plans to seek IRB approval or exemption. IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent the page limits of the Methods portion of the Project Narrative Section.

3. Reporting

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

1) **Discretionary Grant Information System (DGIS) Performance Reports.** Available through the Electronic Handbooks (EHBs), the DGIS is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report **annually**, by the specified deadline. To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are available on https://grants6.hrsa.gov/MchbExternal/DgisApp/formassignmentlist/UT2_1.html. The type of report required is determined by the project year of the award's period of performance.

Type of Report	Reporting Period	Available Date	Report Due Date
New Competing Performance Report	September 1, 2020-August 31, 2021 *(administrative data and performance measure projections, as applicable)*	Period of performance start date	120 days from the available date
Non-Competing Performance Report	September 1, 2020-August 31, 2021 September 1, 2021-August 31, 2022 September 1, 2022-August 31, 2023 September 1, 2023-August 31, 2024	Beginning of each budget period (Years 2–4, as applicable)	120 days from the available date
Project Period End Performance Report	September 1, 2024-August 31, 2025	Period of performance end date	90 days from the available date

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

2) **Progress Report(s)**. The recipient must submit a progress report narrative to HRSA **annually** via the Non-Competing Continuation Renewal in the EHBs, which should address progress against program outcomes (e.g., accomplishments, barriers, significant changes, plans for the upcoming budget year), and include annual data on performance measures identified in the Project Narrative, if not captured by DGIS. Submission and HRSA approval of a progress report will trigger the budget period renewal and release of each subsequent year of funding. Further information will be available in the NOA.

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

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

VII. Agency Contacts

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

Tonya Randall
Grants Management Specialist
Division of Grants Management Operations
Office of Federal Assistance Management
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 594-4259
Fax: (301) 594-4073
Email: trandall@hrsa.gov

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

Jessica DiBari, Ph.D., M.H.S. and Melissa Jenssen, B.S.
Program Officers
Division of Research, Office of Epidemiology and Research
Attn: AIR-P Research Network
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4690 and (301) 945-3933
Email: jdibari@hrsa.gov and mjenssen@hrsa.gov

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

Grants.gov Contact Center
Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)
Email: support@grants.gov

Self-Service Knowledge Base: https://grants-portal.psc.gov/Welcome.aspx?pt=Grants

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

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

VIII. Other Information

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Thursday, January 23, 2020
Time: 1–2 p.m. ET
Call-In Number: 1-800-369-1830
Participant Code: 4796126
Weblink: https://hrsa.connectsolutions.com/autism_intervention_research/

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

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

Tips for Writing a Strong Application

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

Appendix A: Relevant Websites

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

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

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

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

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

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

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

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

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

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

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

Appendix B: Key Terms for Project Abstracts

a) Content Terms (maximum of 10)

Health Care Systems & Delivery

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

Primary Care & Medical Home

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

Insurance & Health Care Costs

- Cost Effectiveness
- Health Care Costs
- Insurance Coverage

Prenatal/Perinatal Health & Pregnancy Outcomes

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

Nutrition & Obesity

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

Parenting & Child Development

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

School Settings, Outcomes & Services

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

Screening & Health Promotion

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

Illness, Injury & Death

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

Mental/Behavioral Health & Well-being

- Bullying & Peer Relationships
- Depression
- Mental Health & Well-being
- Risk Behaviors
- Sexually Transmitted Diseases
- Smoking
- Stress

- Substance Use
- Violence & Abuse

Special Health Care Needs & Disabilities

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

Lifespan & Social Determinants

- Neighborhood
- Lifespan
- Social Determinants of Health

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

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

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

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

Appendix C: Application Completeness Checklist

Funding Opportunity Number: HRSA-20-054 **Application Due Date in Grants.gov:** April 30, 2020	
Requirement	**Yes**
Do you meet the eligibility criteria?	
Did you read the R&R Application Guide (https://www.hrsa.gov/sites/default/files/hrsa/grants/apply/applicationguide/sf-424-rr-app-guide.pdf)?	
Do you have a DUNS number (https://www.dnb.com/duns-number.html)?	
Did your Authorized Organization Representative (AOR) register in SAM (https://www.sam.gov/)?	
Did your AOR register in Grants.gov (https://www.grants.gov/)?	
Is your Abstract no more than one page in length and single spaced?	
Does the Narrative Section of your application fully address: • Background and Significance? • Specific Goals and Objectives? • Project Design, Methods, and Evaluation? • Plan/Schedule of Implementation and Capability of Applicant? • Feasibility? • Evaluation and Technical Support Capacity? • Protection of Human Subjects? • Targeted/Planned Enrollment?	
Did you confirm that your application addressed all of the NOFO Review Criteria?	
Is your Methods Section within the 12-page limit?	
Are your budget and budget justification narrative completed accurately and in the yearly funding limit? **NOTE:** The directions offered in the HRSA SF-424 R&R Application Guide differ from those offered by Grants.gov. Please follow the instructions included in the R&R Application Guide and, *if applicable*, the additional budget instructions in the **NOFO**.	
Did you clearly label all of your attachments?	
Did you include the Biographical Sketches of Key Personnel in the Application?	
Do you know your institution's indirect cost rate?	
Did you use no less than 12-point font and are your page margins at least 1 inch wide in the Narrative and Attachment Sections of the Application? **NOTE:** The Biographical Sketches of Key Personnel can have .5" margins.	
Are your pages, including attachments, within the 80-page limit? **NOTE:** Pages which do not count toward the 80-page limit include: Cover Page, Indirect Cost Rate Agreement, Proof of Non-Profit Status, Budget, and Standard OMB-approved forms.	

Appendix D: Logic Models

The following logic model illustrates HRSA's expectations and goals for the AIR-P.

Program Inputs	Program Outputs		Program Outcomes	
	Activities	Products / Systems	Short-Term / Intermediate	Long-Term / Impact
Eligible Entities, Stakeholders & Key Resources	Activities to create/improve health/service systems and infrastructure	Health/service systems and infrastructure created to support desirable systems or behaviors	Health/service systems or behaviors that lead to improved health outcomes	Improved health or health care outcomes
Domestic public or private entities, including research centers or networks. Interdisciplinary Research Network of national experts and research entities Federal staff	Create and maintain an interdisciplinary research network focused on improving physical health for children and adolescents with ASD and other DD.	Multi-site, interdisciplinary research network for physical health interventions for children and adolescents with ASD and other DD.	Increase the number of resources on physical health issues available to help health professionals and other researchers. Increase collaboration and coordination of research on current and emerging physical health problems among children and adolescents with ASD and other DDs, such as seizures, sleep problems, gastrointestinal (GI) disorder, nutritional deficiencies, and metabolic conditions.	Advance the evidence base and further develop the field of physical health interventions for underserved children and adolescents with ASD or DDs. Increase the translation of research findings into practice. Increase MCH autism-related

Program Inputs	Program Outputs		Program Outcomes	
	Activities	Products / Systems	Short-Term / Intermediate	Long-Term / Impact
Eligible Entities, Stakeholders & Key Resources	Activities to create/improve health/service systems and infrastructure	Health/service systems and infrastructure created to support desirable systems or behaviors	Health/service systems or behaviors that lead to improved health outcomes	Improved health or health care outcomes
Families and community members	Form an interdisciplinary Research Network Steering Committee / Advisory Board composed of diverse professionals and family members.	Interdisciplinary and diverse Research Network Steering Committee / Advisory Board established, and annual in-person meetings convened.	Increase the number of multidisciplinary investigators trained/mentored in the field of autism research. Increase the active contribution and incorporation of stakeholders (researchers, practitioners, and community members) into activities advancing physical health interventions for children and adolescents with ASD and DDs.	research sustainability.
	Create a national research agenda for AIR-P research (in collaboration with MCHB).	National research agenda for AIR-P research.	Increase the number of resources on physical health issues available to help health professionals and other researchers. Increase the active contribution and incorporation of stakeholders (researchers, practitioners, and community members) into activities advancing physical health interventions for children and adolescents with ASD and DDs.	
	Design and implement several multi-site intervention research studies	Multi-site intervention research studies designed and implemented.	Increase the number of resources on physical health issues available to help health professionals and other researchers.	Advance the evidence base and further develop the field of physical health

Program Inputs	Program Outputs		Program Outcomes	
	Activities	**Products / Systems**	**Short-Term / Intermediate**	**Long-Term / Impact**
Eligible Entities, Stakeholders & Key Resources	Activities to create/improve health/service systems and infrastructure	Health/service systems and infrastructure created to support desirable systems or behaviors	Health/service systems or behaviors that lead to improved health outcomes	Improved health or health care outcomes
	to examine and improve upon the physical health of children and adolescents with ASD and other DD.			interventions for underserved children and adolescents with ASD or DDs. Increase the translation of research findings into practice. Increase MCH autism-related research sustainability.
	Develop and evaluate resources such as guidelines, tools, study protocols, or toolkits for use in clinical practice or intervention-based research in community settings.	Resources developed, evaluated, and utilized in clinical practice or intervention-based research in community settings.		
	Develop and implement a dissemination plan for communicating research findings to diverse stakeholders.	Dissemination plan with a timeline and list of proposed products. Manuscripts published in peer-reviewed journals		

Program Inputs	Program Outputs		Program Outcomes	
	Activities	Products / Systems	Short-Term / Intermediate	Long-Term / Impact
		Non-peer-reviewed publications aimed at stakeholders beyond the scientific research community (e.g., reports, blogs, web posting, videos, infographics, lay summary of research publications).		
	Engage family members in AIR-P Research Network studies.	Family members engaged as members of the Research Network Steering Committee. Input from family members incorporated in the design and implementation of AIR-P Research Network studies.	Increase the active contribution and incorporation of stakeholders (researchers, practitioners, and community members) into activities advancing physical health interventions for children and adolescents with ASD and DDs.	
	Engage key audiences (e.g., researchers, health professionals, Title V populations, Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV) populations, families, community members, policymakers) in translating AIR-P research findings into practice.	Key audiences engaged Resources developed that include the input of key audiences and are shared broadly and in varying formats.		
	Develop and maintain a public website for engaging multiple stakeholders and communicating work of the AIR-P Research Network.	Website representing the work of the AIR-P Research Network developed and maintained.		
	Prepare and submit grant applications for external funding opportunities outside of HRSA/MCHB's research grant program.	Grant applications completed and submitted for external funding opportunities.		

Program Inputs	Program Outputs		Program Outcomes	
	Activities	**Products / Systems**	**Short-Term / Intermediate**	**Long-Term / Impact**
	Train and mentor junior/new investigators in ASD and other DD physical health intervention research.	Junior/new investigators trained/mentored.	Increase the number of grant applications submitted for external funding opportunities outside of MCH Research Network program. Increase the capacity of grantees to expand/sustain research initiated by the MCH Research Network program. Increase the number of multidisciplinary investigators trained/mentored in the field of autism research.	Advance the evidence base and further develop the field of physical health interventions for underserved children and adolescents with ASD or DDs. Increase the translation of research findings into practice. Increase MCH autism-related research sustainability.
Performance Measures	***Process Measures*** • DGIS Core 2 • DGIS Core 3 • # of studies developed • # of participants (including demographic data) enrolled in AIR-P Research Network studies • # of total researchers involved in the AIR-P Research Network • # of junior/new investigators being trained or mentored through AIR-P Research Network		***Outcome / Impact Measures*** • # of tools, toolkits, and clinical guidelines • # of research sites	***Outcome / Impact Measures*** • # of peer-reviewed publications • # of non peer-reviewed publications • DGIS Core 1

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

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

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a time line used during program implementation; the work plan provides the "how to" steps. You can find information on how to distinguish between a logic model and work plan at the following website: https://www.cdc.gov/obesity/downloads/CDC-Evaluation-Workbook-508.pdf.

Appendix E: Frequently Asked Questions (FAQs)

1. **Where do I find application materials for the Research Network?**

   All application materials are available through Grants.gov

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

   You can download the application from Grants.gov.

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

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

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

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

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

   1) *Make sure that the AOR from your university/organization is registered in Grants.gov NOW. This process can take up to 1 month and it is better to complete it and have it out of the way before starting any grant application.*
   2) *Read the instructions on Grants.gov carefully and allow time for corrections. Enter information in fields even if it is 0 or the form will remain incomplete. Required fields are highlighted in yellow.*
   3) *There are resources available on the Grants.gov website to help you navigate this new system. Please visit Grants.gov to access these resources.*
   4) *Some business practices will change with the introduction of the new SF-424 R&R Form.*
      - *With the HRSA SF-424 R&R, you will be reporting faculty and staff time in calendar month equivalents.*
      - *Budget details about subcontracts will now be described in a section of the SF-424 R&R called sub-awards.*

- *New applications will now fill out detailed budgets for each of the years in the period of performance. Therefore, submit detailed budgets for each of the 5 years.*

6. What types of institutions can apply?

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

7. We are a foreign organization interested in applying for the Research Network. Are foreign entities eligible to apply?

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

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

According to the HRSA SF-424 R&R Application Guide (as aligned with the Uniform Administrative Requirements at 45 CFR part 75), "any non-federal entity that has never received a negotiated indirect cost rate, (except a governmental department or agency unit that receives more than $35 million in direct federal funding) may elect to charge a de minimis rate of 10 percent of modified total direct costs (MTDC) which may be used indefinitely. The HRSA SF-424 R&R Application Guide also contains information on how to negotiate the indirect cost rate.

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

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

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

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

- *Key personnel such as co-investigators, study coordinator, data manager, and other NCC staff are identified. Applications that do not propose PI, co-investigator, and other key personnel for the successful implementation of a national Research Network will not receive full points in this section of the NOFO.*
- *The PI, staff, and collaborators are well-qualified by training and/or expertise to develop the infrastructure of the Research Network and to accomplish the*

activities of the Research Network as described in this NOFO.

- *The PI and other key personnel demonstrate current and/or past success in publishing the findings of their research.*
- *The applicant has the existing resources/facilities to achieve project objectives and to successfully support the Research Network described in the proposal.*
- *The partnering programs demonstrate the ability and commitment to collaborate with the applicant organization and ability to recruit from their patient population for Research Network research studies.*
- *Costs, as outlined in the budget and required resources sections, are reasonable given the scope of work.*
- *Budget line items that are well described and justified in the budget justification narrative.*
- *Time allocated by key personnel is appropriate to achieve project objectives.*

11. **Can someone who is currently a PI on another agency grant be a PI of the Research Network?**

Yes, however, if selected for funding, the new recipient will need to verify that percent effort across all federally funded grants does not exceed 100 percent.

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

Yes, more than one application per institution is allowable.

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

Include biographical sketches for persons occupying key positions. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch. Given the 80-page limit, it is recommended that biographical sketches be no more than two pages in length per person. Biographical sketches should document education, skills, and experience that are relevant, necessary, and demonstrate capability to fulfill the assigned roles for the proposed project.

14. Are there page limits for the submitted application?

Please consult the NOFO and/or the HRSA R&R Application Guide, referenced throughout the NOFO, for more specific information.

15. Are there any page limitations to the narrative?

The NOFO requires a 12-page limit for Section III - Project Design: Methods and Evaluation, of the narrative. Preliminary studies can be included if applicable and would be included in the 12-page limit as described above. Please consult the NOFO and/or the HRSA R&R Application Guide, referenced throughout the NOFO, for more specific information.

16. Are there font/margin requirements?

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

17. 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.

18. When will you announce your other research NOFOs?

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

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

Please contact:

- *For programmatic questions, the program officers listed in the NOFO via email.*
- *For budget questions, the grants management specialist listed in the NOFO via email.*

20. Does HRSA offer extensions for submitting applications?

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