U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

HRSA
Health Resources & Services Administration

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

UT5 Developmental Behavioral Pediatrics Research Network (DBPNet)

Funding Opportunity Number: HRSA-21-039
Funding Opportunity Type(s): New
Assistance Listings (CFDA) Number: 93.877

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

Application Due Date: February 2, 2021

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

Issuance Date: November 4, 2020

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2021 UT5 Developmental Behavioral Pediatrics Research Network (DBPNet). The purpose of this program is to establish and maintain a national, multi-site, collaborative research network for scientific collaboration and infrastructure building. This Research Network will provide national leadership in research to advance the evidence base in the developmental, behavioral, and psychosocial aspects of pediatric care to improve clinical services and health and related outcomes for children and adolescents with autism spectrum disorder (ASD) and other developmental disabilities across the lifespan.

The FY 2021 President's Budget does not request funding for this program. This notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately. You should note that this program may be cancelled prior to award.

Funding Opportunity Title:	UT5 Developmental Behavioral Pediatrics Research Network (DBPNet)
Funding Opportunity Number:	HRSA-21-039
Due Date for Applications:	February 2, 2021
Anticipated Total Annual Available FY 2021 Funding:	$275,000
Estimated Number and Type of Award(s):	One cooperative agreement
Estimated Award Amount:	Up to $275,000 per year subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2021 through August 31, 2026 (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 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: Tuesday, November 17, 2020
Time: 3–4:30 p.m. ET
Call-In Number: 1-888-972-9684
Participant Code: 5781321
Weblink: https://hrsa.connectsolutions.com/fy21_dbpnet_ta/
In order to access the webinar, please use the "Guest" option, type your name in the field, and press "Enter Room."

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

HRSA will record the webinar and make it available approximately 2 weeks after the webinar 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 UT5 Developmental Behavioral Pediatrics Research Network (DBPNet) Program. The purpose of this program is to establish and maintain a national, multi-site, collaborative research network for scientific collaboration and infrastructure building. This Research Network will provide national leadership in research to advance the evidence base in the developmental, behavioral, and psychosocial aspects of pediatric care to improve clinical services and health and related outcomes for children and adolescents with autism spectrum disorder and other developmental disabilities (ASD/DD) across the lifespan. It will work to develop effective interventions[1] in clinical services and to improve health and related outcomes for children and adolescents with autism spectrum disorder and other developmental disabilities (ASD/DD).

The Research Network will:
- Lead, promote, and coordinate national research activities to improve the health and well-being of children and adolescents with ASD/DD, especially those from underserved[2] populations who may have limited access to effective ASD/DD treatments;[3]
- Develop and maintain an infrastructure to support the design of a portfolio of interdisciplinary research that focuses on fostering the implementation of multi-site intervention research studies, translating research to policy and practice that meets the needs of all children (including those traditionally underserved);
- Coordinate a plan to enhance the research training and mentorship of diverse emerging investigators from traditionally underserved backgrounds through the use of innovative mentorship/research experiences and manuscript development;[4] and
- Address, where applicable, U.S. Department of Health and Human Services' (HHS) and Health Resources and Services Administration's (HRSA) priorities, namely, mental health and telehealth.

For cooperative agreement activities, please see Project Narrative Section III.

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[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. Source: 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 June 25, 2020.
[2] In this NOFO, underserved populations include low-income, racial/ethnic minorities, immigrants, females, 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. Proposals should not duplicate the aims of this separate investment.
[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.

2. Background

This program is authorized by 42 U.S.C. § 280i-1(f) (Title III, § 399BB(f) of the Public Health Service Act, as amended by the Autism Collaboration, Accountability, Research, Education, and Support Act of 2019 (Autism CARES Act) (P.L. 116-60)).

The need for more providers to care for children with, or at risk for, ASD/DD is evident by the high incidence of autism in the United States. A comprehensive picture of ASD among children in the United States is best understood by examining two key estimates of ASD prevalence[5]. According to a study using medical and education records in select communities in the United States, approximately 1 in 54 children have ASD,[6] while parent-reported data from the 2016 National Survey of Children's Health documented that 1 in 40 children aged 3–17 years have a diagnosis of ASD.[7] Children and adolescents with ASD/DD have greater health service needs, which can place a significant financial and emotional burden on their families.[5]

Developmental behavioral pediatric (DBP) providers are trained to consider both the medical and psychosocial aspects of children's and adolescents' developmental and behavioral needs. They evaluate and treat children and adolescents with some of the most prevalent and chronic conditions including ASD, attention deficit hyperactivity disorder (ADHD), developmental delays, learning disorders, and behavioral/conduct disorders. Despite the increase in the prevalence of developmental behavioral conditions among children, the involvement of DBPs in research has been limited. This may contribute to the fact that few evidence-based assessments or interventions specific to the field have been developed. To date, the Society for Developmental Behavioral Pediatrics, the professional society for DBPs, has established one clinical practice guideline. Assessments and management guidelines created by DBPs are critical to ensuring that every provider who treats a child with ASD/DD has access to resources to provide evidence-informed optimal care. These guidelines are especially significant in light of the DBP workforce shortage. The need for DBP providers has outpaced the current workforce, resulting in over 50% of DBPs reporting that patients wait ≥8 weeks to get an initial appointment.[8] There is a dire need to improve access to quality care and treatment for children and adolescents with ASD/DD. This is especially critical to those from underserved populations. These populations encounter persistent disparities in screening, diagnosis, and service access that increases their vulnerability for adverse health outcomes across the lifespan.[9,10] Research Networks are needed to coordinate and provide infrastructure for national DBP research activities and by design may be an effective mechanism for addressing disparities.[9,11]

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

[6] Autism and Developmental Disabilities Monitoring Network (2016 data) (http://www.cdc.gov/ncbddd/autism/data.html)

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

[8] Bridgemohan C, N Bauer, B Nielsen, A DeBattista, H Ruch-Ross, L Paul, N Roizen. A workforce survey on developmental behavioral pediatrics. *Pediatrics* 2018; 141(3): e20172164.

[9] 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.

[10] Bishop-Fitzpatrick L, Kind AJH. A scoping review of health disparities in autism spectrum disorder. *J Autism Dev Disord*. 2017;47(11):3380-3391.

[11] 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,
- State Systems 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 Maternal and Child Health Bureau's (MCHB) Office of Epidemiology and Research, supports the establishment and maintenance of interdisciplinary, national, multi-site, collaborative Research Networks that lead, promote, and coordinate national research activities on both broad and specific MCH topics. In 2019, HRSA MCH Research Networks contributed to improving the lives and health of MCH populations by:

- Enrolling approximately 14,000 participants and utilizing data on an additional 10 million participants in secondary data analyses in 124 research studies;
- Publishing 155 peer-reviewed articles in leading scholarly journals; and
- Developing and distributing 63 clinical guidelines, tools, or toolkits collectively to service providers and families.

Research Network Organization and Functions
The following describes the expectations for a Research Network:

Organization and Functions

The Research Network will consist of a Network Coordinating Center (NCC) and multiple Collaborating Research Entities/Sites (CREs).[12] 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:
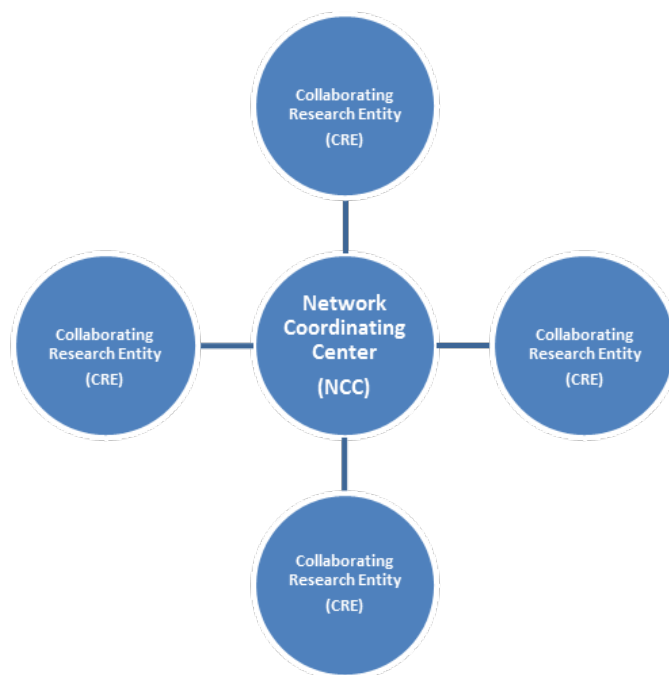
Research Network Organizational Structure with the NCC

The NCC will be located at the project director/principal investigator's (PD/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;
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 other MCHB recipients, 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;

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[12] 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. RNs must continue to innovate, grow the evidence base, and strive to address health disparities in MCH 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. RNs 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 MCH population. RNs must collaboratively develop solutions to current and emerging health and development challenges.

6) Establish and implement a plan to ensure parent, family and/or consumer involvement across populations including underserved populations in Research Network activities and;

7) Collaborate with pertinent partners, such as other HRSA-supported Autism CARES Act Programs (available here: https://mchb.hrsa.gov/maternal-child-health-initiatives/autism), other MCHB recipients, Title V recipients, and MCH Research Network recipients (available here: https://mchb.hrsa.gov/research)..

For cooperative agreement activities, please see Project Narrative Section III.

Research Network Advisory Board or Steering Committee

The Research Network Advisory Board or Steering Committee will be comprised of representatives of the CREs, HRSA/MCHB, and new to this competition at least two community members (e.g., a family advocate). The PI will serve as Chair of the 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, if possible. The PI will meet annually with HRSA/MCHB leadership and other key stakeholder organizations, such as Title V MCH Services Block Grant programs, clinical interest groups, state and local education districts, and federal partners, such as the HHS Centers for Medicare and Medicaid Services, and U.S. Department of Education agencies, as applicable, to brief them on the existence and progress of the Research Network and to engage them in 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.[13]

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[13] 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

Type(s) of applications sought: New

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement is a financial assistance mechanism where HRSA anticipates substantial involvement with 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 will 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 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 will include:

1) Establishing and maintaining an interdisciplinary, multi-site, national Research Network to determine evidence-based practices for interventions in clinical services and health and related outcomes for children and adolescents with ASD/DD 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) that address inequities in developmental behavioral health interventions and treatment in individuals with ASD/DD;
3) <u>New to this competition</u>: Establishing partnerships with programs serving underserved populations and recruiting study participants from these populations, such as HRSA's Health Center Program or Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program;
4) Providing a research environment that supports the professional development and mentorship of diverse emerging investigators in the field of developmental behavioral pediatric health intervention research for ASD/DD, that includes

researchers representing underserved populations to ensure diversity among new trainees;

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 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 protocols;

8) Providing an electronic copy of any products supported by award funds (e.g., guidelines, assessment tools, publications, books, pamphlets, PowerPoint presentations, curricula, videos) to the general public and to the MCH Research Program; and

9) Collaborating with the other HRSA-supported Autism CARES Act Programs, Title V recipients, and MCH Research Network recipients 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 $275,000 to be available annually to fund one recipient. The actual amount available will not be determined until enactment of the final FY 2021 federal appropriation. You may apply for a ceiling amount of up to $275,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The FY 2021 President's Budget does not request funding for this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately.

The period of performance is September 1, 2021 through August 31, 2026 (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 not to 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.

HRSA will not consider any application that does not adhere to the 1" margin guidelines specified in HRSA's *SF-424* Research and Related (*R&R) Application Guide.*

NOTE: Multiple applications from an organization are allowable. In order to diversify the HRSA/MCHB research award portfolio, an individual cannot serve as the project director/principal investigator (PD/PI) on more than one active HRSA MCH Research Network. New to this competition, the PD/PI is expected to commit a minimum percent effort of 20 percent on this project to justify their commitments to the project. To foster interdisciplinary collaboration and increase opportunities for mentorship for emerging MCH researchers, a PD/PI on an active HRSA MCH research grant is encouraged to commit 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. This policy does not apply to PD/PIs 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.

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 notice of funding opportunity (NOFO) following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

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

2. Content and Form of Application Submission

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

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

Application Page Limit

The total size of all uploaded files included in the page limit may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments including biographical sketches (biosketches), and letters of commitment and support required in HRSA's *SF-424 R&R Application Guide* and this NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Please note: If you use an OMB-approved form that is not included in the workspace application package for HRSA-21-039, it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **It is important 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.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification
1) You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. § 3321).
3) Where you are unable to attest to the statements in this certification, an explanation shall be included in *Attachments 7–15: Other Relevant Documents*.

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

Temporary Reassignment of State and Local Personnel during a Public Health Emergency

Section 319(e) of the Public Health Service (PHS) Act provides the Secretary of the Department of Health and Human Services (HHS) with discretion upon request by a state or tribal organization to authorize the temporary reassignment of state, tribal, and local personnel during a declared federal public health emergency. The temporary reassignment provision is applicable to state, tribal, and local public health department or agency personnel whose positions are funded, in full or part, under PHS programs and allows such personnel to immediately respond to the public health emergency in the affected jurisdiction. Funds provided under the award may be used to support personnel who are temporarily reassigned in accordance with § 319(e). Please reference detailed information available on the HHS Office of the Assistant Secretary for Preparedness (ASPR) website via
http://www.phe.gov/Preparedness/legal/pahpa/section201/Pages/default.aspx.

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-21-039
- FUNDING OPPORTUNITY TITLE: UT5 Developmental Behavioral Pediatric Research Network (DBPNet)
- 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 developmental behavioral health of individuals with ASD/DD;
- Critical evaluation of the national significance of this Research Network;
- Knowledge and identification of the needs and issues for children and adolescents with ASD/DD, especially those from underserved populations;
- How proposed interdisciplinary research studies may fill gaps in research and advance the field of developmental behavioral pediatrics; and
- How the national, multi-site, collaborative research network may address identified needs of children and adolescents with ASD/DD, including those of 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 goals and objectives that address the major Research Network activities listed in the Purpose section of this notice. 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 in consultation with HRSA/MCHB, including studies on emerging topics affecting children and adolescents with ASD/DD, especially those from underserved populations;
- The process for developing an integrated Research Network and a plan of proposed activities showing progressive implementation to ensure national level activities 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;
- 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. 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 4**). 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 includes: patient population characteristics for individuals with ASD/DD; average patient numbers; types of ASD/DD-related treatments, interventions, or services currently delivered; and characteristics and structure of staff. **Include letters of agreement from CRE sites in *Attachment 1*.** It is expected that <u>at least six CREs</u> 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, please refer to Appendix E: Collaboration Plan Guidance.

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 <u>12-page limit</u>.

Describe the methodology for accomplishing the work of the Research Network and each of its distinct objectives. Provide 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 goal and objective. 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 of children and adolescents with ASD/DD, and the greater public. Include:

- Peer-reviewed publications: It is expected that the Research Network will produce at least three 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: It is expected that the Research Network will maintain a public Research Network website to disseminate research findings, generate interest in the Research Network, and expand Research Network membership;
- Research acceleration: It is expected that the Research Network will 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; and
- Stakeholder engagement: It is expected that the Research Network will showcase 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 the 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 performance management 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 studies 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. Research Network Activities:

For this cooperative agreement the recipient will perform the activities listed below.

- 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 developmental behavioral pediatrics in accordance with the objectives and functions outlined in this NOFO;
- 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 (including non-physician providers), academics, national experts, research entities, and family members, including those from underserved populations, in accordance with the guidance outlined in this NOFO;
- 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 developmental behavioral pediatrics;
- 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 developmental and behavioral health of children and adolescents with ASD/DD especially those from underserved populations, in consultation with HRSA/MCHB leadership;
- Recruit research 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, MIECHV);

- Engage key audiences such as policymakers; researchers; school systems; health professionals; families; community members; and state, tribal, territorial, and local agencies that support underserved children and adolescents with ASD/DD to advance the translation of research into practice;
- Develop and evaluate resources such as guidelines, tools, or toolkits for use in clinical practice or intervention-based research in communities;
- Train and mentor diverse emerging investigators in developmental behavioral pediatric research;
- Develop and maintain a public website for engaging multiple stakeholders;
- Schedule monthly and ad hoc meetings with the HRSA project officer to ensure ongoing communication and collaboration;
- Ensure challenges and barriers to completing proposed activities and achieving goals are discussed with HRSA project officer in a timely manner;
- Coordinate monthly virtual meetings with the Research Network Advisory Board or Steering Committee and at least one in person meeting annually;
- Meet annually with HRSA/MCHB leadership and other key stakeholders; and
- 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 its 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 3** describing the leadership structure of the Research Network demonstrating collaboration between the PI, co-investigators, and the 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.

iii. Budget

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

Reminder: The Total Project or Program Costs are the total allowable costs (inclusive of direct **and** indirect costs) you incur to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by 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.

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: [14]

- Annual in-person Research Network leadership meeting at a location convenient to the majority of the leadership members;
- 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 Program Grantee Meeting in the Washington, D.C. metropolitan area; and
- An in-person or virtual attendance at the MCHB Autism CARES Act Grantee Meetings, held in the Washington, D.C. metropolitan area. For planning purposes, the in-person and virtual meetings alternate years. It is recommended that the PI plan to attend the in-person meetings in Year 2 and Year 4. Budgets should include travel costs associated with this 1 ½ day grantee meeting.

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

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[14] If planned meetings must be held virtually due to extenuating circumstances, any unused funds may be re-allocated with the approval of your project officer.

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

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 (7) Program Assurances
Biographical Sketches	(5) Resources/Capabilities
Budget and Budget Justification Narrative	(6) Support Requested

Please note that even though the document has an OMB clearance number, it is not a standard form and your response counts against the page limit.

v. Program-Specific Forms
Program-specific forms are not required for application.

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

Attachment 1: Letters of Agreement/Letters of Support

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

Attachment 2: 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 3: 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 4: 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 your logic model should, at a minimum, address the following areas:

> 1. Identify the Problem(s), Target Population(s), and Program Purpose:
>   - What problem does the program address?
>   - Target population(s):

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

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

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

Attachment 5: Proof of Non-Profit Status (Not counted in the page limit)

Attachment 6: Indirect Cost Rate Agreements (Not counted in the page limit)

Check with your sponsored program's 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 7–15: 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 (DUNS) Number Transition to the Unique Entity Identifier (UEI) and System for Award Management (SAM)**

You must obtain a valid DUNS number, also known as the Unique Entity Identifier (UEI), and provide that number in the application. At a future, to-be-determined date, the *DUNS number will be replaced by the UEI, a "new, non-proprietary identifier" requested in, and assigned by, the System for Award Management (SAM.gov). For

more details, visit the following pages: [Planned UEI Updates in Grant Application Forms](#) and [General Service Administration's UEI Update](#).

You must also register with SAM and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d))**.**

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

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

Currently, the Grants.gov registration process requires information in three separate systems:
- Dun and Bradstreet (http://www.dnb.com/duns-number.html)
- System for Award Management (SAM) (https://www.sam.gov)
- Grants.gov (http://www.grants.gov/)

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

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

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

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

4. Submission Dates and Times

Application Due Date
The due date for applications under this NOFO is *February 2, 2021 at 11:59 p.m.ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadline** to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's *SF-424 R&R Application Guide* for additional information.

5. Intergovernmental Review

The UT5 Developmental Behavioral Pediatrics Research Network (DBPNet) Program is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

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

6. Funding Restrictions

You may request funding for a period of performance of up to 5 years, at no more than $275,000 per year (inclusive of direct **and** indirect costs). The FY 2021 President's Budget does not request funding for this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately. 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.

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

The General Provisions in Division A of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) and Continuing Appropriations Act, 2021 and Other Extensions Act (P.L. 116-159) are in effect at the time this NOFO is posted. Please see Section 4.1 of HRSA's *SF-424 R&R Application Guide* for additional information. Awards will be made subsequent to enactment of the FY 2021 appropriation. The NOA will reference the FY 2021 appropriation act and any restrictions that may apply. Note that these or other restrictions will apply as required by law in subsequent appropriations acts for FY 2021.

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. Review criteria are used to review and rank applications. The Research Network has seven review criteria. See the review criteria outlined below with specific detail and scoring points.

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

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

The extent to which the application describes:

- The current research gaps in evidence-based practices in the field of developmental behavioral pediatrics, focused on addressing disparities in effective interventions, treatment, and access to care across the lifespan, especially for underserved populations;
- The awareness of previous work in developmental behavioral pediatrics, including citation of relevant literature and justification of the need for the Research Network;
- An approach using interdisciplinary collaborative multi-site research to address the identified needs of children and adolescents with ASD/DD; and
- The national significance 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 how these studies will address developmental behavioral health outcomes in ASD/DD populations. Applications not proposing intervention studies will not receive points for this NOFO review criteria subsection.

Other Response Areas (10 points)

- Responds to, and describes its abilities to implement, all activities described in the "[Purpose]()" section for this competition;
- Describes clear, concise, and appropriate goals and objectives and their relationship to the identified project;
- Aligns its activities (scientific or other) to address the identified problem(s) and attain 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;
- Proposes an interdisciplinary approach that includes non-physician providers and encompasses the range of providers in the field of developmental behavioral pediatrics;
- Clearly articulates the project in a logic model; and
- Describes collaboration with several partnering programs serving underserved populations, 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*

Dissemination (10 points)

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

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

Other Response Areas (10 points)

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 implementation plan is articulated for the proposed intervention studies;
- 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.

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 developmental behavioral pediatrics.
- The potential impact of project results in advancing and strengthening the evidence base for developmental behavioral pediatric interventions and treatments and access to care for children and adolescents with ASD/DD, especially underserved populations.
- The extent to which project results may be national in scope, the degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding.
- 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.
- An effective plan for engaging other funded Autism CARES Act and MCHB programs (e.g., other Research Networks) 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*

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 (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; and
- The applicant's 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.

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. The extent to which:

- 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](#)

Proposed Sequence or Timetable, Targeted/Planned Recruitment/Enrollment, and Resolution of Challenges (6 points)

The extent to which the application:

- Includes a proposed project with a clear and feasible timeline;
- Demonstrates the feasibility of reaching targeted/planned enrollment levels within the timeline provided;
- Provides details regarding the Targeted/Planned Enrollment for their proposed studies, including information on anticipated sociocultural group categories (e.g., race, ethnicity, language, rural versus urban, socioeconomic, gender);
- Describes a targeted recruitment/enrollment plan taking into account the cultural sensitivities of the target population;
- Anticipates and addresses potential barriers to project progress, such as challenges in recruiting hard-to-reach populations;
- Describes plans to evaluate whether the project objectives are being met according to the timeline provided; and
- Provides assurance that the Research Network platform can be sustained as proposed.

Protection of Human Subjects (4 points)

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: 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).

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.

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

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

VI. Award Administration Information

1. Award Notices

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

2. Administrative and National Policy Requirements

See Section 2.1 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, and it is the recipient's responsibility to monitor the compliance of all funded subrecipients. See 45 CFR § 75.101 Applicability for more details.

Data Rights

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

Human Subjects Protection

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

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

3. Reporting

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 at https://grants4.hrsa.gov/DGISReview/FormAssignmentList/UT5.html. The type of report required is determined by the project year of the award's period of performance.

Type of Report	Reporting Period	Available Date	Report Due Date
a) New Competing Performance Report	September 1, 2021- August 31, 2022 *(administrative data and performance measure projections, as applicable)*	Period of performance start date	120 days from the available date
b) Non-Competing Performance Report	September 1, 2021- August 31, 2022 September 1, 2022- August 31, 2023 September 1, 2023- August 31, 2024 September 1, 2024- August 31, 2025	Beginning of each budget period (Years 2– 4, as applicable)	120 days from the available date
c) Project Period End Performance Report	September 1, 2025- August 31, 2026	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). 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.

VII. Agency Contacts

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

Tya Renwick
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 594-0227
Email: TRenwick@hrsa.gov

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

Maura Maloney, PhD, MS
Program Officer, Office of Epidemiology and Research, Division of Research
Attn: DBPNet
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 18N11
Rockville, MD 20857
Telephone: (301) 443-1087
Email: MMaloney@hrsa.gov

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

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

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs).

For assistance with submitting information in the EHBs, contact the HRSA Contact Center, Monday–Friday, 8 a.m. to 8 p.m. ET, excluding federal holidays at:

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

VIII. Other Information

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Tuesday, November 17, 2020
Time: 3–4:30 p.m. ET
Call-In Number: 1-888-972-9684
Participant Code: 5781321
Weblink: https://hrsa.connectsolutions.com/fy21_dbpnet_ta/
In order to access the webinar, please use the "Guest" option, type your name in the field, and press "Enter Room."

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

HRSA will record the webinar and make it available approximately 2 weeks after the webinar 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 2030
http://www.healthypeople.gov/2030/

HRSA/MCHB Division of MCH Workforce Development
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)
https://medicalhomeinfo.aap.org/Pages/default.aspx

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
- Risky Behaviors
- Sexually Transmitted Infections
- 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

Life Course & Social Determinants
- Life Course
- Neighborhood
- Social Determinants of Health

b) **Targeted Population(s) (as many as apply):**
- African American
- Asian/Pacific Islander
- Hispanic/Latino
- Immigrant
- Low-income
- Native American/Alaskan Native
- Rural
- Special Health Care Needs

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

Appendix C: Application Completeness Checklist

Funding Opportunity Number: HRSA-21-039 Application Due Date in Grants.gov: February 2, 2021	
Requirement	**Yes**
Do you meet the eligibility criteria?	
Did you read the R&R Application Guide	
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 annual 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 no more at least 1" 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 DBPNet.

PROGRAM INPUTS: 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.

STAKEHOLDERS: Organizations, state and local entities, and families addressing the needs of children with ASD/DD.

Key Resources: ASD/DD experts, MCHB/OER guidance and resources, families, public and private funds.

PROGRAM PROCESS What is the planned work for the program?		PROGRAM OUTCOMES What are the program's intended results?	
ACTIVITIES **(What will program inputs do?)**	**OUTPUTS / PRODUCTS** **(What will be created as a result of the activity?)**	**SHORT-TERM / INTERMEDIATE** **(What will change as a result of the product/system implemented?)**	**LONG-TERM / IMPACT** **(What will change if short-term / intermediate outcomes are achieved?)**
Create and maintain a national, multi-site, collaborative infrastructure to conduct research focused on DD (e.g., ASD, ADD/ADHD, and related conditions) that aims to optimize child health and development and improve clinical practice serving children with DDs.	A national, multi-site, collaborative research network for interventions focused on optimizing child health and development and improve clinical practice serving children with ASD and DDs.	Increase the number of resources on developmental pediatric health issues available to help clinicians, researchers, and community members. Increase collaboration and coordination of research on developmental and behavioral pediatrics.	Advance the evidence base on developmental and behavioral pediatrics. Increasing the implementation of evidence-based interventions into practice. Support HRSA's Autism portfolio by supporting interdisciplinary research to advance the evidence base on the effectiveness of interventions to improve the health and well-being of children and adolescents with ASD and DD and to advance best practices for early identification.
Form an interdisciplinary Network Steering Committee / Advisory Board composed of diverse professionals and family members.	Interdisciplinary and diverse Network Steering Committee / Advisory Board established, and annual in-person meetings convened.	Increase the active contribution and incorporation of stakeholders (researchers, practitioners, and community members) into activities advancing interventions on developmental behavioral pediatrics to determine the priority of proposed interventions as well as ensure its success and acceptability in the field of developmental behavioral pediatrics.	
Engage family members in RN studies.	Family members engaged as members of the Network Steering Committee. Input from family members incorporated in the design and implementation of RN studies on children with ASD and DD's.		

PROGRAM PROCESS What is the planned work for the program?		PROGRAM OUTCOMES What are the program's intended results?	
ACTIVITIES **(What will program inputs do?)**	**OUTPUTS /** **PRODUCTS** **(What will be created as a result of the activity?)**	**SHORT-TERM /** **INTERMEDIATE** **(What will change as a result of the product/system implemented?)**	**LONG-TERM /** **IMPACT** **(What will change if short-term / intermediate outcomes are achieved?)**
Create or update a national research agenda for scientific studies building upon advances in research and practice in developmental and behavioral pediatrics (in collaboration with MCHB).	National research agenda for scientific studies building upon advances in research and practice in developmental and behavioral pediatrics.		
Design and implement intervention research studies on research and practice in developmental and behavioral pediatrics.	Intervention research studies designed and implemented.		
Develop and implement a dissemination plan for communicating research findings to diverse stakeholders.	Dissemination plan with a timeline and list of proposed products Manuscripts accepted or published in peer-reviewed journals each year 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)	Increase the spread, breadth, and accessibility of resources on developmental behavioral pediatrics available to help clinicians, researchers, and community members improve the health of children with ASD and DD.	
Collaborate with key audiences (e.g., researchers, clinicians, Title V populations, Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV) populations, families, policymakers) in implementing and utilizing evidence based developmental behavioral pediatrics research.	Key audiences are engaged Resources developed that include the input of key audiences and are shared broadly and in varying formats	Increase the active contribution and collaboration of key audiences with DBPNet to ensure that evidence based developmental behavioral pediatric research is appropriately utilized in their activities, programs, and when creating ASD/DD guidelines and policy.	Increase the use of evidence based developmental behavioral pediatric research findings in practice and ASD/DD programming. Improve the care, quality, and treatment for children and adolescents with ASD and DD.

PROGRAM PROCESS What is the planned work for the program?		PROGRAM OUTCOMES What are the program's intended results?	
ACTIVITIES (What will program inputs do?)	OUTPUTS / PRODUCTS (What will be created as a result of the activity?)	SHORT-TERM / INTERMEDIATE (What will change as a result of the product/system implemented?)	LONG-TERM / IMPACT (What will change if short-term / intermediate outcomes are achieved?)
Develop and evaluate resources such as guidelines, tools, study protocols, or toolkits for use in pediatric or intervention-based research in community settings.	Resources developed, evaluated, and utilized in pediatric practice or intervention-based research in community settings.	Increase the spread, breadth, and accessibility of resources on developmental behavioral pediatrics available to help clinicians, researchers, and community members improve the health of children with ASD and DD.	
Prepare and submit applications for external funding opportunities outside of HRSA/MCHB's research program.	Applications completed and submitted for external funding opportunities.	Increase the capacity of recipients to expand/sustain research initiated by the MCH RN program.	Increase and strengthen the capacity of the research community that focuses on developmental behavioral pediatrics. Advance the evidence base on developmental behavioral pediatrics.
Develop and maintain a public website for engaging multiple stakeholders and communicating the work of the DBPNet.	Publicly available website representing the work of DBPNet developed and maintained.	Increase the number of resources on developmental behavioral pediatrics available to help clinicians, researchers, and community members.	
Train and mentor junior/new investigators on developmental behavioral pediatrics.	Junior/new investigators trained/mentored.	Increase the number of multidisciplinary investigators trained/mentored in the field of developmental behavioral pediatrics.	

Appendix E: Collaboration Plan Guidance

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.

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

- 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.

<u>Responsibility of Each CRE Site</u>: In conducting studies and participating in Research Network activities, each CRE should:

- Describe a plan to establish and sustain the CRE;
- 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 developmental behavioral health research and other related outcomes.

Appendix F: 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 and cooperative agreement 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 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 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 the system. Please visit Grants.gov to access these resources.*
   4) *Some business practices changed with the introduction of the 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 subawards.*
      - *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 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 cooperative agreement, 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?**

   Your 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?**

    Yes, the PI is expected to commit a minimum of 20 percent FTE to this cooperative agreement. In addition, 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 a PI, co-investigator, and other key personnel for the successful implementation of a national Research Network will be deemed non-responsive to 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 award 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 awards does not exceed 100 percent FTE.

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. For details on how to format the biographical sketch, visit: https://mchb.hrsa.gov/research/documents/FORM-Biographical-Sketch-for-Research-Grant-Applicants-Jan2020-2023.docx. Please note that even though the document has an OMB clearance number, it's not a standard form and your response counts against the page limit.

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

The total size of all uploaded files included in the page limit may not exceed the equivalent of **80 pages** *when printed by HRSA. Please see the Application Page Limit section for further 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 officer listed in the NOFO via email.*
- *For budget questions, the grants management specialist listed in the NOFO via email.*

20. Can I send the point of contact/project officer my project proposal/abstract/project summary to review?

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

21. 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.