

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Health Resources and Services Administration**

Maternal and Child Health Bureau  
Division of Research

***Developmental Behavioral Pediatrics Research Network***

**Announcement Type:** New, Competing Continuation

**Funding Opportunity Number:** HRSA-16-039

**Catalog of Federal Domestic Assistance (CFDA) No. 93.877**

**FUNDING OPPORTUNITY ANNOUNCEMENT**

Fiscal Year 2016

**Application Due Date: April 26, 2016**

*Ensure SAM.gov and Grants.gov registrations and passwords are current immediately!  
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Registration in all systems, including SAM.gov and Grants.gov,  
may take up to one month to complete.*

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Authority: Public Health Service Act, § 399BB(f), (42 U.S.C. 280i-1(f)) as amended by the Autism CARES Act of 2014 (P.L. 113-157).

## EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau's (MCHB), Office of Epidemiology and Research is accepting applications for the fiscal year (FY) 2016 Developmental Behavioral Pediatrics Research Network. The purpose of this program is to establish and maintain a national scientific and clinical research network that will promote and coordinate research activities in 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.

Funding Opportunity Title:	Developmental Behavioral Pediatrics Research Network
Funding Opportunity Number:	HRSA-16-039
Due Date for Applications:	April 26, 2016
Anticipated Total Annual Available Funding:	\$275,000
Estimated Number and Type of Award(s):	Up to one (1) cooperative agreement
Estimated Award Amount:	Up to \$275,000 per year
Cost Sharing/Match Required:	No
Project Period:	September 1, 2016 through August 31, 2021 (five (5) years)
Eligible Applicants:	<p>Eligible applications include any public or private entity, including research centers or networks. Faith-based and community-based organizations, Tribes, and tribal organizations are eligible to apply. Non-U.S. entities are not eligible to apply.</p> <p>[See <a href="#">Section III-1</a> of this funding opportunity announcement (FOA) for complete eligibility information.]</p>

### **Application Guide**

All applicants are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide*, available online at <http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf>, except where instructed in this FOA to do otherwise. A short video for applicants explaining the *Application Guide* is available at <http://www.hrsa.gov/grants/apply/applicationguide/>.

# Table of Contents

<b>I. PROGRAM FUNDING OPPORTUNITY DESCRIPTION .....</b>	<b>1</b>
1. PURPOSE.....	1
2. BACKGROUND .....	4
<b>II. AWARD INFORMATION .....</b>	<b>6</b>
1. TYPE OF APPLICATION AND AWARD .....	6
2. SUMMARY OF FUNDING .....	8
<b>III. ELIGIBILITY INFORMATION.....</b>	<b>8</b>
1. ELIGIBLE APPLICANTS .....	8
2. COST SHARING/MATCHING .....	8
3. OTHER .....	8
<b>IV. APPLICATION AND SUBMISSION INFORMATION.....</b>	<b>9</b>
1. ADDRESS TO REQUEST APPLICATION PACKAGE.....	9
2. CONTENT AND FORM OF APPLICATION SUBMISSION.....	9
i. <i>Project Abstract</i> .....	10
ii. <i>Project Narrative</i> .....	10
iii. <i>Budget</i> .....	16
iv. <i>Budget Justification Narrative</i> .....	17
v. <i>Program-Specific Forms</i> .....	17
vi. <i>Attachments</i> .....	18
3. DUN AND BRADSTREET UNIVERSAL NUMBERING SYSTEM NUMBER AND SYSTEM FOR AWARD MANAGEMENT.....	19
4. SUBMISSION DATES AND TIMES.....	20
5. INTERGOVERNMENTAL REVIEW .....	20
6. FUNDING RESTRICTIONS .....	20
<b>V. APPLICATION REVIEW INFORMATION .....</b>	<b>20</b>
1. REVIEW CRITERIA.....	21
2. REVIEW AND SELECTION PROCESS .....	24
3. ASSESSMENT OF RISK.....	24
4. ANTICIPATED ANNOUNCEMENT AND AWARD DATES .....	24
<b>VI. AWARD ADMINISTRATION INFORMATION.....</b>	<b>25</b>
1. AWARD NOTICES .....	25
2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS.....	25
3. REPORTING .....	25
<b>VII. AGENCY CONTACTS .....</b>	<b>28</b>
<b>VIII. OTHER INFORMATION.....</b>	<b>29</b>
<b>IX. TIPS FOR WRITING A STRONG APPLICATION.....</b>	<b>29</b>
<b>APPENDIX: KEY TERMS FOR PROJECT ABSTRACTS.....</b>	<b>30</b>

# **I. Program Funding Opportunity Description**

## **1. Purpose**

This announcement solicits applications for the Developmental Behavioral Pediatrics Research Network Program.

This cooperative agreement opportunity will establish and maintain a national scientific and clinical research network that will promote and coordinate research activities in 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. The Developmental Behavioral Pediatrics Research Network Program was first implemented in 2010. The network infrastructure will support the design and implementation of interdisciplinary research studies that focus on the translation of research to practice; provide the mentoring environment to train a new generation of developmental behavioral pediatrics researchers; and foster the implementation of multi-site research studies.

The awardee will complete the following major activities:

### **Infrastructure Development:**

- Develop and maintain a national network (hereafter referred to as “the Network”) of research entities that foster collaborative relationships in research designed to improve access to care, quality of clinical care and treatment for children and adolescents with ASD and other developmental disabilities; and
- Identify gaps and develop and/or update a research agenda for scientific studies building upon advances in research and practice in developmental and behavioral pediatrics.

### **Communications:**

- Develop a schedule of on-going communication among Network members and with the HRSA/MCHB Project Officer.

### **Network Activities:**

- Implement Network activities and research to improve access to care, quality of clinical care and services, and health outcomes for children and adolescents with ASD and other developmental disabilities. Such activities and research should address the needs of underserved populations, such as low-income, racial/ethnic minorities, individuals with limited English proficiency, individuals who have limited access to services, and/or other vulnerable populations;
- Develop and implement at least three multi-site research studies that will address gaps and promote the research agenda identified by the Network;
- Leverage external funding for network research studies or implement network research through both MCHB and external funding sources for at least one multi-site research study;

- Enhance the research training and mentorship of a diverse group of junior/new investigators through the use of innovative mentorship/research experiences; and manuscript development drawing upon emerging researchers from within the network;
- Translate research findings into clinical practice, as applicable per study findings.

### **Dissemination:**

- Maintain a Network website to disseminate research findings, activities and products and to engage with the field on Network research and other activities;
- Develop and implement a plan to disseminate Network findings through at least two peer-reviewed publications per multi-site study, webinars, annual Network meetings, conference presentations, and other related dissemination activities. These activities should serve to facilitate the transfer of Network findings to a broader audience including researchers, health professionals and providers, policy makers, educators, families, and Title V Children with Special Health Care Needs programs; and
- Collaborate with Autism CARES programs to foster information sharing and to advance efforts to improve the system of services for children and adolescents with ASD and other developmental disabilities.

This Network will advance the evidence base on improving access to care and the quality of care and treatment for children and adolescents with ASD and other developmental disabilities.

Areas of particular interest and priority include, but are not limited to:

- Identifying the most effective and efficient models of assessment and treatment;
- Improving access to care and quality of care for children with ASD and other developmental disabilities;
- Testing innovative treatment models to address disparities in access to care and treatment experienced by vulnerable and underserved communities, including diverse ethnic/racial, cultural, linguistic, socioeconomic, and geographic populations for whom there is little evidence regarding the effectiveness of treatments, or for whom access to effective treatments is limited; and
- Optimizing the health and related outcomes across the lifespan for children and adolescents with ASD and other developmental disabilities.

Consistent with HRSA's mission to improve access to quality services to underserved populations, the MCHB's intent is to ensure that research activities are responsive to the cultural and linguistic needs of special populations, that services are family-centered and accessible to consumers, and that the broadest possible representation of culturally distinct and historically underrepresented groups is supported through programs and projects sponsored by the MCHB.

### **Objectives and Function of the Developmental Behavioral Pediatrics Research Network**

The Developmental Behavioral Pediatrics Research Network will forge partnerships with researchers, clinicians, educators, advocates, families, including state public health programs and other organizations/agencies critical to improving the health and well-being with a focus on, but not limited to, children with ASD and other developmental disabilities. Establishment of strong partnerships between researchers and practitioners is required to assure that new interventions

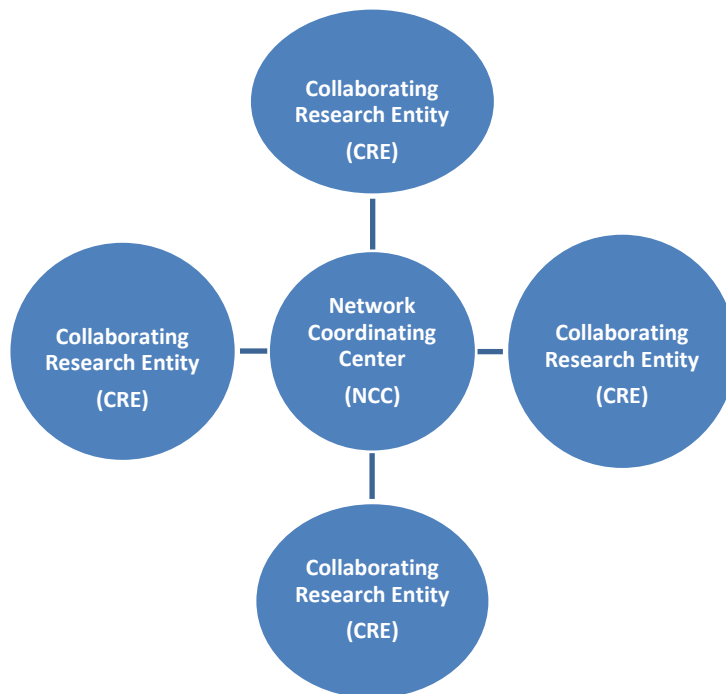
are applied in the clinical care system for the translation of vital research findings to assure better access and quality services for individuals with ASD and other developmental disabilities.

The following describes multiple aspects of the Developmental Behavioral Pediatrics Research Network that applicants should consider in the development of their application:

### Organization and Functions

The Network consists of a Network Coordinating Center (NCC) and multiple Collaborating Research Entities/Sites (CREs). The NCC, as the administrative center of the Network, provides leadership and maintains a partnership with its CREs. A sample of this structure is depicted in the following diagram:

### **Network Organizational Structure**



The NCC is located at the Principal Investigator's institution, which is the recipient of the cooperative agreement. The NCC provides a core of administrative and operational functions that include the following:

- 1) Support a Network infrastructure for research partnership among CREs;
- 2) Provide the Network with administrative and operations support in activities including, but not limited to, meetings, multidisciplinary educational activities, and development of research studies;
- 3) Facilitate the process for the development, selection, implementation, and monitoring of scientific research studies;
- 4) Coordinate a plan to enhance the research training and mentorship of junior/new investigators through the use of innovative mentorship/research experiences and manuscript development;
- 5) Coordinate the dissemination of findings to health professionals, researchers, policymakers, family members and the greater public;

- 6) Facilitate data gathering, data management training, and data quality assurance according to developed protocol;
- 7) Collaborate with Autism CARES or other related programs to foster information sharing, assure synergy, and advance efforts to improve the system of services for children and adolescents with ASD and other developmental disabilities; and
- 8) Attend the monthly Network meetings.

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 policies and procedures to: (1) monitor adverse events; (2) report data and other information to the NCC; and (3) ensure good clinical practice (GCP) or other applicable regulatory requirements.

#### *Network Steering Committee (NSC)*

All major scientific decisions will be determined by majority vote of the Network Steering Committee.

All participating CREs must agree to abide by the study designs and policies approved by the Network Steering Committee.

The Network Steering Committee, by majority vote, will elect a Chair from among the representatives of the CREs. The Network Steering Committee will meet monthly by phone and in person at least once a year.

#### *Collaborating Research Entities (CREs)*

CREs will be public institutions of higher learning and public or private agencies engaged in research or research and training on ASD and other developmental disabilities. The applicant institutions must include faculty members who are well-qualified professionals in the areas of developmental behavioral pediatrics, psychology, and psychiatry; furthermore, institutions must currently support research scientists, post-doctoral fellows and graduate students. CREs may have affiliate faculty from other relevant disciplines such as Maternal and Child Health (MCH) nursing, child development, nutrition, social work, child neurology, speech and language pathology, education, physical therapy, occupational therapy, and public health (e.g., health policy, organization and administration of services, program development, evaluation).

## **2. Background**

This program is authorized by the Public Health Service Act, § 399BB(f), (42 U.S.C. 280i-1(f)) as amended by the Autism CARES Act of 2014 (P.L. 113-157).

Developmental Behavioral Pediatricians (DBPs) 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.<sup>1</sup>

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<sup>1</sup> Kelly DP, Cull WL, Jewett EA, et al. Developmental and behavioral pediatric practice patterns and implications for the workforce: results of the Future of Pediatric Education II Survey of Sections Project. *J Dev Behav Pediatr.* 2003;24:180-183.

There is an increase in the prevalence of developmental behavioral conditions among children, however, the involvement of DBPs in research has been limited, likely contributing to the fact that few evidence-based assessments or interventions specific to the field have been developed and there are no DBP-specific assessment or management guidelines.<sup>2</sup> The high prevalence and impact of the developmental behavioral conditions evaluated and treated by DBPs, in concert with the small size of the field, result in significant challenges for service delivery and a need for research to improve access to and quality of care and treatment and optimize the health outcomes for children and adolescents with these conditions. A DBP Research Network will advance research in this field and effectively investigate issues that will improve scientific understanding, optimize access to care and effective clinical practice in the field.

HRSA's Maternal and Child Health Bureau (MCHB) supports programs to address ASD and other developmental disabilities through education, early detection, and intervention. Specifically, these activities are designed to:

- 1) Increase awareness of ASDs and other developmental disabilities;
- 2) Reduce barriers to screening and diagnosis;
- 3) Support research on evidence-based interventions for individuals with ASD and other developmental disabilities;
- 4) Promote guideline development for interventions; and
- 5) Train professionals to utilize valid screening tools, to diagnose and to provide evidence-based interventions through an interdisciplinary approach (as defined in programs developed under section 501(a)(2) of the Social Security Act) that will also focus on specific issues for children who are not receiving an early diagnosis and subsequent interventions.

The four programs and related areas supported by the MCHB include:

- 1) Training for Professionals:
  - Leadership Education in Neurodevelopmental Disabilities (LEND) training programs;
  - Developmental Behavioral Pediatrics (DBP) training programs; and
  - An Interdisciplinary Training Autism Resource Center.
- 2) Autism Research Programs:
  - Autism research networks that focus on intervention research, research to improve care and services, guideline development and information dissemination; and
  - Maternal and Child Health (MCH) Autism Intervention Research and Secondary Data Analysis Studies grants.
- 3) Autism State Systems Program:
  - State Implementation grants for improving services for children and youth with ASD and other DD; and
  - A State Public Health Coordinating Center that coordinates with the State Implementation grants and develops and implements a strategy for defining, supporting, and monitoring the role of state public health systems in assuring that

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<sup>2</sup> Blum NJ; the DBPNet Steering Committee. The Developmental-Behavioral Pediatrics Research Network: Another Step in the Development of the Field. *J Dev Behav Pediatr.* 2012; 33(1):78-83.



children and youth with autism receive early and timely identification, diagnosis, and intervention.

4) National Evaluation:

- Information and analysis from this evaluation contributed to the HHS Secretary's Report to Congress on progress related to ASD and other developmental disabilities. The awardee of the Network will participate in the national evaluation of the program, providing both qualitative and quantitative data.

The Developmental Behavioral Pediatrics Research Network Program, established in 2010 as a component of HRSA/MCHB's ASD and other developmental disabilities programs, is administered by the MCH Research Program, located within MCHB's Division of Research, Office of Epidemiology and Research (OER). The MCH Research Program has supported groundbreaking investigations that have significantly influenced clinical practice, organization and delivery of health care services, preventive care, and early intervention for the MCH population, including children with special health care needs.

The MCH Research Program supports applied and translational research and research networks relating to MCH services, including services for children and youth with ASD and other developmental disabilities. Funded programs show promise of substantial contributions in enhancing health care services and promoting the health and well-being of mothers, children, and families. For more information about the MCH Research Program, visit our website: <http://www.mchb.hrsa.gov/research>.

## II. Award Information

### 1. Type of Application and Award

Type(s) of applications sought: New, Competing Continuation.

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

As a cooperative agreement, **HRSA Program involvement will include:**

- Assurance of the availability of HRSA/MCHB personnel or designees to participate in the planning and development of all phases of this activity;
- Review of policies and procedures established for carrying out project activities;
- Participation in meetings and regular communications with the award recipient to review mutually agreed upon goals and objectives and to assess progress;
- Facilitation of effective communication and accountability to HRSA/MCHB regarding the project, with special attention to new program initiatives and policy development that have the potential to advance the utility of the Developmental Behavioral Pediatrics Research Network Program;
- Assistance in establishing and maintaining federal interagency and inter-organizational contacts necessary to carry out the project;

- Review of documents developed by the Network such as Network operating procedures, authorship guidelines, etc. but excluding manuscripts for submission to peer-reviewed journals; and
- 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:**

- Develop and maintain a national scientific and clinical network of research entities who collaborate in research activities in developmental, behavioral, and psychosocial aspects of pediatric care to improve clinical services and health and related outcomes for children and adolescents with ASD and other developmental disabilities;
- Identify gaps, and develop and/or update a research agenda for scientific studies building upon advances in research and practice in developmental and behavioral pediatrics;
- Implement Network activities and research to improve access to care, quality of clinical care and services, and health outcomes for children and adolescents with ASD and other developmental disabilities. Such activities and research should address the needs of underserved populations, such as low-income, racial/ethnic minorities, individuals with limited English proficiency, individuals who have limited access to services, and/or other vulnerable populations;
- Develop and implement at least three multi-site research studies that will address gaps and promote the research agenda identified by the Network;
- Leverage external funds for at least one multi-site research study;
- Enhance the research training and mentorship of junior/new investigators through the use of innovative mentorship/research experiences and manuscript development;
- Translate research findings into clinical practice, as applicable per study findings;
- Develop and maintain a Network website to disseminate research findings, activities and products and to engage with the field on Network research and other activities;
- Develop and implement a plan to disseminate Network findings through at least two peer-reviewed publications per multi-site study, webinars, annual Network meetings, conference presentations, and other related activities. These activities should serve to facilitate the transfer of Network findings to a broader audience including researchers, health professionals and providers, policy makers, educators, families and Title V Children with Special Health Care Needs programs;
- Adhere to HRSA requirements pertaining to acknowledgement and disclaimer on all products produced by HRSA award funds. See “**Acknowledgment of Federal Funding**” in Section 2.2 of HRSA’s [\*SF-424 Application Guide\*](#);
- Collaborate with Autism CARES programs to foster information sharing and to advance efforts to improve the system of services for children and adolescents with ASD and other developmental disabilities; and
- Develop a schedule of on-going communication among Network members and with the HRSA/MCHB Project Officer.

## 2. Summary of Funding

This program will provide funding during federal fiscal years 2016 – 2020. Approximately \$275,000 is expected to be available annually to fund one (1) recipient. Applicants may apply for a ceiling amount of up to \$275,000 per year. Funding beyond the first year is dependent on the availability of appropriated funds for “Developmental Behavioral Pediatrics Research Network Program” in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

Effective December 26, 2014, all administrative and audit requirements and the cost principles that govern federal monies associated with this award are subject to the Uniform Guidance [2 CFR 200](#) as codified by HHS at [45 CFR 75](#), which supersedes the previous administrative and audit requirements and cost principles that govern federal monies.

## III. Eligibility Information

### 1. Eligible Applicants

Eligible applications include any public or private entity, including research centers or networks. Faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply. Non-U.S. entities are not eligible to apply.

Foreign entities are not eligible for HRSA awards, unless the authorizing legislation specifically authorizes awards to foreign entities or the award is for research. This exception does not extend to research training awards or construction of research facilities.

### 2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

### 3. Other

Applications that exceed the ceiling amount will be considered non-responsive and will not be considered for funding under this announcement.

Any application that fails to satisfy the deadline requirements referenced in *Section IV.4* will be considered non-responsive and will not be considered for funding under this announcement.

**NOTE: Multiple applications from an organization are not allowable. A Principal Investigator (PI) or Co-Investigator (Co-PI) on an existing MCHB-funded research network cannot serve as PI or Co-PI on more than one MCHB-funded network at a time.**

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 the applicant’s **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*** applicants for this FOA to apply electronically through Grants.gov. Applicants must download the SF-424 application package associated with this FOA following the directions provided at [Grants.gov](https://www.grants.gov).

### 2. Content and Form of Application Submission

Section 4 of HRSA's [SF-424 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 Application Guide in addition to the program-specific information below. All applicants are responsible for reading and complying with the instructions included in HRSA's [SF-424 Application Guide](#) except where instructed in the FOA to do otherwise.

See Section 8.5 of the *Application Guide* for the Application Completeness Checklist.

#### **Application Page Limit**

The total size of all uploaded files may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments including biosketches, letters of commitment and support required in the *Application Guide* and this FOA. Standard OMB-approved forms that are included in the application package are NOT included in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) will not be counted in the page limit. **We strongly urge applicants to take appropriate measures to ensure the application does not exceed the specified page limit.**

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

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

- 1) The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) Where the prospective recipient is unable to attest to any of the statements in this certification, such prospective recipient shall attach an explanation to this proposal.

See Section 4.1 viii of HRSA's [SF-424 R&R Application Guide](#) for additional information on this and other certifications.

## Program-Specific Instructions

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

### *i. Project Abstract*

See Section 4.1.ix of HRSA's [SF-424 Application Guide](#). Include the information requested at the top of the abstract. Prepare the abstract so that it is clear, accurate, concise, and without reference to other parts of the application because it is often distributed to provide information to the public and Congress. Briefly state the principal needs and problem, goals, proposed activities including target population(s), planned coordination, anticipated products, and plans for evaluation.

Abstract content:

- Clearly indicate the FOA number and title.
- **PROBLEM:** Briefly state the principal needs and problems which are addressed by the project.
- **GOAL(S) AND OBJECTIVES:** Identify the major goal(s) and objectives for the project period. 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 Network, including modes of dissemination of project activities and findings.
- **EVALUATION:** Briefly describe the evaluation methods used to assess program outcomes and the effectiveness and efficiency of the project in attaining goals and objectives.

**From the [Appendix](#) select: (a) a maximum of ten (10) significant content terms that describe your project, and as many (b) targeted populations and (c) age ranges as apply. Include the selected (a) content terms, (b) populations, and (c) age ranges targeted at the end of your abstract.**

The project abstract must be single-spaced and limited to one page in length.

### *ii. Project Narrative*

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

Use the following section headers for the Narrative:

*Section I. Background and Significance*

*Section II. Specific Goals and Objectives*

*Section III. Project Design: Methods and Evaluation*

*Section IV. Plan and Schedule of Implementation, and Capability of Applicant*

- *SECTION I - BACKGROUND AND SIGNIFICANCE -- Corresponds to Section V's Review Criteria #1 Need, #2 Response, #4 Impact*

In this section, the applicant should demonstrate a thorough knowledge and understanding of research and practice in developmental behavioral pediatrics on ASD and other developmental disabilities. Provide a brief literature review, identify current research gaps in developmental behavioral pediatrics focused on improving access to care, quality of clinical care and services, and health outcomes for children and adolescents with ASD and other developmental disabilities. Discuss the national significance and impact of a DBP research network and how multi-site DBP research can address issues for children and adolescents with ASD and other developmental disabilities.

- *SECTION II – SPECIFIC GOALS AND OBJECTIVES -- Corresponds to Section V's Review Criteria #2 Response, #4 Impact, #5 Resources/Capabilities*

This section of the narrative **MUST** include a numbered list of the specific goals and objectives (that address the major activities listed in the Purpose section of this announcement) to be accomplished during the funding period. The specific objectives should be succinctly stated. The applicant should be innovative with respect to specific objectives, but should direct attention to the scope of expected activities listed. The applicant should describe the process for developing an integrated research network and present a plan of proposed activities that shows progressive implementation during the five-year project period.

Describe the activities or steps that will be used to achieve each of the project goals. Submit a timeline that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaboration with key stakeholders and partners in planning, designing, and implementing all activities.

Applicants must submit a logic model for designing and managing their project. Include the logic model in this section (Section II) of the narrative. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements. While there are many versions of logic models, for the purposes of this announcement, the logic model should summarize the connections between the:

- Goals of the project;
- Theoretical approach;
- Inputs (e.g., organizational profile, collaborative partners, other resources);
- Target population(s);

- Activities;
- Outputs (i.e., products); and
- Outcomes (i.e., the results of the project, typically describing a change in people or systems).

More information on logic models may be found in [Section VIII](#) of this FOA.

The application should provide documentation (letters of agreement) of participation of Collaborating Research Entities (CREs) sites that will collaborate to fulfill the goals and objectives of the Network, with descriptions of each CRE's characteristics, including patient population characteristics, average patient numbers, types of treatment or services currently delivered, number, characteristics and structure of staff. **Letters of agreement from CRE sites should be included in Attachment 2.** At least one CRE should demonstrate success in recruiting from underserved population(s) such as low-income, racial/ethnic minorities, immigrants, individuals who have limited access to services, and/or other underserved populations as defined by the applicant.

Responsibilities of the National Coordinating Center to the Collaborating Research Entities (CREs):

The application should also address how the Network will manage CRE sites. For example, the application should clearly describe how the Network will provide the CREs with guidance to ensure:

- 1) staff and training needed for the CREs to implement a study protocol and participate in Network activities;
- 2) a data acquisition system to collect intake, treatment and outcome data for all study participants, according to protocol-specific requirements; and
- 3) additional support such as quality control to ensure the successful completion of the scientific goals of a research project and other Network activities.

### Responsibility of Each CRE Site:

Each CRE should, as appropriate, in conducting studies and participating in Network activities:

- Participate in Network subcommittees and agree to attend Network monthly teleconferences and in-person meetings. Applicants should include budgets for CRE travel support to these meetings in their applications;
  - Participate in the development of concept and protocol of observational and clinical trial studies to be conducted by the Network;
  - Participate in observational studies and clinical trials, including subject enrollment, data collection, patient record maintenance, adherence to good clinical practice (GCP), 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 Network activities that enhance the research training and mentorship of junior/new investigators; and,
  - Participate in the translation of critical network findings to practice settings and educational training that will result in improved care and access to care for children with ASD and other developmental disabilities, including those from underserved populations.
- *SECTION III – PROJECT DESIGN: METHODS AND EVALUATION -- Corresponds to Section V's Review Criteria # 2 Response, #3 Evaluative Measures, #4 Impact, #5 Resources/Capabilities*

#### A. Methods:

This section of the narrative must provide detailed descriptions of the methodology for accomplishing each of the specific objectives. The applicant must provide sufficient technical detail to demonstrate the necessary steps to accomplish each objective, and to convey to reviewers adequate information to assess the methodology.

**One important aspect of successful application is the ability to develop a conceptual proposal for Network research to improve care and access to care for children with ASD and other developmental disabilities.** Applicants should include one (1) concept proposal that is no more than two (2) pages in length and address the following:

- Need
- Specific objectives
- Research methods (study design, sampling frame and plan for evaluation)

In this section, also discuss plans to disseminate findings including:

- Peer-reviewed publications. It is expected that the Network will produce at least two peer-reviewed publications per multi-site study conducted by the Network;



- Other dissemination to the research and practice communities, as well as families and communities, including but not limited to: informational products and educational opportunities, including webinars, website material, plenary sessions, abstracts, conference presentations, annual Network meetings, and consumer materials for key stakeholders such as providers, communities, states, and families that will promote the transfer of findings to improve care.

The applicant must also indicate the specific methods to be used to evaluate progress in each area of activity. The applicant must list and discuss anticipated obstacles that may be encountered and indicate how each obstacle will be overcome.

It is crucial that the applicant describe how the interdisciplinary team will function in partnership within the Network to accomplish the goals and objectives. Applicants must anticipate potential problems and challenges that may arise in this process, and propose mechanisms for collaborative resolution.

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

#### B. Evaluation:

Applicants must 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.

Applicants must describe the systems, processes, and staff that will support the organization's performance management requirements through effective tracking of performance outcomes, including a description of how the organization will collect and manage data (e.g., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes. As appropriate, describe the data collection strategies that will be used to collect, analyze, and track data to measure progress and impact/outcomes with different sociocultural groups (e.g., race, ethnicity, language, rural versus urban, socioeconomic, gender), and explain how the data will be used to inform program development and service delivery. Applicants must describe any potential obstacles for implementing the program performance evaluation and how those obstacles will be addressed.

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

- *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*

In this section of the narrative, the applicant must 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.

In addition, an implementation schedule should be provided 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 Network program, the applicant must:

- describe its significant experience and the publication record of key personnel in carrying out interdisciplinary collaborative research and projects related to the goals and objectives of the Network;
- describe how the Network will build the capacity to conduct critical research studies to advance the field of developmental behavioral pediatrics through both MCHB and other external funding sources;
- document the ability to enroll a sufficient number of research participants from the CRE sites. Include information for research studies on ASD and other developmental disabilities (both observational and randomized controlled trials) that each site has participated in the past five (5) years.

If the application is a competing continuation, the applicant must also describe its significant experience and accomplishments in Attachment 5: Summary Progress Report.

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

## NARRATIVE GUIDANCE

In order to ensure that the Review Criteria are fully addressed, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.

<u>Narrative Section</u>	<u>Review Criteria</u>
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
Plan and Schedule of Implementation, and Capability of Applicant	(3) Evaluative Measures, (4) Impact, (5) Resources/Capabilities, (6) Support Requested
Budget and Budget Justification Narrative	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

### iii. Budget

See Section 4.1.iv of HRSA's [SF-424 Application Guide](#). Please note: the directions offered in the SF-424 Application Guide differ from those offered by Grants.gov. Please follow the instructions included in the Application Guide and, *if applicable*, the additional budget instructions provided below.

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

In addition, the Developmental Behavioral Pediatrics Research Network program requires the following:

- The maximum number of budget periods allowed is five (5). A budget period represents 12 months of project effort.
- Applicants for this announcement should use the "Other Sponsored Program/Activities" indirect cost rate. 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% of modified total direct costs (MTDC) which may be used indefinitely. If chosen, this methodology once elected must be used consistently for all federal awards until such time as a non-federal entity chooses to negotiate for a rate, which the non-federal entity may apply to do at any time. See 45 CFR 75, HHS's codification of the Uniform Guidance at <http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4d52364ec83fab994c665943dadf9cf7&ty=HTML&h=L&r=PART&n=pt45.1.75>, particularly § 75.414 (f) Indirect (F&A) costs.

- The PI of the Network is required to attend the MCHB Autism CARES Act In-Person Grantee Meetings, held in the Washington, D.C. metropolitan area. Budget plans should include travel to this in-person grantee meeting for three out of the five budget periods. For planning, it is recommended that the Year 1, 3 and 5 budgets include travel costs associated with this 1 ½ day grantee meeting.

*NOTE:* Travel outside of the U.S. is not supported for the Developmental Behavioral Pediatrics Research Network Program.

The Consolidated Appropriations Act, 2016, Division H, §202, (P.L.114-113) 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.” Please see Section 4.1.iv Budget – Salary Limitation of HRSA’s [SF-424 Application Guide](#) for additional information. Note that these or other salary limitations will apply in FY 2016, as required by law.

***iv. Budget Justification Narrative***

See Section 4.1.v. of HRSA’s [SF-424 Application Guide](#). In addition, the Developmental Behavioral Pediatrics Research Network program requires the following:

**Staffing Plan and Personnel Requirements**

Please refer to instructions in Section 4.1.vi of HRSA’s *SF-424 Application Guide*. Include the position descriptions (roles, responsibilities, and qualifications of proposed project staff) in the Budget Justification under Personnel costs. The budget justification is uploaded into the Budget Narrative Attachment Form. Biographical sketches for any key employed personnel that will be assigned to work on the proposed project must be included as Attachment 1. Due to the HRSA 80-page limit, it is recommended that each biographical sketch is no more than two (2) pages in length and must follow the HRSA font/margin requirements. Biographical sketches should document education, skills, and experience that are relevant, necessary, and demonstrate capability to fulfill the assigned roles for the proposed project.

***v. Program-Specific Forms***

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

HRSA has modified its reporting requirements for SPRANS projects, Community Integrated Service Systems (CISS) projects, and other grant programs administered by MCHB to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act, MCHB’s authorizing legislation. Performance measures for other MCHB-funded grant programs have been approved by the Office of Management and Budget and are primarily based on existing or administrative data that projects should easily be able to access or collect. An electronic system for reporting these data elements has been developed and is now available.

2) *Performance Measures for the “Developmental Behavioral Pediatrics Research Network program”*

To inform successful applicants of their reporting requirements, the listing of MCHB administrative forms and performance measures for this program can be found at: [https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UA6\\_2.html](https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UA6_2.html).

**NOTE:** The performance measures and data collection information is for your PLANNING USE ONLY. These forms are not to be included as part of this application. However, this information will be due to HRSA within 120 days after the Notice of Award.

*vi. Attachments*

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

*Attachment 1: Biographical Sketches of Key Personnel*

Include biographical sketches for persons occupying key positions. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch. Given the 80-page limit, it is recommended that each biographical sketch be no more than two pages in length.

*Attachment 2: Letters of Agreement/Letters of Support*

Provide any documents that describe working relationships between the applicant 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 of support which specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.). Letters of agreement and letters of support must be dated.

*Attachment 3: List of Citations for Key Publications*

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

*Attachment 4: For Multi-Year Budgets--Fifth Year Budget, (NOT counted in page limit)*

After using columns (1) through (4) of the SF-424A Section B for years 1 – 4 of the five-year project period, the applicant will need to submit the budget for year 5 as an attachment. Applicants should use SF-424A Section B. See Section 4.1.iv of HRSA’s [SF-424 Application Guide](#).

*Attachment 5: Summary Progress Report*

**ACCOMPLISHMENT SUMMARY (FOR COMPETING CONTINUATIONS ONLY)**

A well-planned accomplishment summary can be of great value by providing a record of accomplishments. It is an important source of material for HRSA in preparing annual reports, planning programs, and communicating program-specific accomplishments. The accomplishments of competing continuation applicants are carefully considered during the review process; therefore, applicants are advised to include previously stated goals and objectives in their application and emphasize the progress made in attaining these goals and objectives. The Accomplishment Summary will be evaluated as part of Review Criterion 4: Impact and Review Criterion 5: Resources/Capabilities.

The accomplishment summary should be a brief presentation of the accomplishments, in relation to the objectives of the program during the awarded project period. The report should include:

- (1) The period covered (dates).
- (2) Specific Objectives – Briefly summarize the specific objectives of the project as actually funded.
- (3) Results – Describe the program activities conducted for each objective. Include both positive and negative results or technical problems that may be important.
- (4) Impact – Provide a summary of the impact of the project including the dissemination of findings through peer-reviewed publications as well as other dissemination efforts.

*Attachment 6: Evidence of Non-profit Status (Not counted in the page limit)*

*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 Universal Numbering System Number and System for Award Management**

Applicant organizations must obtain a valid DUNS number and provide that number in their application. Each applicant must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during which it has an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR 25.110(b) or (c), or has an exception approved by the agency under 2 CFR 25.110(d)).

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

If an applicant/recipient organization has already completed Grants.gov registration for HRSA or

another federal agency, confirm that the registration is still active and that the Authorized Organization Representative (AOR) has been approved.

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

- Dun and Bradstreet (<http://fedgov.dnb.com/webform/pages/CCRSearch.jsp>)
- 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 Application Guide\*](#).

**Applicants that fail to allow ample time to complete registration with SAM or Grants.gov 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 FOA is *April 26, 2016 at 11:59 P.M. Eastern Time*.

See Section 8.2.5 – Summary of e-mails from Grants.gov of HRSA's [\*SF-424 Application Guide\*](#) for additional information.

#### **5. Intergovernmental Review**

“The Developmental Behavioral Pediatrics Research Network Program” is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR 100.

See Section 4.1 ii of HRSA's [\*SF-424 Application Guide\*](#) for additional information.

#### **6. Funding Restrictions**

Applicants responding to this announcement may request funding for a project period of up to five (5) years, at no more than \$275,000 total cost (direct plus indirect expenses) per year. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

Funds under this announcement may not be used for travel outside of the U.S.

The General Provisions in Division H of the Consolidated Appropriations Act, 2016 (P.L. 114-113) apply to this program. Please see Section 4.1 of HRSA's [\*SF-424 Application Guide\*](#) for additional information. Note that these or other restrictions will apply in FY 2016, as required by law.

All program income generated as a result of awarded funds must be used for approved project-related activities.

## **V. Application Review Information**

## 1. Review Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist the applicant in understanding the standards against which each application will be judged. Critical indicators have been developed for each review criterion to assist the applicant in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. Review criteria are outlined below with specific detail and scoring points.

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

Review Criteria are used to review and rank applications. The Developmental Behavioral Pediatrics Research Network Program has six (6) review criteria:

Criterion 1.	Need	10 points
Criterion 2.	Response	20 points
Criterion 3.	Evaluative Measures	20 points
Criterion 4.	Impact	10 points
Criterion 5.	Resources/Capabilities	30 points
Criterion 6.	Support Requested	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 developmental behavioral pediatrics focused on improving access to care, quality of clinical care and services, and health outcomes for children and adolescents with ASD and other developmental disabilities;
- The national significance and impact of a DBP research network and how multi-site DBP research can address issues for children and adolescents with ASD and other developmental disabilities.

*Criterion 2: RESPONSE (20 points) – Corresponds to Section IV's Background and Significance; Specific Goals and Objectives; Project Design: Methods and Evaluation*  
The extent to which the proposed project responds to the "Purpose" included in the program description. The clarity of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives.

- The extent to which the applicant demonstrates awareness of previous work in the area of this project, including citation of relevant literature and justification of the need for the Network.
- The extent to which the goals and objectives are clear, concise, and appropriate.
- The extent to which the aims of the project 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.

- The extent to which the applicant describes critical research and methodology that challenges and seeks to shift current research, practice, or service paradigms by utilizing innovative theoretical concepts, approaches or methodologies, instrumentation, or interventions. The extent to which a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions is proposed.
- The extent to which the applicant addresses and includes information on all activities described in the “Purpose” section for this competition.
- The extent to which the proposed logic model is clear.

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

The strength and effectiveness of the method proposed to monitor and evaluate the project results. Evidence that the evaluative measures will be able to assess: 1) to what extent the program objectives have been met, and 2) to what extent these can be attributed to the project.

- The extent to which the objectives are time-framed and measurable.
- The extent to which the proposed activities are capable of attaining project goals and objectives.
- The extent to which the plan and methodology for establishing and managing the Network described in the proposal are appropriate, feasible, and of high quality.
- The degree to which a familiarity and experience with data gathering procedures as they relate to collaborative multi-site research are described.
- The degree to which the methods include an effective publication and dissemination plan.
- The dissemination plan includes but is not limited to producing at least two peer-reviewed publications per multi-site Network study, disseminating information to scientific and professional audiences, website and webinars.
- The degree to which the methods section includes other dissemination to the research and practice communities, as well as families and communities that will promote the transfer of findings to improve care.
- The degree to which measurable evaluation measures are included for each described objective, with a timeline for evaluation consistent with the plan and schedule of implementation.

*Criterion 4: IMPACT (10 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 the establishment of a 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 lead and promote coordinated research activities to improve care, access to care and health outcomes for children and adolescents with ASD and other developmental disabilities.

The feasibility and effectiveness of plans for dissemination of project results. The potential impact of project results in improving care, access to care and health outcomes for children and adolescents with ASD and other developmental disabilities.

- The extent to which the project will advance the field with research to improve care, access to care and health outcomes for children and adolescents with ASD and other developmental disabilities.
- The extent to which there is an effective publication and dissemination plan to facilitate the transfer of Network findings to a broad audience including researchers, health and related professionals, policy makers, educators, and families.
- The extent to which the applicant has a feasible plan for meeting the expectation to produce the expected minimum number of peer-reviewed publications (i.e., at least two peer-reviewed publications per multi-site Network study).
- The extent to which the applicant describes a plan to ensure successful collaboration with all key partners identified in the proposal.
- For competing continuation applications, the extent to which the applicant describes the impact of the project including the dissemination of findings through peer-reviewed publications as well as other dissemination efforts. (Attachment 5)
- The extent to which there is an effective plan for coordination with the other Autism CARES Act Programs.

*Criterion 5: RESOURCES/CAPABILITIES (30 points) – Corresponds to Section IV's Specific Goals and Objectives; Project Design: Methods and Evaluation; Plan and Schedule of Implementation, and Capability of Applicant*

The extent to which project personnel and collaborators are qualified by training and/or experience to implement and carry out the project. The capabilities of the applicant organization and collaborators, and the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project.

The PI and project team's documented history of leadership in the conduct of multi-site, interdisciplinary, collaborative research and publication record on advancing the field of Developmental Behavioral Pediatrics with research to improve access to care, quality of care and health outcomes for children and adolescents with ASD and other developmental disabilities.

- The extent to which the PI, staff, and collaborators are well qualified by training and/or expertise to develop the infrastructure of the Network and to accomplish the activities of the Network as described in this FOA.
- The extent to which the PI and other key personnel demonstrate current and/or past success in publishing the findings of their research.
- The extent to which the applicant has the existing resources/facilities to achieve project objectives and to successfully support the Network described in the proposal.
- For competing continuation applications, the extent to which the applicant describes their significant experience and accomplishments in attaining the goals and objectives during the previously awarded project period (Attachment 5).

*Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's Plan and Schedule of Implementation, and Capability of Applicant; and Budget and Budget Justification Narrative*

The reasonableness of the proposed budget for each year of the project period 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.
- The extent to which budget line items are well described and justified in the budget justification.
- The extent to which time allocated by key personnel is appropriate to achieve project objectives.

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

Please see Section 5.3 of HRSA's [\*SF-424 Application Guide\*](#).

This program does not have any funding priorities, preferences or special considerations.

## **3. Assessment of Risk**

The Health Resources and Services Administration 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](#)).

Include IF the award made will be greater than \$150,000, the simplified acquisition threshold, over the period of performance-

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

A determination that an applicant is not qualified will be reported by HRSA to FAPIIS.

The decision not to make an award or to make an award at a particular funding level, is discretionary and is not subject to appeal to any HHS Operating Division or HHS official or board.

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

It is anticipated that awards will be announced prior to the start date of September 1, 2016.

## **VI. Award Administration Information**

### **1. Award Notices**

The Notice of Award will be sent prior to the start date of September 1, 2016. See Section 5.4 of HRSA's [\*SF-424 Application Guide\*](#) for additional information.

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

See Section 2 of HRSA's [\*SF-424 Application Guide\*](#).

#### **Human Subjects Protection:**

Federal regulations (45 CFR 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 research involving human subjects is anticipated, recipients must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR 46), available online at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

#### **Rights in Data:**

In all cases, whether HHS funded all or part of the project or program resulting in the data, the Federal Government must be given a royalty-free, nonexclusive, and irrevocable license for the Federal Government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes, e.g., to make it available in government-sponsored databases for use by other researchers. Additional information on the HHS Grants Policy Statement on “Rights in Data” is available online at <http://www.hrsa.gov/grants/hhsgrantspolicy.pdf>.

### **3. Reporting**

MCHB intends to update the Discretionary Grant Information System with new Discretionary Grant Performance Measures. As announced in the Federal Register on November 6, 2015 (<https://www.gpo.gov/fdsys/pkg/FR-2015-11-06/pdf/2015-28264.pdf>), the draft Performance measures introduce a new performance measure framework and structure that will better measure the various models of MCHB grant programs and the services each funded program provides. The performance data will serve several purposes, including grantee monitoring, performance reporting, MCHB program planning, and the ability to demonstrate alignment between MCHB discretionary programs and the MCH Title V Block Grant program. This revision will allow a more accurate and detailed picture of the full scope of activities supported by MCHB-administered grant programs, while reducing the overall number of performance measures from what is currently used. The proposed performance measures can be reviewed at: <http://mchb.hrsa.gov/dgis.pdf>. In addition to the reporting on the new performance measures, grantees will continue to provide financial and program data, if assigned.

Pending approval from the Office of Management and Budget (OMB), the new package will apply to all MCHB discretionary grantees. New and existing grants awarded on or after October

1, 2016, will be required to report on measures assigned by their Project Officer. Additional instructions will be provided on how to access the new DGIS once it becomes available for grantee reporting. For grant activities funded with 2015 dollars, grantees will continue to report on their currently assigned measures in DGIS.

The successful applicant under this FOA must comply with Section 6 of HRSA's [SF-424 Application Guide](#) and the following reporting and review activities:

- 1) **Progress Report(s).** The recipient must submit a progress report to HRSA on an **annual** basis. Further information will be provided in the award notice.
- 2) **Other required reports and/or products.**
  - a) **Semi-Annual Performance Report.** Within six months from the annual award date, the awardee must submit a semi-annual performance report. Further information will be provided to the award recipient.
  - b) **Final Comprehensive Report(s).** A final comprehensive report is due within 90 days after the project period ends. The final report collects program-specific goals and progress on strategies, core performance measurement data, impact of the overall project, the degree to which the awardee achieved the mission, goal and strategies outlined in the program, awardee objectives and accomplishments, barriers encountered, and responses to summary questions regarding the awardee's overall experiences over the entire project period. The final report must be submitted on-line by awardees in the Electronic Handbooks system at <https://grants.hrsa.gov/webexternal/home.asp>.
- 3) **Dissemination.**

The awardee of the Developmental Behavioral Pediatrics Research Network Program will be required to notify their HRSA project officer as soon as they are aware their research is being or has been published. Awardees must report back to HRSA regarding the execution of their dissemination plans as part of the semi-annual performance report, non-competing continuation (NCC) application and the final comprehensive report including but not limited to: peer-reviewed publications, informational products and educational opportunities, including website material, webinars, plenary sessions, abstracts, conference presentations, and consumer materials for key stakeholders such as researchers, providers, communities, states, and families that will promote the transfer of findings to improve care.

Prompt and timely presentation and publication in the scientific literature of Network findings from research and research-related activities is required. As per HHS grants policy guidelines (See "Publications" section on page II-73 at <http://www.hrsa.gov/grants/hhsgrantspolicy.pdf>), the awardee agrees to acknowledge HRSA support in the publications, presentations, and other products resulting from research and other activities conducted under this program. Peer-reviewed publications are the cardinal measure of success of the MCH Research Program.
- 4) **Performance Reports.**

HRSA has modified its reporting requirements for SPRANS projects, CISS projects, and other grant programs administered by MCHB to include national performance

measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act, MCHB's authorizing legislation. Performance measures for other MCHB-funded grant programs have been approved by the Office of Management and Budget and are primarily based on existing or administrative data that projects should easily be able to access or collect.

**a) Performance Measures and Program Data**

To prepare successful applicants for their reporting requirements, the listing of MCHB administrative forms and performance measures for this program can be found at:

[https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UA6\\_2.HTML](https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UA6_2.HTML).

**1. Performance Reporting**

Successful applicants receiving HRSA funds will be required, within 120 days of the Notice of Award (NoA), to register in HRSA's Electronic Handbooks (EHBs) and electronically complete the program-specific data forms that appear for this program at: [https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UA6\\_2.HTML](https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UA6_2.HTML).

This requirement entails the provision of budget breakdowns in the financial forms based on the award amount, the project abstract and other grant/cooperative agreement summary data as well as providing objectives for the performance measures.

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

**b) Project Period End Performance Reporting**

Successful applicants receiving HRSA funding will be required, within 90 days from the end of the project period, to electronically complete the program-specific data forms that appear for this program at: [https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UA6\\_2.HTML](https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UA6_2.HTML). The requirement includes providing expenditure data for the final year of the project period, the project abstract and grant/cooperative agreement summary data as well as final indicators/scores for the performance measures.

**5) Integrity and Performance Reporting.** The Notice of Award will contain a provision for integrity and performance reporting in [FAPIS](#), as required in [2 CFR 200 Appendix XII](#).

## VII. Agency Contacts

Applicants may obtain additional information regarding business, administrative, or fiscal issues related to this FOA by contacting:

Tonya Randall, Grants Management Specialist  
Division of Grants Management Operations, OFAM  
, Room 10W09A  
Health Resources and Services Administration  
5600 Fishers Lane, Room 10W09A  
Rockville, MD 20857  
Telephone: (301) 594-4259  
Fax: (301) 594-6096  
E-mail: [trandall@hrsa.gov](mailto:trandall@hrsa.gov)

Additional information related to the overall program issues and/or technical assistance regarding this funding announcement may be obtained by contacting:

Romuladus E. Azuine, DrPH., MPH, RN.  
Public Health Analyst, Division of Research, Office of Epidemiology and Research  
Attn: Developmental Behavioral Pediatrics Research Network Program  
Maternal and Child Health Bureau  
5600 Fishers Lane, Room 10-77  
Health Resources and Services Administration  
Rockville, MD 20857  
Telephone: (301) 443-2410  
E-mail: [RAzuine@hrsa.gov](mailto:RAzuine@hrsa.gov)

Applicants may need assistance when working online to submit their application forms electronically. Applicants should 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, seven days a week, excluding federal holidays at:

Grants.gov Contact Center  
Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)  
E-mail: [support@grants.gov](mailto:support@grants.gov)  
iPortal: <https://grants-portal.psc.gov/Welcome.aspx?pt=Grants>

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday-Friday, 8:00 a.m. to 8:00 p.m. ET:

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

## **VIII. Other Information**

### **Relevant Websites:**

#### **MCH Research Website**

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

#### **MCHB Autism Programs Website**

<http://mchb.hrsa.gov/programs/autism/>

#### **Interagency Autism Coordinating Committee**

<http://iacc.hhs.gov/index.shtml>

#### **Human Subjects Assurances**

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

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

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

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

#### **Healthy People 2020**

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

### **Logic Models:**

Additional information on developing logic models can be found at the following website:

[http://www.cdc.gov/nccdphp/dnpao/hwi/programdesign/logic\\_model.htm](http://www.cdc.gov/nccdphp/dnpao/hwi/programdesign/logic_model.htm).

Although there are similarities, a logic model is not a work plan. A work plan is an “action” guide with a timeline used during program implementation; the work plan provides the “how to” steps. Information on how to distinguish between a logic model and work plan can be found at the following website: <http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf>.

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

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



## **Appendix: 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 Birth weight
- 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
- ❑ SIDS/SUID
- ❑ Trauma & Injury

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

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

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

- ☐ ADD/ADHD
- ☐ Asthma
- ☐ Autism
- ☐ Chronic Illness
- ☐ Developmental Disabilities
- ☐ Special Health Care Needs
- ☐ YSHCN Transition to Adulthood

***Life Course & Social Determinants***

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

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

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

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

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