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

Maternal and Child Health Bureau
Office of Epidemiology and Research
UJ2 Autism Single Investigator Innovation Program (Autism-SIIP)

Autism Transitions Research Project (ATRP)

Announcement Type: New

Funding Opportunity Number: HRSA-17-097

Catalog of Federal Domestic Assistance (CFDA) No. 93.877

FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2017

Application Due Date: February 13, 2017

Ensure SAM.gov and Grants.gov registrations and passwords are current immediately!
Deadline extensions are not granted for lack of registration.
Registration in all systems, including SAM.gov and Grants.gov,
may take up to one month to complete.

Issuance Date*:* December 08, 2016

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Authority: Public Health Service Act, § 399BB(f) (42 U.S.C. 280i-1(f)), as amended by the Combating Autism Reauthorization Act of 2011 (P.L. 112–32) and the Autism CARES Act of 2014 (P.L. 113–157).

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau, Office of Epidemiology and Research is accepting applications for the fiscal year (FY) 2017 Autism Transitions Research Project (ATRP).

The purpose of this award is to support research designed to advance the evidence base regarding factors associated with healthy life (physical, social, mental health, and educational/occupational) outcomes among adolescents and young adults with Autism Spectrum Disorder (ASD) who are transitioning to adulthood.

Funding Opportunity Title:	Autism Transitions Research Project (ATRP)
Funding Opportunity Number:	HRSA-17-097
Due Date for Applications:	February 13, 2017
Anticipated Total Annual Available Funding:	$500,000
Estimated Number and Type of Award(s):	One (1) cooperative agreement
Estimated Award Amount:	Subject to the availability of appropriations, the ceiling amount of the award is $500,000 total cost per year
Cost Sharing/Match Required:	No
Project Period:	Approved projects will be awarded project periods of up to five (5) years, September 1, 2017 to August 31, 2022.
Eligible Applicants:	Eligible applicants 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. [See Section III-1 of this funding opportunity announcement (FOA) for complete eligibility information.]

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Application Guide

You (the 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 FOA to do otherwise. A short video explaining the *Application Guide* is available at http://www.hrsa.gov/grants/apply/applicationguide/.

Technical Assistance

A Technical Assistance call will be held on Tuesday, January 3, 2017 at 3:00 p.m. Eastern Standard Time. The MCHB Project Officer will provide an overview of the FOA and be available to answer general questions until 4:00 p.m. Eastern Standard Time. Otherwise, grantees are encouraged to contact the Project Officer listed at the end of this FOA by email.

Call information is as follows: call number: **877-429-7311**, passcode: **2057439#**.

There will be no webinar with this call.

Table of Contents

I. Program Funding Opportunity Description

1. Purpose

This announcement solicits applications for the Autism Transitions Research Project (ATRP). The ATRP supports the implementation and completion of programmatic research studies that examine factors associated with healthy life transitions among adolescents and young adults with Autism Spectrum Disorder (ASD) who are transitioning to adulthood in order to:

- Advance the evidence base available to researchers, providers, policy makers, educators, adolescents and young adults with ASD and their families, and the public regarding factors associated with healthy life (physical, social, mental health, and educational/occupational) outcomes among this population;
- Address the critical need that exists for ASD transitions research that targets the social environment and not just the individual; and
- Provide national leadership and education in research on healthy transitions to adulthood for this population.

Applicants are encouraged to consider research topics of interest to HRSA's Maternal and Child Health Bureau (MCHB), including but not limited to proposed studies that:

- Harness existing national sources of data to provide benchmark indicators on life outcomes and risk factors among youth and young adults with ASD in the U.S., including information on basic demographic characteristics specific to this population;
- Use primary and secondary data collection methods and statistical techniques to identify service models and interventions that show efficacy in promoting healthy life outcomes among transitioning adolescents and young adults with ASD;
- Improve the current understanding of what constitutes healthy life outcomes for transitioning youth with ASD through the collection and analysis of both primary and secondary data;
- Use primary and secondary data to develop measurement tools designed to improve our understanding of life outcomes among adolescents and young adults with ASD;
- Help develop and test service models and interventions that promote healthy outcomes through engaging multiple levels of the social environment (e.g., family, peer, and community supports) that influence outcomes among this population;
- Help set the direction of future national research on this topic by identifying gaps that currently exist in the understanding of life outcomes, service needs and access, and service program models for transitioning adolescents and young adults with ASD;
- Identify barriers that limit access to and efficacy of services for transitioning adolescents and young adults with ASD; and

- Promote greater national and public awareness of factors associated with healthy outcomes for this population by providing leadership in the dissemination of findings from ATRP research.

2. Background

ASD is now recognized as a significant public health issue, with a Centers for Disease Control and Prevention study finding that 1 in every 68 American children meet diagnostic criteria. In response to this acute public health need, the Autism CARES Act of 2014 reauthorized research and education activities related to ASD.

The Interagency Autism Coordinating Committee (IACC) names research on adult outcomes and services, including the transition to adulthood, as one of its seven major research topics in its strategic plan for autism research. In its 2013 Strategic Plan, IACC notes recent calls for research that focus on outcomes related to quality of life, and interventions that target the social environment and not just the individual.

Currently, research on quality of life outcomes among ASD populations is limited by the dearth of information available on how adolescents and young adults with ASD fare as they enter adulthood. This project will support a programmatic series of studies designed to address this gap and so advance the evidence base on factors associated with healthy life outcomes among adolescents and young adults with ASD in order to improve transition care and services for this population.

CARES Act
This program is authorized by the Public Health Service Act, § 399BB(f) (42 U.S.C. 280i-1(f)), as amended by the Combating Autism Reauthorization Act of 2011 (P.L. 112–32) and the Autism CARES Act of 2014 (P.L. 113–157).

In response to the Autism CARES Act initiative, HRSA's Maternal and Child Health Bureau (MCHB) supports programs to improve the quality of care among those diagnosed with autism and related other developmental disabilities through education, early detection, and intervention**.**

The four programs and related areas supported by 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:
   - UA3 Autism Research Network Program that focuses on intervention research, research to improve care and services, guideline development and information dissemination;
   - R40 Autism Field-initiated Innovative Research Studies (Autism FIRST);
   - R40 Autism Secondary Data Analysis Research (Autism SDAR); and

- UJ2 Autism Single Investigator Innovation Program (Autism SIIP).

3) State Autism Demonstration and Policy Programs
   - State Autism Demonstration grants are implementing State Autism plans and creating models for how to develop systems of services for children with ASD and other developmental disabilities; and
   - A State Public Health Coordinating Center coordinates with the State Autism Demonstration awards and develops and implements a strategy for defining, supporting, and monitoring the role of state public health in assuring that children and youth with ASD and other developmental disabilities receive early and timely identification, diagnosis, and intervention.

4) Evaluation
   - Information and analysis from this evaluation of MCHB CARES investments contributed to the HHS Secretary's Report to Congress on progress related to ASD and other developmental disabilities as required in the legislation.

MCHB Division of Research
The MCHB Division of Research within the Office of Epidemiology and Research supports applied and translational research and research networks relating to MCH services, including services for children and youth with ASD and other special health care needs. Research projects address critical MCH questions including public health systems and infrastructure, health disparities, quality of care, and promoting the health and wellbeing of MCH populations, issues which also support the goals of the Health Resources and Services Administration. Emphasis is placed on projects that show promise of substantial contribution to the advancement of the current knowledge pool, and when used in states and communities should result in improvements in health and health services. The UJ2 Autism Single Investigator Innovation Program (Autism SIIP) is a part of the MCH Extramural Research Program, administered by the Division of Research within the Office of Epidemiology and Research within MCHB.

For more information about the MCHB Division of Research, visit our website: http://www.mchb.hrsa.gov/research.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New

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 for awards made under HRSA-17-097: Autism Transitions Research Project (ATRP) 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 ATRP;
- Assistance in establishing and maintaining federal interagency and inter-organizational contacts necessary to carry out the project;
- Review of documents such as ATRP website material, white papers, and 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.

Under a cooperative agreement, the ATRP recipient's responsibilities will include:

- Adhere to HRSA guidelines 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 R&R Application Guide.*
- Identify gaps in the knowledge base, and develop a research program designed to fill those gaps;
- Plan and conduct primary and secondary research designed to better understand and address the needs of transitioning adolescents and young adults with ASD;
- Develop tools that will lead to better measurement of the life outcomes among adolescents and young adults with ASD;
- Leverage Research Network activities to obtain additional external funding in order to advance critical research that will address identified gaps and promote the research agenda;
- Advance the evidence base on this topic through primary and secondary data collection and analyses resulting in at least two peer-reviewed publications per project year;
- Develop and implement a dissemination plan that serves to facilitate the transfer of research findings to a broader audience such as researchers, health care providers, policy makers, and transitioning youth and their families;
- Set aside funds in the budget for this grant to participate in a two-day annual national all-grantee meeting organized by the Maternal and Child Health Bureau for its research award recipients. This meeting will take place in the Washington, DC area, and will be an opportunity to share best practices, disseminate results, and discuss research priorities with MCHB leadership, staff, and stakeholders;
- Coordinate with MCHB research networks or projects funded through the Autism CARES Act of 2014; and
- Develop a schedule of ongoing communication with the HRSA/MCHB Project Officer.

2. Summary of Funding

Approximately $500,000 is expected to be available annually to fund one (1) recipient. You may apply for a ceiling amount of up to $500,000 total costs per year. The actual amount available will not be determined until enactment of the final FY 2017 federal budget. This program announcement is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, applications can be processed, and funds can be awarded in a timely manner. The project period is September 1, 2017 through August 31, 2022 (five (5) years). Funding beyond the first year is dependent on the availability of appropriated funds for the Autism Transitions Research Project in subsequent fiscal years, recipient satisfactory 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 will be subject to the Uniform Guidance 2 CFR part 200 as codified by HHS at 45 CFR part 75, which supersede the previous administrative and audit requirements and cost principles that govern federal monies.

III. Eligibility Information

1. Eligible Applicants

Eligible applicants 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.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

Applications that exceed the $500,000 total costs per year ceiling amount will be considered non-responsive and will not be considered for funding under this announcement. This ceiling includes both direct and indirect expenses.

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. For example, different investigators (or research teams) from the same institution cannot put in separate applications for this same funding opportunity announcement.

Due to funding limitations and in order to diversify our research portfolio, the following additional eligibility requirement applies:

- The PI/PD of any currently active grant or cooperative agreement funded through the MCHB Division of Research Extramural Research Program can serve for no more than 10 percent time on a new UJ2 proposal.
- Co-PIs of currently active grants and cooperative agreements funded through the MCHB Division of Research Extramural Research Program do not have a limit on the percent time they can serve on a new UJ2 proposal.

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 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.

Please make sure you submit your application to the correct announcement number. Applications submitted to the wrong competition will be deemed nonresponsive.

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 Research and Related (R&R) application package associated with this FOA following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

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 *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 FOA to do otherwise.

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

Application Page Limits
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 narrative and budget justification, biographical sketches (biosketches), attachments, and letters of commitment and support required in HRSA's *SF-424 R&R Application Guide* and this FOA. Standard OMB-approved forms that are included in the application package are NOT included in the page limit (Reminder: biographical sketches **do** count 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 you to take appropriate measures to ensure your application does not exceed the specified page limit.**

In addition to the overall 80-page limit, please note that SECTION C Methodology/ Research Strategy of the application narrative is STRICTLY LIMITED TO 12 PAGES. Applications that do not adhere to the stated page limit for Section C of their narrative will be deemed nonresponsive to the FOA and marked ineligible for review.

Applications must be complete, within the specified page limits, 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 R&R Application Guide* (including the budget, budget justification, staffing plan and personnel requirements, assurances, certifications, and abstract), please include the following:

i. *Project Abstract*
See Section 4.1.ix of HRSA's *SF-424 R&R Application Guide.* Clearly indicate the PI/PD name and institution, the project title, and the funding opportunity number (e.g., HRSA-17-097). The Abstract is limited to one page and should include:

- A brief background of the project;
- Specific aims, objectives, or hypotheses;
- The significance of the proposed research and relevance to public health;
- The unique features and innovation of the project;
- The methodology (action steps) to be used;

- Expected results; and
- Description of the impact your findings will have on the health and wellbeing of the target population.
- **From the Appendix, select:**
    1. **A maximum of 10 significant content terms that describe your project**
    2. **As many targeted populations as apply**
    3. **As many age ranges as apply**
    4. **Include the selected (1) content terms, (2) populations, and (3) age ranges targeted at the end of your abstract.**

A complete and informative abstract is critical to the review of your application.

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:

A. INTRODUCTION

Not applicable to this competition. The project narrative in response to this FOA begins with B. Specific Aims.

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

1) Needs and Alignment (Corresponds to Section V's Review Criteria: #1 Need)

- Write a brief statement of the research problem or gap;
- Indicate the problem's relevance to the health and wellbeing of adolescents and young adults with ASD and, if appropriate, the sociocultural determinants of health and health disparities impacting this population; and
- Include a programmatic overview of the proposed studies and how they will address the research problem or gap, thus improving the health and wellbeing and/or service delivery for this population.

2) Goals and Hypotheses (Corresponds to Section V's Review Criteria: #2 Response)

- Summarize the overall project purpose and goals;
- Briefly describe the goals and specific objectives of each proposed study;
- If applicable, list the hypotheses for each study;
- This FOA encourages study designs that allow for the examination of multiple levels of influence on transition outcomes (e.g., individual, family, community factors).

C. RESEARCH STRATEGY -- Corresponds to Section V's Review Criteria: #2 Response, #3 Evaluative Measures, and #4 Impact

Organize the Research Strategy section in the specified order using the instructions provided below. Start each section with the appropriate section heading – Significance, Work Plan, Scientific Innovation and Importance. Provide the full reference for supporting citations used in the Bibliography and References Cited section.

Section C, Research Strategy (Significance, Work Plan, Scientific Innovation and Importance) is limited to 12-pages in length. Applications that exceed this 12-page limit in the Research Strategy section will be deemed nonresponsive, and will not be considered for funding under this announcement.

1) Significance (Corresponds to Section V's Review Criteria #2 Response)

- Describe the background scientific literature, with focus on its pertinence to and rationale for the current research problem;
- Explain the critical problem, barrier to progress, or gap in the evidence base in the field that the proposed project addresses;
- Describe the relevance of the problem to the health and wellbeing of adolescents and young adults with ASD;
- Summarize the expected outcomes, with attention to how these outcomes will address the unmet needs of the targeted population; and
- Discuss the multiple levels of influence on transition outcomes (e.g., individual, family, community factors) that the project will address.

2) Work Plan (Corresponds to Section V's Review Criterion #3 Evaluative Measures)

- Describe the overall study design, research strategies and methods, population, and analyses to be used to accomplish the specific aims of the project;
- For primary data, describe the procedures for data collection and instrumentation as appropriate, including information/citations regarding the established validity of the instruments used if applicable;
- For secondary data, describe the databases to be used and their sources, and identify specific types of variables to be used as part of the project;
- Describe the participant population, including demographic information (i.e., targeted ages, expected racial/ethnic background and socioeconomic status, rural/urban, etc.);
- Describe eligibility inclusion/exclusion criteria;
- Describe the sampling design and methods;
- Provide power analyses based on expected enrollment as appropriate;
- Include a description of strategies for any participant recruitment; and
- Include how the data will be analyzed as well as any resource sharing plans as appropriate.

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

- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields related to health and/or human development;
- Describe the impact that the results of the proposed research will exert on the research field(s) involved;
- Explain how the application challenges and seeks to shift current research or practice paradigms;
- Describe any novel theoretical concepts, approaches or methodologies, policies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, policies, or interventions;
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, policies, or interventions; and
- Describe how the concepts, methods, technologies, treatments, services, policies, or preventive interventions that drive this field will be changed if the proposed aims are achieved.

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

Public Health Impact

- Identify the projected application of findings to the health and wellbeing of this population and/or the ways that services are organized and delivered;
- Describe how the project's expected outcomes are likely to have an impact on service delivery strategies involved, and/or improve the health and wellbeing of adolescents and young adults with ASD;
- Describe how the findings will address issues or concerns at the regional or national level; and
- Describe how the proposed study specifically addresses issues with expected broad public health impact.

Publication and Dissemination Plan

- Describe plans for publication and dissemination of project findings and results, including a plan for producing the expected minimum number of peer-reviewed publications (i.e. two (2) publications per project year).
- Describe a plan to advance the transfer of findings into practice by disseminating findings, reports, and/or award project outputs to key target audiences, including researchers, providers, State Title V and children with special health care needs programs and other program(s) serving the targeted population, policymakers, families, and the general public. Recipients will have implemented their plan to advance the transfer of findings into practice by the end of the project period. In terms of communication channels, recipients may distribute research findings and

information on project activities and findings through: targeted email messages, newsletter articles, conference presentations, webcasts, fact sheets, infographics, policy briefs, and website and social media posts, as appropriate.

- Past MCHB research recipients should demonstrate publications from their previous MCH research award. (NOTE: Peer-reviewed publications are the cardinal measure of success of the MCH Extramural Research Program).

PRELIMINARY STUDIES

- Information regarding Preliminary Studies may be placed between Section D, Impact and Dissemination, and Section E, Organizational Information/Environment. It does **not count in the 12-page limit for Section C, but does count in the overall 80-page limit.**
- Use this section to provide an account of preliminary studies of the PI and co-PI(s) pertinent to this application, including his/her preliminary experience with and outreach to the targeted population. This information will also help to establish the scientific research experience and competence of the investigator(s) to pursue the proposed research project. In addition, preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed research.

BIBLIOGRAPHY AND REFERENCES CITED

- The Bibliography/References cited may be placed between Section D, Impact and Dissemination, and Section E, Organizational Information/Environment. It does **not count in the 12-page limit for Section C, but does count in the overall 80-page limit.**

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

Organizational Resources

This information is used to assess the capability of the organizational resources available to perform the effort proposed. NOTE: The SF-424 R&R Table of Contents Page refers to Environment as "Facilities & Other Resources." This section on "Environment" can be included as an attachment in the Other Project Information Form, box 10, or included as part of the research narrative.

- Identify the facilities to be used (laboratory, clinical setting, computer lab, office, and/or other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work.
- Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical and other resources, and intellectual environment). In describing the scientific environment in which the work will be done, discuss ways in which the proposed study will benefit from unique features of the scientific

environment or will employ useful collaborative arrangements that enhance the scientific environment in which the project will be conducted.

- For Early Stage Investigators (defined as up to 10 years following attainment of the field-relevant doctoral degree), describe institutional investment in the success of the investigator; examples of such investment would be: resources for professional development, travel, training; collegial support such as career enrichment opportunities and availability of professional peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support.
- If there are multiple performance sites, describe the resources available at each site.

Qualifications of Research Team's Key Personnel

The qualifications of the research team's key personnel are assessed as part of Section V's Review Criterion 5 Resources/Capabilities. To assess the qualifications of the research team's key personnel, the following three (3) items are used:

1. Preliminary Studies following Section C. Research Strategy;
2. Staffing Plan in Budget Narrative; and
3. Biographical Sketches of key personnel.

Biographical sketches should follow the format described below. When applicable, biographical sketches should include training, language fluency and experience working with the culturally and linguistically diverse populations that are served by their programs.

NOTE: The Biographical Sketch may not exceed five pages per investigator, keeping in mind the overall 80-page limit. Follow the formats and instructions below.

Professional Information: At the top of page one, include Name, Position Title, Education/Training including: institution and location, degree, month/year degree attained, field of study. Then complete sections A, B, C, and D as described below:

- **Personal Statement**

Briefly describe why you are well-suited for your role(s) in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

- **Positions and Honors**

  List previous positions in chronological order, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

- **Contribution to Science**

  Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other nonpublication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations.

- **Research Support**

  List both selected ongoing and completed research projects for the past 3 years (federal or non-federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include percent effort or direct costs.

  Don't confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, "Other Support" information is required for all applications that are selected to receive funding awards. HRSA staff will request complete and up-to-date "other support" information from you after peer review. This information will be used to check that the proposed research has not already been federally-funded.

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

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

Proposed Sequence or Timetable

- Provide a sequence or timetable for the project that includes the activities or steps that will be taken to achieve each of the activities proposed during the

entire project period. Use a timeline that includes each activity and identifies responsible staff.

Resolution of Challenges

- Discuss any challenges that are likely to be encountered in designing and implementing the research activities described in the work plan, and approaches that will be used to resolve such challenges. Examples include recruitment of study sites and study participants, staff training and standardization of research protocols across multiple sites, putting culturally/linguistically competent project staff in place quickly, recruiting participants from specific populations, obtaining necessary databases for secondary analyses, etc.
- Discuss alternative strategies should any of these potential challenges arise.
- Discuss the feasibility of reaching targeted/planned enrollment levels.
- Establish feasibility by describing any strategies that will be used to address the management of any high risk aspects of the proposed work.
- If appropriate, describe any procedures, situations, or materials that may be hazardous to personnel, and precautions to be exercised.

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

- Describe a plan for performance evaluation (evaluating project progress towards its specific aims) that will contribute to continuous quality improvement of project efforts. The project performance evaluation should reflect the Specific Aims described in Section B above, as well as the specific timeline goals set in the Proposed Sequence or Timetable under Section F Feasibility above (e.g., all staff identified and trained by month 4, data collection begun by month 6, etc.). The purpose is to monitor ongoing processes and the progress towards the aims and objectives of the project.

H. PROTECTION OF HUMAN SUBJECTS -- Corresponds to Section V's Review Criterion #7 Program Assurances

If human subjects are involved, the project should be in compliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR part 46) (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). Please refer to instructions provided in HRSA's SF-424 R&R Application Guide, Appendix: Supplemental Instructions for Preparing 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.

This section is required for applicants answering "yes" to the question "Are human subjects involved?" on the R&R Other Project Information form. If the answer is "No" to the question but the proposed research involves human specimens and/or data from subjects, applicants must provide a justification in this section for the claim that no human subjects are involved.

Discuss plans to seek Institutional Review Board (IRB) approval. IRB approval is not required at the time of application submission but must be received prior to

initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.

I. TARGETED/PLANNED ENROLLMENT -- Corresponds to Section V's Review Criterion #7 Program Assurances

- Provide details about the targeted/planned enrollment for the study. Information should include targeted/planned enrollment totals by:
    - Ethnic Category (Hispanic Heritage): "Hispanic or Latino" or "Not Hispanic or Latino"
        - Gender distribution within each Ethnic Category (Hispanic Heritage)
        - Total planned enrollment by Ethnic Category (Hispanic Heritage)
    - Racial Categories
        - American Indian/Alaska Native
        - Asian
        - Native Hawaiian or Other Pacific Islander
        - Black or African American
        - White
        - More than One Race
        - Gender distribution within each racial category
        - Total planned enrollment by racial category

- The "Ethnic Category (Hispanic Heritage): Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects. Also list any proposed racial/ethnic subpopulations, if applicable.
- The "Total Planned Enrollment" means the number of subjects that are expected to be enrolled during the entire period of the study and are needed to evaluate the research question. The "Total Planned Enrollment" will be reported in two ways in the table: by self-reported "Ethnic Category (Hispanic Heritage)" and by self-reported "Racial Categories."
- Describe how the project will assure cultural competence in terms of including individuals from the study population in the planning and implementation of the research project and in adapting the research methodology to reflect an understanding of and valuing the culture of the study population.

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.	
Narrative Section	Review Criteria
B. Specific Aims: 1) Needs and Alignment	(1) Need
B. Specific Aims: 2) Goals and Hypotheses	(2) Response
C. Research Strategy: 1) Significance	(2) Response
C. Research Strategy: 2) Work Plan	(3) Evaluative Measures
C. Research Strategy: 3) Scientific Innovation and Importance	(4) Impact
D. Impact and Dissemination	(4) Impact
E. Organizational Information/ Environment	(5) Resources/Capabilities
Budget and Budget Justification (below)	(6) Support Requested
F. Feasibility	(7) Program Assurances
G. Evaluation and Technical Support Capacity	(7) Program Assurances
H. Protection of Human Subjects	(7) Program Assurances
I. Targeted/Planned Enrollment	(7) Program Assurances

iii. *Budget*

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

Travel

The following travel is required to be budgeted for the ATRP:
The budget should reflect the travel expenses associated with participating in meetings that address MCH research efforts and other proposed trainings or workshops. All applicants must budget for attendance at the MCHB Research Network meeting each year in the Washington, DC area for up to two people (the PI and one other attendee) for two days. **Meeting attendance is an award requirement.**

In addition to the MCHB Research Network meeting, all MCHB recipients funded through the Autism CARES Act (including research, training, and state demonstration recipients) are required to attend an Autism Cares grantee meeting. This meeting is held every other year in Washington, DC, and is planned for the years 2017 and 2019. (Off year MCHB Autism CARES grantee meetings are held virtually.)

Sufficient funds must be set aside to attend this in-person meeting in 2017 and 2019.

Travel outside of the United States and its territories is not supported for the Autism Transitions Research Project.

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.

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

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 R&R Application Guide* for additional information. Note that these or other salary limitations may apply in FY 2017, 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 Autism Transition Research Project requires the following:

Staffing Plan and Personnel Requirements
Within Personnel Costs, include the staffing plan by providing position descriptions (roles, responsibilities, and qualifications of proposed project staff) in the "Budget Justification" section that will be uploaded in SF-424 R&R Budget Period – Section F – K Form, Box K. This staffing plan should describe the complementary and integrated expertise of the investigators and show that the leadership approach, governance and organizational structure are appropriate for the project. The staffing plan should reflect the commitment of the research team in conducting and completing the study. (NOTE: A current PI of a research network award from the MCH Extramural Research Program can serve for no more than 10 percent time on a new proposal and only in a capacity other than as Principal Investigator (PI)

Copies of biographical sketches for all senior/key personnel and other significant contributors must be submitted as an attached file to each SF-424 R&R Senior/Key Person Profile. **Applicants must follow the instructions for biographical sketches found in this FOA. Biosketches count in the overall 80-page limitation.**

v. *Program-Specific Forms*

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

HRSA has modified its reporting requirements for SPRANS projects, Community Integrated Service Systems (CISS) projects, and other grant/cooperative agreement programs administered by MCHB to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act, MCHB's authorizing legislation. Performance measures for other MCHB-funded grant/cooperative agreement 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 Autism Transitions Research Project (ATRP)

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

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

vi. *Attachments*

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

Attachment 1: Letters of Agreement/Letters of Support

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

Attachment 2: Key Publications or Condensed Citations with Abstracts

A list of citations for key publications 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 3: Surveys, Questionnaires, Data Collection Instruments, Clinical Protocols

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

Attachment 4: Explanation on Delinquent Federal Debt, if applicable.

Attachment 5: Proof of Nonprofit Status (Not counted in the page limit).

Attachments 6-15: Other Relevant Documents

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

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

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

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

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

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

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

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

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 *February 13, 2017 at 11:59 P.M. Eastern Time*.

See Section 8.2.5 – Summary of e-mails from Grants.gov of HRSA's *SF-424 R&R Application Guide* for additional information.

5. Intergovernmental Review

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

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

6. Funding Restrictions

You may request funding for a project period of up to 5 years, at no more than $500,000 total cost (direct and indirect expenses) per year. Awards for the first year are subject to the availability of appropriations. 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 (HRSA-17-097) may not be used for travel outside of the U.S. or its territories.

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 R&R Application Guide* for additional information. Note that these or other restrictions will apply in FY 2017, as required by law.

You are required to have the necessary policies, procedures and financial controls in place to ensure that your organization complies with the all federal funding requirements and prohibitions such as lobbying, gun control, abortion, etc. 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.

V. Application Review Information

1. Review Criteria

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

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

NOTE: The terms *project, research project* and *study* are used interchangeably.

Review Criteria are used to review and rank applications. The ATRP has seven (7) review criteria:

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

Criterion 1: NEED (5 points) -- Corresponds to Program Narrative Section B Specific Aims: Needs and Alignment

B. Specific Aims: Needs and Alignment

- The extent to which the proposed research project clearly describes a research problem or gap;
- The extent to which the project narrative describes the relevance of this research problem or gap to the health and wellbeing of adolescents and young adults with ASD and, if appropriate, the sociocultural determinants of health and health disparities impacting the target population;
- The extent to which the project narrative provides a coherent programmatic overview of the proposed studies and how they will address the research problem or gap, thus improving the health and wellbeing and/or service delivery for this population.

Criterion 2: RESPONSE (15 points) -- Corresponds to Program Narrative Sections B Specific Aims: Goals and Hypotheses; and C Research Strategy: Significance

B. Specific Aims: Goals and Hypotheses

- The extent to which the overall project purpose and goals are listed clearly and succinctly;
- The extent to which the goals and specific objectives of each proposed study are clear, concise, and appropriate;
- The extent to which the hypotheses, if applicable, are logically derived from the research literature, clearly stated, and are related to the defined problem.

C. Research Strategy: Significance

- The extent to which the investigators demonstrate awareness of previous and current scientific research in the area of the project;
- The extent to which the cited literature is pertinent to the research problem and provides a rationale for the research;
- The extent to which the project narrative clearly describes the critical problem, barrier to progress, or gap in the evidence base or field that the proposed project addresses;
- The extent to which the relevance of the research problem to the health and wellbeing of adolescents and young adults with ASD is clearly described;
- The extent to which the project, in the expert scientific judgment of the reviewers, addresses a critical problem or barrier to progress in the field;
- The extent to which the study's expected outcomes are clearly and succinctly summarized, with attention to how these outcomes will address the unmet needs of the target population;
- The extent to which the study design examines multiple levels of the social environment (e.g., family, peer, and community supports) that influence outcomes among this population.

Criterion 3: EVALUATIVE MEASURES (30 points) -- Corresponds to Program Narrative Section C Research Strategy: Work Plan

C. Research Strategy: Work Plan

Overall Study Design

- The extent to which the research plan and activities described are well-reasoned and coherent as a whole;
- The extent to which the scientific activities described in the proposal are capable of addressing the problem and attaining the project objectives; that is, the effectiveness of the design and methods proposed to accomplish study goals and answer the research questions posed;
- For efficacy studies, if included in the study design:
    - The degree to which proper controls are included;
    - The extent to which methods for randomization into ex versus control groups are clearly described and appropriate to answer the research questions posed;
- The extent to which the description of the study design and procedures are explicit enough to permit replication;
- The extent to which all significant threats to internal and external validity of the design have been adequately acknowledged and addressed;
- The degree to which the project activities are replicable and generalizable;
- As appropriate, the extent to which the project assures cultural competence in the planning and implementation of the research project.

Population Description, Sampling, and Recruitment

- The extent to which the study population is clearly described (i.e., targeted ages or age ranges, expected racial/ethnic background and socioeconomic status, urban/rural, etc.) and appropriate to the research questions posed;
- The extent to which the sampling design and methods are appropriate;
- The extent to which the sample size is adequate and justified in terms of statistical power;
- The extent to which expected differences between groups are defined in terms of statistical as well as clinical significance;
- The extent to which there is a basis for anticipating the quality of sample estimates and the degree to which the quality is adequate for the purpose of the study;
- The extent to which the proposed inclusion of minorities and members of both sexes/genders, as well as the inclusion of children is justified in terms of the scientific goals and research strategy proposed;
- The extent to which the eligibility criteria for entry into the study are well defined;

- The extent to which the recruitment plan is clearly described;
- The extent to which letters of agreement from study sites supporting recruitment are in place;
- The extent to which methods used for participant recruitment are feasible;
- The extent to which the targeted enrollment is feasible to complete within the project period, given recruitment methods.

Data Collection

- The extent to which procedures for data collection are described clearly;
- If new data are to be collected, the extent to which instruments have been selected or developed and are adequate and appropriate to answer the research questions being posed;
- The extent to which adequate attention is given to reliability and validity (psychometric properties);
- The extent to which any self-reported data can provide convincing validity for intended measurements, e.g., self-reported blood pressure, parent-reported anthropometric data;
- The extent to which databases and types of variables to be used for secondary analyses are clearly described and adequate to answer the research questions being posed.

Plan for Data Analysis

- The extent to which the project narrative includes a data analytic plan appropriate to the research questions being asked;
- The degree to which plans for data analysis are presented in detail;
- The extent to which the plans describe the process of data analysis and the rationale for the sequence of steps to be taken;
- The appropriateness of the data analytic plan and statistical methods to the nature of the data, design and samples;
- The extent to which sufficient time is allocated for data analysis and reporting.

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

C. Research Strategy: Scientific Innovation and Importance

- The extent to which the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields relevant to children and youth with ASD, and their families as appropriate, if the aims of the project are achieved;
- The extent to which successful completion of the aims will change the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field;

- The extent to which the expected outcomes are likely to have an impact on the relevant fields of research;
- The extent to which the proposed project challenges and seeks to shift current research or health care practice paradigms by utilizing innovative theoretical concepts, approaches or methodologies, instrumentation, or interventions;
- The extent to which the concepts, approaches or methodologies, instrumentation, or interventions are novel to one (or more) fields of research or novel in a broad sense;
- 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 overall scientific approach proposes an innovative solution, intervention or strategy;
- The extent to which project results are likely to exert a sustained influence on the research field(s) involved.

D. Impact and Dissemination

Public Health Impact

- The extent to which the proposal identifies the envisioned application of findings to the health and wellbeing of this population and/or the ways that services are organized and delivered;
- The extent to which the expected outcomes are likely to have an impact on service delivery strategies involved;
- The extent to which the expected outcomes are likely to help improve the health and wellbeing of adolescents and young adults with ASD, and their families as appropriate;
- The extent to which findings will address issues or concerns at the regional or national level;
- The extent to which the proposed study specifically addresses transition-related issues with expected broad public health impact.

Publication and Dissemination Plan

- The extent to which there is an effective publication and dissemination plan;
- The degree to which the proposal provides a sound plan for producing the expected minimum number of peer-reviewed publications (i.e. two (2) publications per project year);
- The degree 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 proposal clearly demonstrates a plan to advance the transfer of findings into practice by disseminating findings, reports, and/or award project outputs to key target audiences, including researchers, providers, State Title V and children with special health care needs programs

and other program(s) serving the targeted population, policymakers, families, and the general public.

CRITERION 5: RESOURCES/CAPABILITIES (30 points)

E. Organizational Information/Environment

- The capabilities of the applicant organization, and quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed research project;
- The extent to which the scientific environment in which the work will be done contributes to the probability of project success;
- The adequacy of the institutional support, equipment, and other physical resources available to the PI and co-investigators for the proposed project;
- The extent to which the project will benefit from unique features of the scientific environment, subject populations, or collaborative arrangements.

Research Team -- Corresponds to Preliminary Studies; Staffing Plan/Budget Narrative; Biographical Sketches

- The extent to which the Biographical Sketches indicate that the PI, co-Investigators, staff, and other research collaborators are well qualified by training and/or expertise to conduct the research;
- The extent to which the Staffing Plan provided in the Budget Narrative describes personnel who have the disciplinary training and experience to meet the project goals;
- If Early Stage Investigators, the appropriateness of their experience and training. If established investigators, the degree to which they have demonstrated an ongoing record of research accomplishments that have served to advance the field;
- The extent to which the proposal describes relevant preliminary studies performed by key personnel, indicating the capacity to conduct the research as described.

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

- The reasonableness of the proposed budget in relation to the objectives, the complexity of the research 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 realistic and appropriate to achieve project objectives;

- The extent to which other current and pending award support is described. (Note: A current PI of an MCH Research Network award can serve for no more than 10 percent time on a new proposal, and only in a capacity other than PI).

CRITERION 7: PROGRAM ASSURANCES (5 points) -- Corresponds to F. Feasibility; G. Evaluation and Technical Support Capacity; H. Protection of Human Subjects; and I. Targeted/Planned Enrollment

F. Feasibility

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

Proposed Sequence or Timetable

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

Resolution of Challenges

- The extent to which potential barriers to project progress are anticipated and addressed.
- The extent to which you provide assurance that the research can be conducted and completed as proposed.
- The extent to which you demonstrate the feasibility of reaching targeted/planned enrollment levels within the timeline provided.

G. Evaluation and Technical Support Capacity

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

H. Protection of Human Subjects

- The extent to which adequate protections are afforded to human subjects, including children and youth, and the extent to which measures are in place to ensure the security of the research data (data security);
- The extent to which the proposal is in compliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR part 46). See the instructions in HRSA's SF-424 R&R Application Guide, Appendix: Supplemental Instructions for Preparing the

Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy;

- The extent to which you discuss plans to seek Institutional Review Board (IRB) approval (IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects).

I. Targeted/Planned Enrollment

- The extent to which the proposal provides details regarding the Targeted/Planned Enrollment for the study, including information on anticipated ethnic, racial and gender categories;
- The extent to which appropriate diversity is planned with regard to the target population; and
- The extent to which the project provides assurance regarding cultural competence as appropriate.

2. Review and Selection Process

The objective research review process provides an assessment of each application's scientific merit and potential impact on the field to the individuals responsible for making award decisions. The highest ranked applications receive priority consideration for award within available funding. In addition to the ranking based on merit criteria, HRSA approving officials also may apply other factors in award selection, (e.g., federal recipient performance), if specified below in this FOA. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

Please see Section 5.3 of HRSA's *SF-424 R&R Application Guide*.

3. Assessment of Risk and Other Pre-Award Activities

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).

Applications receiving a favorable objective review that HRSA is considering for funding are reviewed for other considerations. These include, 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. You may be asked to submit additional programmatic or awards 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 an award will be made. Following review of all applicable information, HRSA's approving and business management officials will determine whether an award can be made, if special conditions are required, and what level of funding is appropriate.

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

Effective January 1, 2016, HRSA is required to review and consider any information about the applicant that is in the Federal Recipient 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 your comments, in addition to other information in FAPIIS in making a judgment about your 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 HHS Awarding Agency Review of Risk Posed by Applicants.

A determination that an applicant is not qualified will be reported by HRSA to FAPIIS (45 CFR § 75.212).

4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing awards prior to the start date of September 1, 2017.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award prior to the start date of September 1, 2017. See Section 5.4 of HRSA's *SF-424 R&R Application Guide* for additional information.

2. Administrative and National Policy Requirements

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

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 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 part 46), available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

3. Reporting

On June 10, 2016, the Office of Management and Budget approved MCHB to collect new performance measures from recipients as part of its Discretionary Grant Information System (DGIS). The new performance measures reflect MCHB's strategic and priority areas including financial and demographic information, health domain and

program-specific measures, and program-specific measures that highlight the unique characteristics of discretionary grant/cooperative agreement projects that are not already captured. Collectively, these data communicate the MCHB "story" to a broad range of stakeholders on the role of the Bureau in addressing the needs of maternal and child health populations. These performance data will also serve several purposes, including recipient monitoring, performance reporting, MCHB program planning, and the ability to demonstrate alignment between MCHB discretionary programs and the MCH Title V Block Grant program.

These new performance measures will allow a more accurate and detailed picture of the full scope of activities supported by MCHB-administered grant/cooperative agreement programs, while reducing the overall number of performance measures from what was previously used. The MCHB Project Officer will assign a subset of measures relevant to the program for which the recipients will report. In addition to reporting on the new performance measures, recipients will continue to provide financial and program data. The new reporting package can be reviewed at: http://mchb.hrsa.gov/sites/default/files/mchb/Data/Discretionary_Grant_Information_System_Performance_Measure_Update.pdf.

New and continuing awards issued on or after October 1, 2016, will be required to report on the new measures. For successful competing continuation awards, recipients will report on their previous year activities (defined as those completed before October 1, 2016) using the forms and measures in DGIS as assigned in the previous FOA.

The successful applicant under this FOA must comply with Section 6 of HRSA's *SF-424 R&R 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) Final Report Narrative. The recipient must submit a final report narrative to HRSA after the conclusion of the project.

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

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

Prompt and timely presentation and publication in the scientific literature of findings resulting from research and analyses undertaken is required. As per HHS awards policy guidelines (See "Publications" section on page II-73 at http://www.hrsa.gov/grants/hhsgrantspolicy.pdf), the recipient agrees to acknowledge HRSA support in the publications and oral presentations resulting from research and/or activities conducted under this program. Peer reviewed

publications are the cardinal measure of success of the MCH Research Program. The number of publications resulting from each funded project contributes to the total number of publications by which the MCH Research Program is evaluated annually.

5) Performance Reports. HRSA has modified its reporting requirements for SPRANS projects, CISS projects, and other grant/cooperative agreement programs administered by MCHB to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act, MCHB's authorizing legislation.

a) Performance Measures and Program Data

After the Notice of Award (NoA) is released, the MCHB Project Officer will inform recipients of the administrative forms and performances measures they must report.

b) Performance Reporting Timeline

Successful applicants receiving HRSA funds will be required, within 120 days of the NoA, to register in HRSA's Electronic Handbooks (EHBs) and electronically complete the program-specific data forms that are required for this award. 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.

c) 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. 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.

6) Integrity and Performance Reporting. The Notice of Award 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 obtain additional information regarding business, administrative, or fiscal issues related to this FOA by contacting:

Ms. Ernsley P. Charles
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Room 10N146A
Rockville, MD 20857
Telephone: (301) 443-8329
Fax: (301) 443-9354
E-mail: echarles@hrsa.gov

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

Robin L. Harwood, Ph.D.
Health Scientist, Division of Research
Attn: Autism Transitions Research Program (ATRP)
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 18N116
Rockville, MD 20857
Telephone: (301) 443-3888
Fax: (301) 480-0508
E-mail: rharwood@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, 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
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 HRSA's EHBs, contact the HRSA Contact Center, Monday-Friday,8:00 a.m. to 8:00 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

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

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

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

Inclusion of Children Policy Implementation
http://grants.nih.gov/grants/funding/children/children.htm

Institute of Medicine
https://www.nationalacademies.org/hmd/

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

MCH Training Web Site
http://www.mchb.hrsa.gov/training

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

National Center for Medical Home Implementation
http://www.medicalhomeinfo.org/

Technical Assistance

A Technical Assistance call will be held on Tuesday, January 3, 2017 at 3:00 p.m. Eastern Standard Time. The MCHB Project Officer will provide an overview of the FOA and be available to answer questions until 4:00 p.m. Eastern Standard Time.

Call information is as follows: call number: **877-429-7311**, passcode: **2057439#**.

There will be no webinar with this call.

IX. Tips for Writing a Strong Application

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

Appendix: Key Content, Population, and Age Range 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 & Wellbeing

- Bullying & Peer Relationships
- Depression
- Mental Health & Wellbeing
- 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 & Wellbeing (Preconception/Interconception/Parental)
- Prenatal (till 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)