
EVALUATION DESIGN PLAN

MCHB Combating Autism Initiative Evaluation

Autism Research Program



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I. INTRODUCTION

This document details a proposed plan for the evaluation of 1) the Research Network grant program and 2) the R40 MCH Autism Intervention Research Program grantees. These programs were implemented by Health Resources and Services Administration's (HRSA) Maternal and Child Health Bureau (MCHB) as part of the *MCHB Combating Autism Act Initiative (CAAI)*. The Research Network grant program, which began in 2008, includes support for one physical/medical health intervention research effort and one behavioral, mental, social, and/or cognitive health intervention research effort. The R40 grant program, which began in 2009, supports 5 two-year grants and two-one year grants to conduct research on evidence-based practices for interventions to improve the health and well-being of children and adolescents with Autism Spectrum Disorder (ASD) and other Developmental Disabilities (DD).

The evaluation of the research grant program will take place over three consecutive project phases including a base year and two option years. Each phase is briefly described below.

Phase I. Planning and Evaluation Design. Phase I took place over the first eight months of the contract, beginning in October 2008 and ending in May 2009. During this phase, we gathered information on the grantees' activities and available data sources, developed and refined the research questions and logic models to guide the program evaluation, developed a draft evaluation design, conferred with grantees to review the evaluation design and obtain feedback, and finalized the design.

Phase II. Data Collection. Phase II began in June 2009 and will end in March 2011. During this time, we will develop data collection protocols and/or tools, provide specifications for modifying existing tools, collect data from grantees, and deliver periodic presentations to MCHB staff on the preliminary results. We will also prepare presentations for the annual grantee meetings in December 2009 and December 2010.

Phase III. Data Analysis and Reporting. In Phase III, beginning in April 2011 and ending in September 2011, we will analyze the data and submit our final evaluation report. Additionally, we will write the MCHB contribution to the Report to Congress as required by Section 399DD of the *Combating Autism Act of 2006 (CAA)*. This report will summarize the activities and outcomes for the Research Networks and R40 Grantees and will report on national performance measures, as required.

A. CHALLENGES TO THIS EVALUATION

Every evaluation has potential challenges. In the case of the research grantees, one potential challenge, for example, involves the relatively short duration of the project, which may prevent measurement of some long term outcomes, such as publication of

research findings. Accordingly, we have developed an evaluation plan that includes the collection of short term/interim data that can feasibly be obtained within the project timeline. From these data, we can establish a baseline, providing the necessary foundation for evaluating long term outcomes in the future.

A second challenge is the September 2011 due date for the final Report to Congress. We will need draft materials for this report by June 2011, to provide adequate time for review by MCHB and revisions. This timeline means the individual evaluation report for the research grants must be completed and reviewed by MCHB by May 2011. To make these deadlines and to have sufficient time to analyze the information collected, data collection must end by March 15, 2011. As a result, the evaluation will not be able to obtain a third year of data. Discretionary Grant Information Systems (DGIS) data will not be due until December 31, 2011, and grantees' final reports are not due until November 30, 2011. The only information the evaluation will have for the final year of grant activities will be collected either at the December 2010 grantee conference or through telephone interviews that could be conducted as late as February/March 2011. The last round of data collection will cover no more than the first three months of FY 2011 (the first three months of the third year of funding for the six grantees awarded in 2008 and the first three months of the second year of funding for the three grantees awarded in 2009).

B. OVERVIEW OF EVALUATION PLAN

Chapter II reviews the goals and objectives of the *Combating Autism Act of 2006* (CAA), and MCHB's Combating Autism Act Initiative. Chapter III provides an overview of the autism intervention research program. Chapters IV, V and VI describe our proposed plan for evaluating the research grantees' performance in meeting the MCHB's goals under the CAAI. As such, Chapter IV provides an overview of the evaluation design plan for the Research Networks and the R40 Grantees. Chapter V outlines our data collection methodology. Chapter VI provides plans for data analysis. Chapter VII presents our proposed plans for writing the final reports. Attachments A and B provide detailed logic models for each of the Research Networks and Attachments C and D provide a detailed listing of proposed activities for each of the Research Networks. This listing will be used to keep track of the activities completed during the Research Networks' 3-year grant. Attachment E presents the DGIS data collection forms that will be available during the grant cycle. Attachments F and G present our proposed data collection protocols.

II. THE 2006 COMBATING AUTISM ACT AND MCHB'S COMBATING AUTISM ACT INITIATIVE

A. OVERVIEW OF CAA LEGISLATION

1. Intent of the Legislation: Goals and Objectives

In response to the growing need for research and resources devoted to Autism Spectrum Disorders (ASD), the U.S. Congress passed the *Combating Autism Act of 2006* (CAA)¹. The goal of the CAA is to enable all children to reach their full potential by developing a system of services that includes:

- Screening children early for ASD and other developmental disabilities (DD);
- Conducting early, interdisciplinary evaluations to confirm or rule out ASDs and other DDs; and
- Providing evidence-based, early interventions when a diagnosis is confirmed.

2. Funding Levels

In FY 2008, Congress appropriated a total of \$168 million to the following agencies for activities under the CAA:

- **National Institutes of Health (NIH)** received \$114.5 million for research into causes, diagnosis, early detection and treatment through the Centers of Excellence;
- **Centers for Disease Control and Prevention (CDC)** received \$16.5 million to conduct research and surveillance activities, including collection of state-level epidemiologic data; and
- **Health Resources and Services Administration (HRSA)** received \$37 million to increase awareness, reduce barriers to screening and diagnosis, promote evidence-based interventions, and train health care professionals (note: the appropriation of \$37 million included a transfer of approximately \$20 million of Special Projects of Regional and National Significance (SPRANS) funds to the Autism and Other Developmental Disorders program).

¹ Public Law 109-416§42 U.S.C.§1

B. HRSA'S COMBATING AUTISM ACT INITIATIVE

1. Goals and Objectives

In response to the CAA, HRSA implemented the *Combating Autism Act Initiative* (CAAI) through its Maternal and Child Health Bureau (MCHB). MCHB administers a broad range of programs that promote and support the development of family-centered, culturally/linguistically competent, community-based systems of care. These programs are often structured to meet the needs of specific population groups, such as low-income families, racial and ethnic minority families, children with special health care needs, and rural families. MCHB also builds maternal and child health services capacity by training health professionals, developing standards of care, and increasing assessment, planning and quality assurance capabilities of state and local government MCH programs.

The overall goal of HRSA/MCHB's *Combating Autism Act Initiative* (CAAI) is to enable all children to reach their full potential by developing a system of services that includes improving the physical, behavioral, mental, social and/or cognitive health and well-being of children and adolescents with ASD and other DD by developing a system of services that address the three goals of the CAA:

1. Screening children as early as possible for ASD and other DD
2. Conducting early, interdisciplinary evaluations to confirm or rule out ASD and other DD
3. If a diagnosis is confirmed, providing early, evidence-based interventions

Additionally, in alignment with guidance from the CAA, the CAAI specifies five main objectives:

1. Increase public/provider awareness of ASDs and other DD
2. Reduce barriers to screening and diagnosis
3. Support research on evidence-based interventions
4. Promote the development of evidence-based guidelines and tested/validated intervention tools
5. Train professionals to use valid and reliable screening tools, to confirm or rule out a diagnosis of ASD/DD and to provide evidence-based interventions.

2. Activities

To achieve these goals and objectives, HRSA/MCHB has provided support to three different programs that focus on training, research and implementation, respectively. Each program is briefly described below.

1. Training Programs

- *Expansion of Existing Leadership Education in Neurodevelopmental Disabilities (LEND) training programs.* Eighteen existing grantees received additional funding of approximately \$200,000 each and four new LEND programs were established and funded at a level of approximately \$550,000 each per year.²
- *Expansion of Existing Developmental Behavioral Pediatrics (DBP) training programs.* Six existing grantees received additional funding of approximately \$50,000 per year.³
- *A National Combating Autism Interdisciplinary Training Resource Center cooperative agreement.* One grantee received \$500,000 in funding.

2a. Research Networks Program

- *Two Autism Intervention Research Networks.* These Networks focus on intervention research, guideline development and information dissemination. One network is focused on physical/medical health intervention research (AIR-P, with \$4 million) while the other is focused on behavioral, mental, social, and/or cognitive health intervention research (AIR-B, with \$2 million).

2b. R40: MCH Autism Intervention Research Program.

- *Five intervention research grantees.* These grantees are to conduct research leading to improvements in interventions that address the health and well-being of children and adolescents with ASD and other DD. Each grantee to receive funds of approximately \$400,000 per year for two years.
- *Two secondary data analysis grantees.* These grantees are to conduct research leading to improvements in interventions that address the health and well-being of children and adolescents with ASD and other DD, utilizing existing secondary data. Each grantee to receive funds of approximately \$100,000 for one year.

² Another 16 LEND grantees maintained their funding from the previous year, resulting in a total of 38 LEND grantees in FY 2008.

³ Another 4 DBP grantees did not receive an expansion over their existing level of approximately \$192,000 per year. Note that all of the DBP grantees were awarded before the CAAI funds were allocated; thus, the DBP grantee guidance did not specifically require autism-specific training.

3. State Implementation Grants

- *Nine state grantees.* These grantees will implement state autism plans and develop models for systems of services for children with ASD and other DD. Each grantee received funding of approximately \$300,000 each year (*note: 6 were funded in 2008 and 3 were funded in 2009*).
- *One State Public Health Coordinating Center.* This center will coordinate with the State Implementation grantees to develop and implement a strategy for defining, supporting, and monitoring the role of state public health agencies in assuring that children and youth with ASD and other DD receive early and appropriate identification, diagnosis, and intervention. One grantee received funding of \$250,000.

III. AUTISM INTERVENTION RESEARCH PROGRAM

The *Combating Autism Act of 2006* tasked HRSA/MCHB with establishing a platform from which to conduct research on evidence-based interventions for ASD and other developmental disabilities.

In September 2008, MCHB awarded funds to two research networks: the Autism Intervention Research Network on Physical Health (AIR-P Network) and the Autism Intervention Research Network on Behavioral Health (AIR-B Network). *Note that HRSA/MCHB's, Division of Research, Training and Education's (DRTE) Maternal and Child Health Research Program released the grant guidance for these Research Networks in May, 2008 with a due date of June 24, 2008.*

Grant funds are available for three years, through September 2011. According to the grant guidance, each grantee was required to develop, among other things, a) a research agenda; b) a management and operations plan and c) a process for proposal development. Additionally, the networks were tasked to:

- Support research studies that will lead to the advancement of the current knowledge pool and lead to improvements in interventions that address the physical and behavioral health needs of children and adolescents with ASD and other DD,
- Increase the development of guidelines for evidence-based interventions,
- Increase the number of validated tools for interventions, and
- Increase information dissemination to health professionals and the public, especially families impacted by ASD and other DD.

Additionally, with additional funding authorized for FY 2009 and 2010, MCHB initiated the R40 MCH Autism Intervention Research Grant Competition, as part of the Combating Autism Act Initiative. There were two separate grant programs funded:

1. R40 MCH Autism Intervention Research Program – to support research on evidence-based practices for interventions to improve the health and well-being of children and adolescents with ASD and other DD. Each grantee award is no more than \$400,000 per year. MCHB funded 5 grantees under the R40 MCH Autism Intervention Research Program, each for a project period up to two years.
2. R40 MCH Autism Intervention Secondary Data Analysis Studies (SDAS) Program – to support research on evidence-based practices for interventions to improve the health and well-being of children and adolescents with ASD and other DD, utilizing exclusively the analysis of

existing secondary data. Each grantee award is no more than \$100,000 for one year. MCHB funded two grantees under the SDAS Program, each for a project period of one year.

The objectives of the R40 Grant Program are to:

- Advance the current knowledge pool leading to improvements in interventions that address the health needs of children and adolescents with ASD and other DD, and
- Disseminate information to health professionals and the public, especially families impacted by ASD and other DD.

The objectives are achieved in part by the prompt and timely presentation and publication of findings in the peer-reviewed scientific literature

Collectively, the two grant programs are referred to as the R40 MCH Autism Intervention Research Grant Program. MCH funded the awards beginning September 1, 2009. *The grant guidance for the R40 grantees was released in April, 2009 with a due date of May 18, 2009.*

In the tables below, we provide a complete listing of each grantees' proposed activities cross-walked to their goals and objectives.

A. AUTISM INTERVENTION RESEARCH NETWORK FOR PHYSICAL HEALTH (AIR-P)

Information on grantee:

Network Coordinating Center: [Massachusetts General Hospital](#) for Children (MGHfC)

Director: Dr. James M. Perrin, MD, Professor of Pediatrics at Harvard Medical School and Director of the MGH Center for Child and Adolescent Health Policy

Funding amount: \$4 million per year for a 3 year period

Collaborating Research Entities/Sites (CREs): In partnership with the Autism Treatment Network (ATN), a program established in 2005 and acquired by Autism Speaks in 2007. The 15 AIR-P's CREs are the 15 ATN member sites and include:

1. Baylor College of Medicine
2. Cincinnati Children's Hospital Medical Center
3. Children's Hospital, Columbia University Medical Center
4. Kaiser Permanente Northern California,
5. Kennedy-Krieger Institute,
6. LADDERS/MassGeneral Clinic,

7. Oregon Health & Science University,
8. Seattle Children's Hospital Research Institute/University of Washington,
9. University of Arkansas for Medical Sciences
10. University of Colorado Denver
11. University of Missouri-Columbia,
12. University of Pittsburgh,
13. University of Rochester Medical Center, and
14. Vanderbilt University.

Other partners: Autism Speaks, the Emmes Corporation, and NICHQ.

This network uses a collaborative network infrastructure currently in place. The ATN works with 'network' sites to standardize care, enhance access to a medical home, and ensure rapid dissemination and implementation of treatments. Autism Speaks provides the infrastructure to maintain all activities of the ATN, including a Data Coordinating Center, a Clinical Coordinating Center and a patient registry. Through use of this ATN, the AIR-P is able to leverage an existing structure with extensive experience in providing care, as well as single and multi-site research.

The goal of the AIR-P is to establish and maintain a network infrastructure from which to conduct research on evidence-based interventions to improve the *physical health and well-being* of children and adolescents with ASD and other DD. Physical health may include but is not limited to medical, dental, visual, nutrition and speech/hearing components.

The AIR-P's objectives are to:

- Conduct research on evidence-based practices for interventions to improve the physical health and well-being of children and adolescents with ASD and other DD;
- Develop evidence-based guidelines and validate tools for interventions to improve the health care of children and adolescents with ASD and other DD, and
- Disseminate the Network's research findings, guidelines, and validated tools to health professionals and the public, especially families impacted by ASD and other DD.

RESEARCH NETWORK FOR PHYSICAL HEALTH (AIR-P)

Goal: to improve medical treatment for children and youth with ASD by establishing standards of clinical care and evidence based guidelines. The focus is on problems associated with GI, nutrition and sleep disorders in individuals with ASD.

| CAAI Goal | Objectives | Activities | Evaluation Criteria |
|--|--|--|---|
| <p>Goal 1a. Conduct Research on Evidence-Based Practices: To conduct multi-site research studies that address gaps in our knowledge of treatment research for ASD</p> | <p>Objective #1: to implement a collaborative mechanism to develop innovative research concepts and protocols that will help improve care for children with ASD</p> <p>Objective #2: to carry out a series of pilot studies providing preliminary findings and to seek outside funding opportunities to develop full scale implementation and intervention research</p> <p>Objective #3: to conduct and develop at least 2 intervention focused research projects in areas including sleep, GI, nutritional and neurological disorders</p> | <p>Study #1: Development of a Parent based Sleep Education Program for Children with ASD Outcome from #1: screening tool for nutritional sufficiency; detailed implementation manual for preferred intervention</p> <p>Study #2: Improved Diet and Nutrition for Children with ASD Outcome from #2: tool for nutritional screening of children with ASD in primary care settings); also, educational materials for nutritional counseling in primary care settings</p> <p>Generate research concepts on an on-going basis. Develop rating process to rank proposals.</p> | <p># of research concepts/protocols developed into pilot study proposals (Plan is for the subcommittees to generate 3 study proposals per year and submit to funder)</p> <p># of studies successfully funded (Plan is to acquire external funding for 1-2 of the 3 study proposals per year)</p> <p>2 peer-reviewed publications (one per research project) in a main journal</p> <p>3 presentations per year on results</p> <p>Acquire/secure external funding</p> |
| <p>Goal 1b. Validate Tools: To test and validate tools that can be used to improve outcome measures of treatment studies in autism</p> | <p>Objective #4: to conduct research projects on the validation of clinically-relevant tools focused in the areas of sleep and nutrition</p> | | |
| <p>Goal 2. Develop Evidence Based Guidelines: To develop guidelines for the implementation of interventions for children with ASD and their families.</p> | <p>Objective #5: to develop 2 consensus based clinical guidelines based on the findings of AIR-P research products and other existing evidence</p> | <p>Identify topics for change packages, develop change packages, implement change packages, review findings from ATN registry</p> | <p>Develop and disseminate two consensus guidelines</p> |
| <p>Goal 3. Disseminate Information on Research, Guidelines, and Validated Tools: To disseminate information about evidence based interventions and valid tools for children with ASD and their families.</p> | <p>Objective #6: To disseminate toolkits, research findings and clinical consensus guidelines to pediatricians other PCPs, specialized physicians and families</p> <p>Objective #7: To collaborate with the CAAI programs and other training programs in developing and implementing trainings based on research findings, tools and clinical consensus guidelines.</p> | <p>1 training symposium per year with physicians, specialists, sub specialists and families</p> | <p># of trainings (plan is one overall training symposium per year; also one annual training at each CRE site) # of participants</p> <p>Diverse audiences reached</p> <p># of presentations to families and providers</p> <p># presentations at conferences</p> <p>Special module on the AS website</p> <p>Collaboration with LEND and AIR-B by participating in annual LEND conference</p> |

B. AUTISM INTERVENTION RESEARCH NETWORK FOR BEHAVIORAL, MENTAL, SOCIAL, AND COGNITIVE HEALTH (AIR-B)

Information on grantee:

Network Coordinating Center: [Regents of the University of California at Los Angeles](#) (UCLA)

Director: Dr. Connie Kasari, Ph.D., Professor of Education and Psychiatry and Biobehavioral Sciences

Funding amount: \$2 million per year for a 3 year period

Collaborating Research Entities/Sites (CREs): There are four CREs, including:

1. Kennedy Krieger Institute's Center for Autism and Related Disorders;
2. Florida State University Autism Institute;
3. University of Michigan's Autism and Communication Disorders Center;
and
4. University of Washington's NIH funded Autism Center of Excellence.

Other partners: RAND Corporation (guideline development) and SISStat (the database management and statistics unit) at UCLA.

The goal of the AIR-B is to establish and maintain a network infrastructure from which to conduct research on evidence-based interventions to improve the *behavioral, mental, social, and/or cognitive health and well-being* of children and adolescents with ASD and other DD.

The AIR-B's objectives are to:

- Conduct research on evidence-based practices for interventions to improve the *behavioral, mental, social, and/or cognitive health and well-being* of children and adolescents with ASD and other DD,
- Develop evidence-based guidelines and validate tools for interventions to improve the *behavioral, mental, social, and/or cognitive health and well-being* of children and adolescents with ASD and other DD, and
- Disseminate the Network's research findings, guidelines, and validated tools to health professionals and the public, especially families impacted by ASD and other DD.
- Also, the Network plans to identify necessary adaptations of evidence based practices for use by underserved and underrepresented populations.

RESEARCH NETWORK FOR BEHAVIORAL, MENTAL, SOCIAL AND COGNITIVE HEALTH (AIR-B)

Goal: to develop and advance evidence-based treatments, guidelines, tools and information that can be disseminated to professionals and families affected by ASD.

| CAAI Goal | Objectives | Activities | Evaluation Criteria |
|--|---|---|--|
| <p>Goal 1. Conduct Research on Evidence-Based Practices: To conduct multi-site research studies that address gaps in our knowledge of treatment research for ASD</p> | <p>Objective #1: to test the efficacy of evidence based treatments across multiple sites and contexts to determine the generalizability of interventions for core deficits Objective #2: to examine the acceptance and efficacy of interventions for under-served and under-represented populations</p> | <p>Study #1: CAIR-N Parent Mediated Joint Engagement Intervention (randomize multi site study) Study #2: CAIR-N Study of Peer Relationships at School (randomized multi site study)</p> | <p>Acquire/secure external funding</p> |
| <p>Goal 2a. Validate Tools: To test and validate tools that could be used to improve outcome measures of treatment studies in autism</p> | <p>Objective #3: to validate measures of core deficits in children with autism that can be completed with unobtrusive and rapid methods for ease of implementation in the community Objective #4: to provide manuals for interventions that reflect important active ingredients that can be widely implemented in community settings Objective #5: to validate tools which have sensitivity and applicability in diverse under-represented and underserved populations</p> | <p>4 measures for validation that address core deficits 3 intervention manuals with adaptations for developmental age and background (diversity)</p> | <p>Developed standardized and well-validated outcome measures that are not labor intensive and can be applied in a number of settings by non-researchers (thorough PDAs or other handheld devices) Results of pilot tests of experimental measures (compared with standardized) Met need for valid tools and meaningful outcome measures in treatment research (other than IQ)</p> |
| <p>Goal 2b. Develop Evidence Based Guidelines: To develop guidelines for the implementation of interventions for children with ASD and their families</p> | <p>Objective #6: to identify and address challenges faced in the implementation of evidence based guidelines Objective #7: to develop guidelines which have relevance for underrepresented populations</p> | <p>Broad based guideline that focuses on the evaluation of the proposed assessment approaches and treatments for children with ASD AND includes the use of medical treatments for behavioral features of ASD (RAND) By: Synthesize literature, convene panel to discuss evidence, and develop guidelines, develop easy to query database to be posted on website; presentation on guidelines, and final report</p> | <p>Provide scientific evidence on approaches to assessment, behavioral, educational and medical interventions and their impact on ASD Met need for treatment guidelines that are grounded in evidence and improvement evident in shorter period of time (3 months)</p> |
| <p>Goal 3. Disseminate Information on Research, Guidelines, and Validated Tools: To disseminate information about evidence based interventions and valid tools for children with ASD and their families.</p> | <p>Objective #8: to collectively and collaboratively publish papers on topics of interest and need to the autism community (interventions, tools guidelines). Objective #9: to develop a method of dissemination to reach the widest and most diverse population of consumers.</p> | <p>1. Print publication goals: 3 primary publications in year 1 and 5 in year 3 2. Presentations dissemination (one annual presentation at IMIFAR conference) 3. Establish partnerships to increase dissemination (such as AIR-P, State and local MCH agencies, 0-3 and FRCNCA to disseminate information and provide training) 4. Public web development (including multi level searchable databases for interdisciplinary teams done by SISat) 5. Virtual home (with both a public and private domain; done by SISat)</p> | <p><u>Yr 1 Publications:</u> 1. review of intervention science in ASD identifying gaps 2. summary for professionals emphasizing the key components of an interdisciplinary, comprehensive intervention plan 3. summary of available interventions for families and consumers. <u>Yr 3 Publications:</u> 1. evidence based guidelines on social communication core deficits and medical treatments 2. treatment manual from study 1 3. treatment manuals from study 2 4. reports on outcome findings from study 5. reports on outcome findings from study</p> |

C. R40 MCH AUTISM INTERVENTION RESEARCH GRANTS

Below is a listing of the Autism Intervention Research Projects funded 9/1/2009.

| | Organization | Location | Type of Grantee | Research Study Topic | Study Description |
|---|---|-----------------|-----------------|---|---|
| 1 | Brandeis University | Waltham, MA | MCH research | Assessing a Participant Directed Service System for Low Income Children with Autism | Evaluate a Medicaid supportive services waiver program in Massachusetts that uses a participant direction model to choose and manage services for young children with autism spectrum disorder and their families. |
| 2 | Boston Medical Center | Boston, MA | MCH research | Supporting the Well-being of Families of Young Children with Autism Spectrum Disorders | Determine whether an evidence-based empowerment strategy targeted to mothers of young children with autism spectrum disorders promotes family well-being by decreasing the burden of maternal depressive symptoms and parenting stress and improving maternal social functioning. |
| 3 | Kennedy Krieger Institute | Baltimore, MD | MCH research | Parent-Mediated vs Center-Based Intervention for Toddlers with ASD: An RCT | To evaluate whether parent-mediated intervention and center-based intervention provided by a clinician yield comparable outcomes for minority and underserved toddlers with autism spectrum disorders. |
| 4 | University of New Hampshire | Concord, NH | MCH research | Family-Centered Transition Planning for Students with Autism Spectrum Disorders | Demonstrate a Family-Centered Transition Planning model designed to empower families and high school students with autism spectrum disorders transitioning to adult life. |
| 5 | University of Colorado Denver | Aurora, CO | MCH research | Telehealth Delivery of a Family-Focused Intervention to Reduce Anxiety in Youth with Autism Spectrum Disorders in Rural Colorado | Develop and evaluate the use of interactive televideo technology to deliver a promising mental health intervention to families of children with autism spectrum disorders who are geographically removed from specialty medical centers. |
| 6 | University of North Carolina at Chapel Hill | Chapel Hill, NC | SDAS | The Effectiveness of Special Education Services for Children with Autism: A National Longitudinal Study | Assess the effectiveness of special education services for children with autism spectrum disorders by measuring the effect of high quality treatment on outcomes. |
| 7 | University of Massachusetts | Boston, MA | SDAS | Services and Outcomes for Transition Age Young Adults with Autism Spectrum Disorders: Secondary Analysis of the NLTS2 and RSA 911 | Identify factors associated with and influencing a successful transition into adulthood for young adults with autism spectrum disorders. |

IV. OVERVIEW OF THE EVALUATION DESIGN

A. PURPOSE

The evaluation design plan was developed to assess the grantees' performance in meeting the goals of HRSA/MCHB's CAAI. The evaluation of this grant program will rely, to a large extent, on qualitative research methods to assess program implementation, systems change, and outcomes. However, where quantitative measures are available, we will ask grantees to report on them.

1. Evaluation Goals and Objectives

The overall goals of the evaluation are 1) to measure CAAI activities and assess whether such activities meet the objectives of the legislation that mandated them, and 2) to assess the efforts of the MCHB in addressing the nation's growing need to improve the physical, behavioral, mental, social, and cognitive health and well-being of children and adolescents with an ASD and other DD. The evaluation will provide an excellent source of data for HRSA/MCHB to meet their commitment to improving the well-being of our Nation's mothers and children by measuring the short- and intermediate-term impacts of the CAAI programs on children and families affected by ASD and other DD. It will also lay the foundation for potential future measurement of the initiative's long-term impact.

The objectives of the evaluation include the following:

1. Determine whether the grantees' are accomplishing the intended goals and objectives of MCHB's CAAI;
2. Identify problems or barriers that surfaced during implementation and how these problems or barriers were resolved;
3. Identify any existing gaps in the grantees' activities; and
4. Measure the CAAI outputs and outcomes for the Report to Congress.

2. Use of Results

The results of this evaluation will allow MCHB to assess the performance of the grantees in achieving their short- and intermediate-term outcomes during the three year evaluation period. In addition, the results will provide MCHB with greater insight into how to structure funding efforts in the future. The evaluation can determine which activities were more successful and which were less successful for funding research studies, leveraging investment and bringing evidence-based research into practice. Additionally, the data will be used in the Report to Congress on the effectiveness of the Research Networks in achieving the goals and objectives of the *Combating Autism Act of 2006*.

B. RESEARCH QUESTIONS

In this section we present the major questions that we plan to address in this evaluation, as well as the data we plan to collect in order to answer each question and the proposed data sources.

1. Overall Research Questions

To frame the work, we first linked this grant program to the objectives of HRSA's CAAI. We determined that the Research Network grants linked to four of the five objectives established for the CAAI (which are numbered below according to the ordering established by HRSA—see Chapter III). Additionally, we determined that the R40 Grantees linked to two of the five objectives established for the CAAI. These are shown below.

CAAI

Objective Research Question

1. How effective are the Research Networks and R40 Grantees in increasing public/provider awareness of ASD and other DD?
(Note: this question corresponds to Research Network Goal 3: Disseminate information on research, guidelines, and validated tools).
2. How effective are the Research Networks in reducing barriers to the development and implementation of evidence based interventions?
3. How effective are the Research Networks and R40 Grantees in supporting research on evidence-based interventions for children and adolescents with ASD and other DD?
(Note: this question corresponds to Research Network Goal 1: Conduct research on evidence-based practices)
4. How effective are the Research Networks in:
 - a. Promoting evidence based guideline development for interventions?
(Note: this question corresponds to Research Network Goal 2b: develop evidence based-guidelines for the implementation of interventions)
 - b. Testing and validating tools?
(Note: this question corresponds to Research Network Goal 2a: Test and validate tools)

2. Crosswalk for the Research Questions, Data Elements and Proposed Data Sources

Below, we provide a detailed list of research questions for the evaluation, the associated data elements, and proposed data sources. The detailed research questions were developed based on our understanding of the grantee's particular goals, objectives, and related activities. The questions are designed to 1) qualitatively describe and document how the grantees use federal funds to achieve their program objectives, and 2) quantitatively measure the short term and intermediate outcomes of their federally funded activities and to set the foundation for measuring the long-term impact on individuals with ASD and other DD in the future. Many of the questions are qualitative, process-level questions (e.g., how did the program increase awareness?). However, where quantitative data elements exist (such as Discretionary Grants Information System [DGIS] measures), we included these measures as specific questions.

Prior to developing these research questions, we reviewed each of the grant applications and developed a short summary for each grantee of its project goals, objectives, activities, and key outcomes. Additionally, we developed a logic model for each of the Research Networks that provided a visual picture of *the short term, intermediate and long term outcomes* that are critical to assessing the program's success in meeting the CAII objectives (see Attachments A and B). These models link the Research Network activities to the desired short-term, intermediate-term, and long-term effects. *Note that the intermediate objectives are grouped by the MCHB CAAI objectives and the long term outcomes are grouped by the three goals of the CAAI (identified in Chapter II above).*

An overview of the evaluation design is presented in Table IV.1 and a logic model for the evaluation is presented in Appendix A. In Table IV.1 information is first organized by objective. Listed under each objective are a set of research questions. For each question we report the likely data source (or sources) for the information needed to answer the question and the types of analyses to be used to assess the information collected (implementation, network, and outcomes analyses). Specifically, column 1 provides the research question (grouped by the overall CAAI objectives listed above). Column 2 provides the key data source (or sources). Column 3 indicates the type of analysis we will use to assess the information collected (implementation, network and outcomes analyses). Last, column 4 lists the detailed data elements. These will be reported in MCHB's 2011 Report to Congress on the outcomes of the CAAI.

TABLE IV.1

CROSSWALK OF DATA ELEMENTS BY RESEARCH QUESTION

| Research Questions | Key Data Sources | Type of Analysis | Data Element |
|---|--|---|---|
| Objective #1: How effective are the Autism Intervention Research Networks and R40 Grantees in increasing public/provider awareness of ASD and other DD (e.g., research based information, valid and reliable screening tools, and evidence-based interventions for ASD)? | | | |
| <p>What did the grantees do to increase <i>awareness</i> of research-based information and evidence-based interventions among <i>health professionals</i>?</p> <p>a. How are they disseminating information about ASD to health professionals?</p> <p>b. Which efforts have been most successful and why?</p> <p>c. What outreach was developed for providers? Did the grantees develop their own outreach materials/programs or did they use materials developed by others? Were the activities linked to the state LEND program or other DBP programs?</p> <p>d. How did the grantees coordinate with the other organizations to conduct or expand outreach?</p> <p>e. What has been the impact of these activities?</p> | <ul style="list-style-type: none"> - Grant applications - Progress reports - Grantee interviews | <ul style="list-style-type: none"> -Implementation -Outcome | <ul style="list-style-type: none"> - Written description of activities related to forums for translating research into practice and their impact - Dissemination plan that includes a written description of initiatives aimed at disseminating research-based information to <i>health professionals</i> - Types of materials developed for health professionals <p>Quantitative data</p> <ul style="list-style-type: none"> - Number of materials (e.g., studies/briefs, articles or informational materials) developed for health professionals - Number of professional outreach sessions conducted - Number of health professionals reached |
| <p>What did the grantees do to increase <i>awareness</i> of research-based information and evidence-based interventions on the part of <i>families of children with ASD and the public</i>?</p> <p>a. How are they disseminating information about ASD to families and the public?</p> <p>b. Which efforts have been most successful and why?</p> <p>c. What outreach was developed for families and the public? Did the grantees develop their own outreach/ programs or did they use materials developed by others? Were the activities linked to the state LEND program or other DBP programs?</p> <p>d. How did the grantees coordinate with the other organizations to conduct or expand outreach?</p> <p>e. What has been the impact of these activities?</p> | <ul style="list-style-type: none"> - Grant applications - Progress reports - Grantee interviews | <ul style="list-style-type: none"> -Implementation -Outcome | <ul style="list-style-type: none"> - Written description of activities and their impact - Dissemination plan that includes a written description of initiatives aimed at disseminating research-based information to <i>families and the public</i> - Types of materials developed for families and the public <p>Quantitative data</p> <ul style="list-style-type: none"> - Number of materials (e.g., studies/briefs, popular articles or informational materials) developed for families and the public - Number of family outreach sessions conducted - Number of families reached |
| <p>What other types of outreach have the grantees done?</p> | <ul style="list-style-type: none"> - Progress reports | <ul style="list-style-type: none"> -Implementation | <ul style="list-style-type: none"> - Written description of activities and their impact |

TABLE IV.1

CROSSWALK OF DATA ELEMENTS BY RESEARCH QUESTION

| Research Questions | Key Data Sources | Type of Analysis | Data Element |
|---|--|-----------------------------|---|
| a. Have autism-specific websites been developed? b. How successful are these websites in disseminating information? | - Grantee interviews | | Quantitative data - Number of Web “hits” on autism specific websites |
| Have the grantees presented at scientific conferences? | - Progress reports - Grantee interviews | -Implementation | - Written description of activities and their impact Quantitative data - Number of scientific conference presentations made on evidence-based interventions by type of conference - Number of scientific conference presentations related to measures/tools |
| [For Research Networks]: How have the CREs been enlisted to help increase awareness among health providers and the families/public? a. What activities have the CREs undertaken? b. How have the CREs’ activities increased provider and public awareness? c. How do the CREs help to link the research to the minority and underserved population groups (e.g., underserved)? | - Grant applications - Progress reports - Grantee interviews | -Implementation -Network | - Written description of CRE activities and their impact Quantitative data - Number of families participating in research through CREs by key demographic information - Number of clinicians engaged in research through CREs - Number of outreach sessions conducted through CREs - Collaborations with partners (e.g., LENDs) |
| Objective #2: How effective are the Autism Intervention Research Networks in reducing barriers to the development and implementation of evidence based interventions? | | | |
| To what extent have the Networks been successful in implementing: a. their research agenda? b. their management and operations plan? c. a process for proposal development? What have been the barriers to implementation, if any? | - Grant applications - Progress reports - Grantee interviews | Implementation | - Written description of Network implementation activities - Written description of proposal process - Steering committee convened to establish by-laws and assess adherence (and other committee structures as required by guidance) |

TABLE IV.1

CROSSWALK OF DATA ELEMENTS BY RESEARCH QUESTION

| Research Questions | Key Data Sources | Type of Analysis | Data Element |
|--|--|------------------|---|
| What have the Networks done to reduce barriers to interventions? a. What specific barriers (if any) have the research networks focused on? b. What progress was made to reducing barriers? c. What have the CREs done to reduce barriers? | - Grant applications - Progress reports - Grantee interviews | Implementation | - Written description of Network activities to reduce barriers - Content analysis of research presentations and publications Quantitative data - Number of scientific conference presentations related to reducing barriers |
| How have the Networks' activities reduced barriers to interventions for minority and underserved populations? a. How effective were these activities? b. How has the awareness of research increased among various minority and underserved population groups? | - DGIS #10 | Implementation | - Written description of activities and their impact Quantitative data - Degree to which cultural competence elements are incorporated into the policies, guidelines, contracts and training (DGIS #10) - Number of studies that are responsive to the cultural and linguistic needs of special populations - Number of studies that support a broad representation of culturally distinct and underrepresented groups |
| To what extent were families of children with ASD involved in the research studies? a. How did family input change the design or implementation of these studies? b. Were the families representative of underserved populations? | -Grant applications -Progress reports -Grantee interviews - DGIS #7 | Implementation | - Written description of family participation Quantitative data - Degree of family participation in program and policy activities (DGIS #7) - Number of studies that are family centered |
| What types of partnerships have been fostered to reduce barriers to intervention (e.g., LEND, state public health programs and other organizations)? How successful have these partnerships been? | -Progress reports -Grantee interviews | Implementation | - Written description of partnerships |
| Objective #3: How effective are the Autism Intervention Research Networks and R40 Grantees in supporting research leading to evidence-based interventions for children and adolescents with ASD and other DD? | | | |
| What studies have the grantees planned or undertaken to support research on evidence based interventions? a. What strategies did they use to develop and fund proposals? b. What steps did they take to ensure the participation of | - Grant applications - Progress reports - Grantee | Outcome | - Written description of Network activities to improve evidence based intervention - Narrative on how the CREs were integrated into the research activities - Narrative on stakeholder participation |

TABLE IV.1

CROSSWALK OF DATA ELEMENTS BY RESEARCH QUESTION

| Research Questions | Key Data Sources | Type of Analysis | Data Element |
|--|--|-----------------------|---|
| <p>stakeholder groups, including underserved and minority populations, in the design and execution of study protocols? c. [For Research Networks]: How did the CREs participate?</p> | <p>interviews - DGIS #3</p> | | <p>Quantitative data - Number of research proposals developed and/or funding sought - Number of funded studies currently in process - Number of studies completed - Number of new interventions endorsed by a professional organization, such as the AAP</p> |
| <p>What strategies were implemented to sustain the process after the end of the federal grant period? a. Which activities will continue? Which will end? b. For those activities that will continue, what will be the source of funding?</p> | <p>- Progress reports - Grantee interviews</p> | <p>Implementation</p> | <p>- Written description of Network activities to sustain funding and sustain activities Quantitative Data - Quantity of additional funding obtained as a consequence of HRSA Combating Autism Act Initiative</p> |
| <p>How effective have the Research Networks been at publishing their research findings related to interventions?</p> | | | <p>Quantitative data Publications: - Number of manuscripts in preparation on interventions - Number of manuscripts submitted on interventions - Number of manuscripts in press/accepted on interventions - Number of MCHB completed projects publishing findings in peer reviewed journals on evidence based interventions (similar to DGIS #03) Number above BY TYPE of publication. - how many are related to interventions? - how many are related to reducing barriers? - how many are related to Network activities and functions? - how many are focused on tools/measures? - how many are focused on guidelines?</p> |
| <p>Objective #4a: How effective are the Autism Intervention Research Networks in testing and validating tools?</p> | | | |

TABLE IV.1

CROSSWALK OF DATA ELEMENTS BY RESEARCH QUESTION

| Research Questions | Key Data Sources | Type of Analysis | Data Element |
|--|--|------------------|---|
| What steps are the Networks taking to validate measures and/or tools? <ol style="list-style-type: none"> Do the measures address the core deficits? Are the Networks taking steps for adaptations for developmental age and background? How have the measures/tools been disseminated? Where and how have the measures/tools been adopted? What has been the impact of the measures/tools? | <ul style="list-style-type: none"> - Grant applications - Progress reports - Grantee interviews | Outcome | <ul style="list-style-type: none"> - Written description of Network activities to test or validate tools (may or may not yet be validated as used in psychological testing) <p>Quantitative data</p> <ul style="list-style-type: none"> - Number of measures/tools tested or validated by type |
| How effective have the Research Networks been at promoting adoption of validated tools? | <ul style="list-style-type: none"> - Progress reports - Grantee interviews | Outcome | Written description of Network use of guidelines <p>Quantitative data</p> <ul style="list-style-type: none"> -Number of tools developed, tested or validated by type -Number of tools piloted within the network -Number of tools adopted beyond the network |
| How effective have the Research Networks been at publishing their research findings related to measures/tools? | | Outcome | <p>Quantitative data</p> <ul style="list-style-type: none"> - Publications |
| Objective #4b: How effective are the Autism Intervention Research Networks in promoting evidence (or consensus) based guideline development for interventions? | | | |
| What evidence (or consensus) based guidelines for interventions have the Networks developed? <ol style="list-style-type: none"> What steps have the Networks taken to ensure that the guidelines are relevant to underserved populations? Have the Networks taken steps to identify challenges in implementing guidelines? How have the guidelines been disseminated? Where and how have the guidelines been adopted? What has been the impact of the guidelines? | <ul style="list-style-type: none"> - Grant applications - Progress reports - Grantee interviews | Outcome | <ul style="list-style-type: none"> - Written description of Network activities to develop evidence (or consensus) based guidelines and to promote guideline development - Expert panel convened to assess guidelines - Number of guidelines developed and type |

TABLE IV.1

CROSSWALK OF DATA ELEMENTS BY RESEARCH QUESTION

| Research Questions | Key Data Sources | Type of Analysis | Data Element |
|--|--|------------------|--|
| How effective have the Research Networks been at promoting adoption of guidelines? | <ul style="list-style-type: none"> - Progress reports - Grantee interviews | Outcome | <p>Written description of Network use of guidelines</p> <p>Quantitative data</p> <ul style="list-style-type: none"> - Number of communities - Number of guidelines piloted - Number of guidelines disseminated |
| How effective have the Research Networks been at publishing their research findings related to guidelines? | | Outcome | <p>Quantitative data</p> <ul style="list-style-type: none"> - Number of guidelines developed by type - Number of guidelines piloted in the network⁴ - Number of guidelines adopted beyond the network⁵ (NICHQUE and RAND can measure this) - Number of published evidence-based (or consensus based) guidelines by type |

⁴ Or piloted in communities

⁵ In the marketplace

C. GRANTEE INVOLVEMENT

1. MCHB Autism Grantee Kick-Off Meeting (December, 2008)

During the first Autism Grantee Meeting held on December 15-16, 2008, we held a breakout session with each of the Research Networks and their CREs to engage funded grantees in discussions about the evaluation plans and activities. In this session, we presented the proposed evaluation design to the grantees and obtained their feedback in an open discussion forum. During the session, we took notes and recorded the grantees' suggestions for improving the research questions, logic model, and overall evaluation process. Following the meeting, we compiled and submitted individual summaries of each breakout discussion (as well as a list of the proposed/recommended changes). Additionally, the grantees raised some general issues and questions about the evaluation, for which we requested guidance from MCHB (we submitted to MCHB a list of general issues raised both in the breakout discussions and in the Q&A following our general presentation). The feedback received from the grantees was then used to revise the logic model and research questions following the meeting. Additionally, we incorporated the guidance that we received from MCHB in regard to the list of general issues that were raised during the grantee meeting.

2. Ongoing Communication

At the conclusion of the breakout session at the annual meeting, the Research Networks agreed to participate in an on-going process to refine the logic models and research questions. Correspondingly, we sent the revised research questions and logic models to the MCHB Research Network Project Officers (POs), who distributed them to the Research Network grantees. Grantees were provided a two-week period to review the document and provide feedback. Both Research Networks provided written comments back to MCHB and Insight. Additionally, a teleconference was held with the AIR-P to discuss revisions to the research questions. The feedback obtained during this teleconference was incorporated into the research questions and logic models.

V. DATA COLLECTION METHODOLOGY

The data collection methods used in this evaluation include three *existing data collection mechanisms*: 1) the grant application, 2) annual and bi-annual progress reports, and 3) DGIS reports and two *new data collection mechanisms*: 1) grantee interviews and 2) Research Network specific data forms. Combined, the data sources provide both a *qualitative* analysis of the program implementation and a *quantitative* analysis of the outputs and outcomes of each funded program. Each of these data sources is described in detail below.

Table V.1 provides a summary of the data collection sources and schedule for the evaluation of state implementation grantees.

TABLE V.1

DATA COLLECTION SCHEDULE

| Data Source | Data Collection Schedule | | |
|--|------------------------------|--|---|
| | Research Networks (FY08) | R40 Research program 2 year grantees (FY09) | R40 Research program 1 year grantees (FY09) |
| <i>Existing MCHB Data Collection Tools</i> | | | |
| Grant Application Narrative | October 2008 | October 2009 | October 2009 |
| Summary Progress Reports | March 2009 March 2010 | March 2010 | |
| Final Report | - | | October 2010 |
| DGIS | January 2009 January 2010 | n/a January 2010 | n/a January 2010 |
| <i>New Data Collection Tools</i> | | | |
| Grantee interviews | December 2009 March 2011 | n/a March 2011 | December 2010 |
| Questionnaire | December 2009 March 2010 | n/a | n/a |

NOTE: Because Insight's Final Reports are due in mid-2011, the project schedule will only allow us to include information obtained until March, 2011 in our analyses.

A. EXISTING MCHB DATA COLLECTION TOOLS

Below, we describe the three existing MCHB data collection tools that we will draw upon for this evaluation.

1. Grant Applications

The grant application provides a baseline description of the program and the activities each grantee intends to pursue. To help inform the evaluation design, Insight read the applications thoroughly and developed short lists of the activities for each grantee. The lists for the Research Networks are included in Appendix B. Each grantee will be asked to review and update the project descriptions during the annual grantee meetings in the

fall of 2009 and 2010. These updates will help the evaluation team track changes between the proposed and actual activities.

2. Annual and Biannual Continuation Application/Summary Progress Reports

A non-competing continuation application is required for continuation of grant funding for a subsequent budget period. The continuation application, also referred to as a summary progress report, submits the budget request for the next year of funding and serves as the primary source of information regarding activities, accomplishments, outcomes, and obstacles related to achieving project outcomes during the current budget period. It also provides documentation necessary to justify continuation of the project, including plans for upcoming project periods. Additionally, a final report is required from each grantee.

As much as possible, we would like to build upon existing data collection mechanisms to reduce respondent burden to the grantees. As such, *we envision using the annual and biannual continuation guidance reports/applications as a key data collection tool.*

a. Data Elements

We will obtain all text submitted with the biannual progress reports. This includes information on 1) significant accomplishments and achievements, 2) problems and challenges, 3) comparison of project work with objectives and 4) future plans.

Additionally, we will obtain relevant text submitted as part of the annual continuation applications. This includes the following information:

- Project Abstract
- Project Summary – A list of major accomplishments, problems encountered, changes in direction made, changes in protocols affected and the plans for the coming budget period.
- Description of the Project – A description of the original project plan and the approved changes that have been made since the original project plan.
- Study Population - For all ongoing research studies, a summary of the study population in terms of sample size and inclusion of participants by gender and ethnic minorities. Current information on recruitment in relation to the original target sample size will be shown in table form.
- Accomplishments – A description of what was accomplished during the time period, including progress on specific goals and objectives. Here, grantees will describe linkages that have been established with other CAAI programs. If preliminary and/or final data analyses were made, results will be shown with the interpretations and conclusions reached.

Using the MCHB Performance Measure 03 Form, grantees will list all publications that have resulted.

- Problems – A description of problems that arose during the period covered by the report and what the consequences were for the time needed to complete network activities.
- Work Planned for the Next Budget Period by major project phases – A description of changes in direction and efforts, changes in personnel, and budget allocations, if any.
- Evaluation/Impact – A description of the potential impact of network research and activities on the health care of the individuals being served. If data have been analyzed, description of the potential impact of these findings.

This will provide us a comprehensive picture of the project, including project activities and accomplishments for the past year.

Additionally, we will obtain all relevant data tables completed by grantees for their continuation application. For example, we are interested in reporting results from the Inclusion Enrollment Report (Attachment E).

We are also interested in including data from Form 7: Discretionary Grant Project Summary Data (Attachment E).

b. Data Acquisition Plan and Schedule

The annual progress reports are scheduled to be submitted directly to MCHB on May 12/13, 2009 (year 1- for an anticipated September 30th continuation award date), May 12/13, 2010 (year 2), and May 12/13, 2011 (year 3).

The bi-annual progress reports will be submitted directly to MCHB also. We have already obtained the March 1, 2009 biannual progress report and anticipate obtaining copies of these progress reports as well directly from HRSA soon after receipt.

The annual progress reports for the R40 grantees are scheduled to be submitted directly to MCHB. Final Reports for the R40 MCH Autism Intervention Secondary Data Analysis Studies (SDAS) Program grantees are scheduled to be submitted to MCHB immediately following the end of the grant.

3. Discretionary Grant Information System (DGIS)

The DGIS measures are specified in the continuation guidance reports. DGIS provides MCHB with the needed quantitative data to assess and track grantee performance over

time (e.g., outcomes and impacts). There are no plans to modify the DGIS for this 3 year grant period, as DGIS changes cannot be made and implemented within this time frame.

a. Data Elements

We do, however, plan to extract several data items from DGIS. These include the following:

1. DGIS #03: The percent of completed MCHB supported projects publishing findings in peer-reviewed journals. The data collection form is shown in Attachment E.
2. [For Research Networks only]: DGIS #7: The degree to which MCHB supported programs ensure family participation in program and policy activities. The data collection form is shown in Attachment E.
3. DGIS #10: The degree to which MCHB supported programs have included cultural competence elements into their policies, guidelines, contracts, and training. The data collection form is shown in Attachment E

b. Data Acquisition Plan and Schedule

Since the Research Network grants started on September 1, 2008, the first time that the Research Networks will use the DGIS is calendar year 2009. Since the R40 grants have an anticipated start date of September 1, 2009, the first time that they will use the DGIS is calendar year 2010. Grantees have 120 days (4 months) following the end of the grant year to report to DGIS, and data is available soon afterward. That means that the earliest that we can extract DGIS data from DGIS is December 31st of 2009 and December 31st of 2010. *Note: Year 3 DGIS information (year 2 for R40 Grantees), due December 31st, 2011, will not be available for our report due September of 2011. As such, we propose that these three DGIS measures be incorporated into the grantee's biannual progress report for 2011. The R40 MCH Autism Intervention Secondary Data Analysis Studies (SDAS) Program grantees will only report once - by December 31, 2010.*

B. NEW DATA COLLECTION TOOLS

1. Grantee Interviews

In-depth interviews with grantees will be used to examine how the grantees are meeting their proposed goals and objectives. We anticipate meeting with grantees when they convene for the annual conference. This qualitative research is an essential component of the evaluation insofar as it will supplement any questions that arise from the grantee progress reports and help to tie specific activities to the observed outcomes.

We plan to conduct semi-structured, in-depth interviews with grantees at two points in time (see schedule below). An interview guide will be developed prior to each in-depth interview. The guides would be modified for each interview to capture the short term effects of the activities conducted. These interview protocols will capture detailed information on the types of activities that increase public awareness and reduce barriers to screening and diagnosis.

Given the later start date and the somewhat more limited activities of the grantees under the R40 Grant Program, Insight designed a separate, more limited, data collection instrument for this program. These interview protocols will capture detailed information on their activities and how they met their proposed goals and objectives.

a. Data Elements

The semi-structured interviews will be used to obtain additional details on items contained in the grantee's annual and biannual progress reports to ensure completeness of the data received. Additionally, we will monitor the grantees' progress in completing each of the activities they proposed in their grant application and identify problems or barriers that surfaced during implementation and how these problems or barriers were resolved.

b. Data Acquisition Plan and Schedule

For the Research Networks, we plan to hold these telephone interviews: 1) following receipt of their first annual progress report (December, 2009); and 2) in March 2011. The interviews will be held with the principal investigator or their designee. Prior to conducting each interview, we will send out an informational e-mail describing the purpose of the telephone interviews, identifying what will be covered, and seeking their assistance to schedule the meeting.

For the R40 Grantees, we plan to hold these telephone interviews: 1) for 1 year grantees: following receipt of their first final progress report (December, 2010); and 2) for 2 year grantees: following the grant period and close to March, 2011. The interviews will be held with the principal investigator or their designee. Prior to conducting each call, we will send out an informational e-mail describing the purpose of the telephone interviews, identifying what will be covered, and seeking their assistance to schedule the meeting.

2. Research Network Specific Data Forms

As our research design indicates, we intend to collect data from grantees, but the data will be tailored to the data reporting capabilities of the grantee. Because the data reporting capabilities of each Research Network varies, we will develop a data reporting form that will be tailored to each grantee. The grantee will populate the form with data they are able to report. Grantees will be asked to report aggregated data and many of the data elements will be derived from the activities identified in their grant proposals and summarized in Attachments C and D. Once designed, Insight will ask grantees to report

the data at the conclusion of each grant year. The periodic data forms will be aggregated over time to reflect the cumulative activities of the grantees and cross-indexed against the checklist of grantee activities in Attachments C and D.

VI. DATA ANALYSIS PLAN

The analysis of the grants will be designed to assess grantees' achievement of the four CAAI objectives (see Overview of the Design in Chapter IV). Below, we describe how we will approach the analysis of each objective to draw conclusions about the influence of the research program grants on 1) general awareness of interventions for ASD and other DD, 2) barriers to ASD and other DD intervention services, 3) supporting research leading to evidence-based interventions for children and adolescents with ASD and other DD, 4a) testing and validating tools and 4b) promoting evidence (or consensus) based guideline development for interventions.

We will begin with an introduction describing the extent to which the grantees have been successful in implementing their research agenda, management and operations plan and process for proposals, including the challenges with each. All analyses will be descriptive in nature. Whenever possible, data will be used to describe and document accomplishments. Our analysis plan will be designed to ensure that the data gathered are directly related to the research questions and that the final reports satisfy the goals and objectives of the evaluation.

Since the purpose of the R40 grantees is to Advance Knowledge and Disseminate Information, that they will contribute to two research objectives including #1, general awareness of interventions for ASD and other DD and #3, supporting research leading to evidence-based interventions for children and adolescents with ASD and other DD (see Section A and Section C below).

A. AWARENESS OF INTERVENTIONS FOR ASD AND OTHER DD

The Insight team will use both qualitative and quantitative research methods to determine the extent to which the grantees increased awareness of ASD and other DD. An implementation analysis will be used to describe each grantee's awareness building activities. Each grantee will be asked to provide a written description of their awareness activities and estimate their impact. The grantees will also provide a copy of their dissemination plan, as well as a description of the types of materials that were developed, including Web sites, and the outreach and training sessions conducted.

Additional narrative will include:

- Activities to increase awareness among health professionals, families of children with ASD and the public
- Dissemination methods that were most successful and reasons for success (including website development for study findings, guidelines and tools)
- Types of outreach materials developed
- Coordination with other organizations and partners
- Outcomes of awareness building efforts (if possible, any attitude or awareness changes)

- Characterization and level of collaborations
- Description of efforts to include/reach traditionally underserved groups to share guidelines and results

Additionally, this section will also begin to talk about *partnerships* formed between the research networks, their CREs and LEND/DBP institutions, States and other MCHB grantees. Both the AIR-P and AIR-B are required to forge partnerships with researchers, clinicians, educators, advocates, families, state public health programs and other organizations/agencies. Establishment of strong partnerships between researchers and practitioners is essential to ensure that new interventions, evidence-based guidelines, tools, and systems management approaches are implemented in the health care system. Additionally, establishment of strong partnerships with the public, families and the advocacy community is also essential to translate vital research findings into better access and quality services for individuals with ASD and other DD. The quantitative data will be summarized as illustrated in Table VI.1 and VI.2⁶.

TABLE VI.1

GRANTEES' ACTIVITIES AND ACCOMPLISHMENTS RELATED TO
INCREASING PUBLIC AND PROVIDER AWARENESS OF ASD AND DD

HEALTH PROFESSIONALS AND FAMILIES REACHED

| Target Populations | AIR-B | | AIR-P | | R40 Grantees |
|--|--------------------|--------------------|--------------------|-----------------------|-----------------|
| | Grant Year 2009 | Grant Year 2010 | Grant Year 2009 | Grant Year 2010 | Total |
| Health professionals | | | | | |
| Number of materials (e.g., studies/briefs, articles or informational materials) developed for health professionals | | | | | |
| Number of outreach sessions conducted for health professionals by type of outreach | | | | | |
| Number of training sessions conducted for health professionals | | | | | |
| Total number of Grand Rounds | | | | | |
| Number of health professionals reached through training sessions | | | | | |
| Number of health professionals reached through outreach sessions | | | | | |
| Number of health professionals engaged in research | | | | | |
| Families of children with ASD and the public | | | | | |
| Number of materials (e.g., studies/briefs, popular articles or informational materials) developed | | | | | |

⁶ We note that while the two Research Networks appear side-by-side, direct comparison of the two Research Networks is often not appropriate since they have committed to different activities or different levels of effort with respect to a particular activity, particularly for each year.

| Target Populations | AIR-B | | AIR-P | | R40 Grantees |
|--|--------------------|--------------------|--------------------|-----------------------|-----------------|
| | Grant Year 2009 | Grant Year 2010 | Grant Year 2009 | Grant Year 2010 | Total |
| for families and the public | | | | | |
| Number of outreach sessions conducted for families and the public by type of outreach | | | | | |
| Number of individuals reached through outreach sessions | | | | | |
| Number of families participating in research by key demographic information (including minority and underserved population groups) | | | | | |

Note: if this information is available by CRE, we will produce one table for each of the Network's CREs.

Note: we determined not to report information by discipline due to burden on grantee's reporting.

TABLE VI.2

GRANTEES' ACTIVITIES AND ACCOMPLISHMENTS RELATED TO
INCREASING PUBLIC AND PROVIDER AWARENESS OF ASD AND DD

OUTREACH ACTIVITIES

| Outreach Activities | AIR-B | | AIR-P | | R40 Grantees |
|--|--------------------|--------------------|--------------------|-----------------------|-----------------|
| | Grant Year 2009 | Grant Year 2010 | Grant Year 2009 | Grant Year 2010 | Total |
| Number of Web "hits" on autism specific websites | | | | | |
| Number of collaborations with partners (by LENDs, States, etc.) by type of collaboration | | | | | |

Through qualitative means, we will examine the training activities, outreach activities and partnerships/collaborations that have the most impact.

B. BARRIERS TO ASD AND OTHER DD INTERVENTION SERVICES

The research network grantees are in the unique position to help to reduce barriers to ASD and other DD intervention services through a variety of activities. For example, one of MCHB's intents for the Research Networks is to ensure that project interventions are responsive to the cultural and linguistic needs of special populations, that products are family-centered and accessible to consumers, and that the broadest possible representation of culturally distinct and historically underrepresented groups is supported through projects sponsored by the MCHB. As such, Insight will document what grantees did to ensure that studies included under-representative groups and efforts to ensure that families were included in the research. This section will be the key area where we begin to discuss the extent to which *minorities and underserved populations* were included in

the research studies and outreach activities. Additionally, we will also address the extent to which *families were involved* in the research studies and outreach activities. Additional narrative will include:

- What barriers the grantees have focused on
- How have barriers to interventions been reduced (particularly for minority and underserved populations)
- Participation of underserved and minority populations
- Relevance of research to underserved and minority populations
- Relevance of tools tested/validated to underserved and minority populations
- Relevance of evidence (or consensus) based guidelines for interventions to underserved and minority populations

Finally, each grantee’s data will be summarized as shown in Table VI.3 below.

TABLE VI.3

GRANTEES’ ACTIVITIES AND ACCOMPLISHMENTS RELATED TO
REDUCING BARRIERS TO ASD AND OTHER DD INTERVENTION SERVICES

DIVERSITY AND FAMILY CENTERED ACTIVITIES

| Criteria | AIR-B | | AIR-P | |
|--|-----------------|-----------------|-----------------|-----------------|
| | Grant Year 2009 | Grant Year 2010 | Grant Year 2009 | Grant Year 2010 |
| Minority and underserved populations | | | | |
| Degree to which cultural competence elements are incorporated into the policies, guidelines, contracts and training (DGIS #10) | | | | |
| Number of studies that are responsive to the cultural and linguistic needs of special populations | | | | |
| Number of studies that support a broad representation of culturally distinct and underrepresented groups | | | | |
| Engage in family centered activities | | | | |
| Degree of family participation in program and policy activities (DGIS #7) | | | | |
| Number of studies that are family centered | | | | |

NOTE: we will use the current definition of family centered care – to assure the health and well being of children and their families through a respectful family professional partnership that honors the strengths, cultures, traditions and expertise that everyone brings to this relationship.

A further aspect of reducing barriers is the extent to which groups which have traditionally been overlooked have been incorporated into research studies by the Research Networks. Each Research Network grantee will be asked to report, in narrative form, on their efforts to include hard-to-reach population groups. Each grantee will also provide the data identified in Table VI.4 with respect to study participants.

TABLE VI.4

PARTICIPANTS ENROLLED
IN GRANTEES' EVIDENCE-BASED INTERVENTION RESEARCH

| | AIR-B | | AIR-P | |
|----------------------------------|--------------------|--------------------|--------------------|--------------------|
| | Grant Year 2009 | Grant Year 2010 | Grant Year 2009 | Grant Year 2010 |
| Race | | | | |
| White | | | | |
| African American | | | | |
| Asian | | | | |
| American Indian/Alaska Native | | | | |
| Native Hawaiian/Pacific Islander | | | | |
| More than One Race | | | | |
| Unknown or Not Reported | | | | |
| Ethnicity | | | | |
| Hispanic | | | | |
| Non-Hispanic | | | | |
| Unknown | | | | |
| Gender | | | | |
| Male | | | | |
| Female | | | | |

C. RESEARCH LEADING TO EVIDENCE-BASED INTERVENTIONS FOR CHILDREN AND ADOLESCENTS WITH ASD AND OTHER DD

One of the fundamental tasks for the grantees is to support research leading to evidence-based interventions for children and adolescents with ADD and other DD. In order for the Insight evaluation team to assess the grantee's support efforts, each grantee will provide a written description of its activities to improve evidence based intervention, including narratives on how the CREs were integrated into the research activities and on stakeholder participation. We will begin with an introduction describing the extent to which the programs have been successful in implementing their research agendas and publishing findings. All analyses will be descriptive in nature. Whenever possible, data will be used to describe and document accomplishments. Additional narrative will seek to link research to underserved populations; family well-being, coping, resilience, and healthcare issues; transition into adulthood, including employment and healthcare issues; and service systems and infrastructure.

Additional narrative will include:

- What intervention studies have been undertaken
- Strategies for developing and funding proposals
- Challenges in implementing studies
- Participation of CREs in studies
- How have the studies been disseminated
- Adoption of studies across the U.S. (if possible)
- Impact of studies (if available)

We will also discuss the potential sustainability of the research c, including strategies to sustain the study development process after the end of federal grant period including potential sources of funding for activities that will continue.

Because the data we obtain to assess the effectiveness of awareness building activities is likely to vary greatly by grantee, the evaluation will present the information obtained as case studies and illustrations of what grantees learn about their activities and their ability to raise awareness of ASD and other DD intervention services that children and families need. We will summarize the data as shown in Table VI.5 below.

TABLE VI.5

GRANTEES' ACTIVITIES AND ACCOMPLISHMENTS RELATED TO
SUPPORTING RESEARCH LEADING TO EVIDENCE BASED INTERVENTIONS

PUBLICATIONS AND SCIENTIFIC CONFERENCES

| Publication Activities | AIR-B | | AIR-P | | R40 Grantees |
|--|--------------------|--------------------|--------------------|-----------------------|-----------------|
| | Grant Year 2009 | Grant Year 2010 | Grant Year 2009 | Grant Year 2010 | Total |
| Total Publications | | | | | |
| Number of manuscripts in preparation | | | | | |
| Number of manuscripts submitted | | | | | |
| Number of manuscripts in press/accepted | | | | | |
| Number of manuscripts published | | | | | |
| Reducing Barriers | | | | | n/a |
| Number of manuscripts in preparation | | | | | |
| Number of manuscripts submitted | | | | | |
| Number of manuscripts in press/accepted | | | | | |
| Number of manuscripts published | | | | | |
| Interventions | | | | | |
| Number of manuscripts in preparation | | | | | |
| Number of manuscripts submitted | | | | | |
| Number of manuscripts in press/accepted | | | | | |
| Number of manuscripts published | | | | | |
| Network Activities and Functions | | | | | n/a |
| Number of manuscripts in preparation | | | | | |
| Number of manuscripts submitted | | | | | |
| Number of manuscripts in press/accepted | | | | | |
| Number of manuscripts published | | | | | |
| Measures/Tools | | | | | |
| Number of manuscripts in preparation on measures/tools | | | | | |
| Number of manuscripts submitted | | | | | |

| Publication Activities | AIR-B | | AIR-P | | R40 Grantees |
|---|--------------------|--------------------|--------------------|-----------------------|-----------------|
| | Grant Year 2009 | Grant Year 2010 | Grant Year 2009 | Grant Year 2010 | Total |
| on measures/tools Number of manuscripts in press/accepted on measures/tools Number of manuscripts published on measures/tools | | | | | |
| Guidelines Number of manuscripts in preparation on guidelines Number of manuscripts submitted on guidelines Number of manuscripts in press/accepted on guidelines Number of manuscripts published on guidelines | | | | | |
| Total scientific conference presentations Number of scientific conference presentations related to reducing barriers to intervention Number of scientific conference presentations related to intervention Number of scientific conference presentations related to Network activities and functions | | | | | |

Grantees will be asked to provide the title of the publication, the journal, citation and a brief abstract of any proposed or published article (see Table VI.6 below).

TABLE VI.6

GRANTEES' ACTIVITIES AND ACCOMPLISHMENTS RELATED TO
SUPPORTING RESEARCH LEADING TO EVIDENCE BASED INTERVENTIONS

| Grantee | Study Title | Primary Data Collection Method/ Secondary Data Used | Study Populations | Highlights of Findings |
|---------|-------------|--|-------------------|------------------------|
| | | | | |
| | | | | |

In addition, data will be presented, such as in Table VI.7 to support findings regarding research leading to evidence-based interventions for children.

TABLE VI.7

GRANTEES' ACTIVITIES AND ACCOMPLISHMENTS RELATED TO
SUPPORTING RESEARCH LEADING TO EVIDENCE BASED INTERVENTIONS

| | AIR-B | | AIR-P | |
|---|--------------------|--------------------|--------------------|--------------------|
| | Grant Year 2009 | Grant Year 2010 | Grant Year 2009 | Grant Year 2010 |
| Activities planned or undertaken to support research on evidence based interventions | | | | |
| Number of research proposals developed and/or funding sought | | | | |
| Number of funded studies currently in process | | | | |
| Number of studies completed | | | | |
| Sustainability | | | | |
| Dollar amount of outside funding obtained | | | | |

D. TOOLS AND GUIDELINES

1. Testing and Validating Tools

One of the major goals of the two research networks is to test and validate tools that could be used to improve outcome measures of treatment studies in autism. Each Research Network grantee will provide a written description of its activities to test or validate tools. Additional narrative will include:

- What tools/measures have been developed; how they address core deficits
- How measures were adapted for developmental age and background
- Challenges in testing and validating measures/tools
- How have the measures/tools been disseminated
- Adoption of measures/tools across U.S.
- Impact of measures/tools (if available)

Each grantee will be asked to provide the data identified in Table VI.8 related to testing and validating tools.

TABLE VI.8

GRANTEES' ACTIVITIES AND ACCOMPLISHMENTS RELATED TO
TESTING AND VALIDATING TOOLS

| | AIR-B | | AIR-P | |
|---|-------|------|-------|------|
| | 2009 | 2010 | 2009 | 2010 |
| Activities to validate measures and/or tools | | | | |
| Number of measures/tools developed, tested or validated (by type) | | | | |
| Number of tools piloted within the network | | | | |
| Number of tools adopted beyond the network | | | | |

2. Promoting Evidence (or Consensus) Based Guideline Development for Interventions

Another major goal of the two research networks is to promote evidence (or consensus) based guideline development for interventions. The Insight evaluation team will assess the extent to which the grantees have achieved this goal. One data source will be a written description by each Research Network of the activities undertaken to develop evidence (or consensus) based guidelines and to promote guideline development. Additional narrative will include:

- What guidelines have been developed
- Expert panels' assessment of guidelines
- Challenges in implementing guidelines
- How have the guidelines been disseminated
- Adoption of guidelines across U.S.
- Impact of guidelines (if available)

Each grantee will be asked to provide the data identified in Table VI.9 with respect to the development of evidence (consensus) based guidelines.

TABLE VI.9

GRANTEES' ACTIVITIES AND ACCOMPLISHMENTS RELATED TO
DEVELOPMENT OF EVIDENCE (CONSENSUS) BASED GUIDELINES

| | AIR-B | | AIR-P | |
|---|--------------|------|--------------|------|
| | 2009 | 2010 | 2009 | 2010 |
| Activities to develop evidence (or consensus) based guidelines for interventions | | | | |
| Number of guidelines developed (by type) | | | | |
| Number of guidelines piloted within the network | | | | |
| Number of guidelines adopted beyond the network (note: NICHQUE and RAND can measure this) | | | | |
| Number of published guidelines by type | | | | |

VII. FINAL REPORTS

A. REPORT TO MCHB

The final report will be designed for MCHB's Division of Research, Training and Education (DRTE) through the Maternal and Child Health Research Program to determine the success of the Research Networks in meeting the overall CAAI goals and objectives, as well as their own goals and objectives. We envision that the final report will include the following chapters:

Executive Summary

- I. Introduction
- II. The 2006 Combating Autism Act
- III. Description of Research Grantee
 - A. Goals and objectives of each Research Network
 - B. Activities and accomplishments of each Research Network
 - C. Challenges to implementation
 - D. The R40 Grantees
- IV. Evaluation Design
 - A. The Research Networks
 - B. The R40 Grant Program
- V. Effectiveness of Research Networks
 - A. Increasing public and provider awareness of interventions for ASD and other DD
 - B. Removing barriers to ASD and other DD Intervention Services
 - C. Supporting research leading to evidence-based interventions for children and adolescents with ASD and other DD
 - D. Promoting evidence/consensus based guideline development for interventions
 - E. Testing and validating tools to screen for and diagnose ASD and other DD

VI. Effectiveness of the R40 Grant Programs

VII. Conclusions (and future activities)

Attachments illustrating the logic models and research questions and questionnaires

B. DRAFT CHAPTER FOR REPORT TO CONGRESS

Insight will also prepare and submit a draft chapter for the MCHB contribution to the HHS Secretary's Report to Congress, as required in Section 399DD of the legislation. This chapter will summarize the activities and outcomes of the Research Network and other CAAI grantees, and report evaluation results by major objectives. In addition, the HHS Secretary's Report to Congress will address several key outcomes, as described below.

The Combating Autism Act of 2006 requires that the DHHS provide, at a minimum, the following core elements in the report to Congress:

- Description of the amounts expended on the implementation of the particular provisions of the *Combating Autism Act of 2006*;
- Information on the incidence of autism spectrum disorders and trend data of such incidence since the date of enactment of the *Combating Autism Act of 2006*;
- Information on the average age of diagnosis for children with autism spectrum disorders and other developmental disabilities (DD), including how that age may have changed over the 4-year period beginning on the date of enactment of this Act;
- Information on the average age of intervention for individuals diagnosed with an autism spectrum disorder and other developmental disabilities, including how that age may have changed over the 4-year period beginning on the date of enactment of this Act;
- Information on the average time between initial screening and confirmation/ruling out a diagnosis of ASD or other developmental disability, as well as information on the average time between diagnosis and evidence-based intervention for individuals with an autism spectrum disorder or other developmental disabilities;
- Information on the effectiveness and outcomes of interventions for individuals diagnosed with an autism spectrum disorder, including various subtypes, and other developmental disabilities and how the age of the child may affect such effectiveness;

- Information on the effectiveness and outcomes of innovative and newly developed intervention strategies for individuals with an autism spectrum disorder or other developmental disabilities; and
- Information on services and supports provided to individuals with an autism spectrum disorder and other developmental disabilities who have reached the age of majority (as defined for purposes of section 615(m) of the *Individuals with Disabilities Education Act* (20 U.S.C. 1415(m))).

REFERENCES

Combating Autism Act of 2006. Public Law. No. 109-416, § SEC. 399BB, 120 Stat 2821, 2823-2827 (2006).

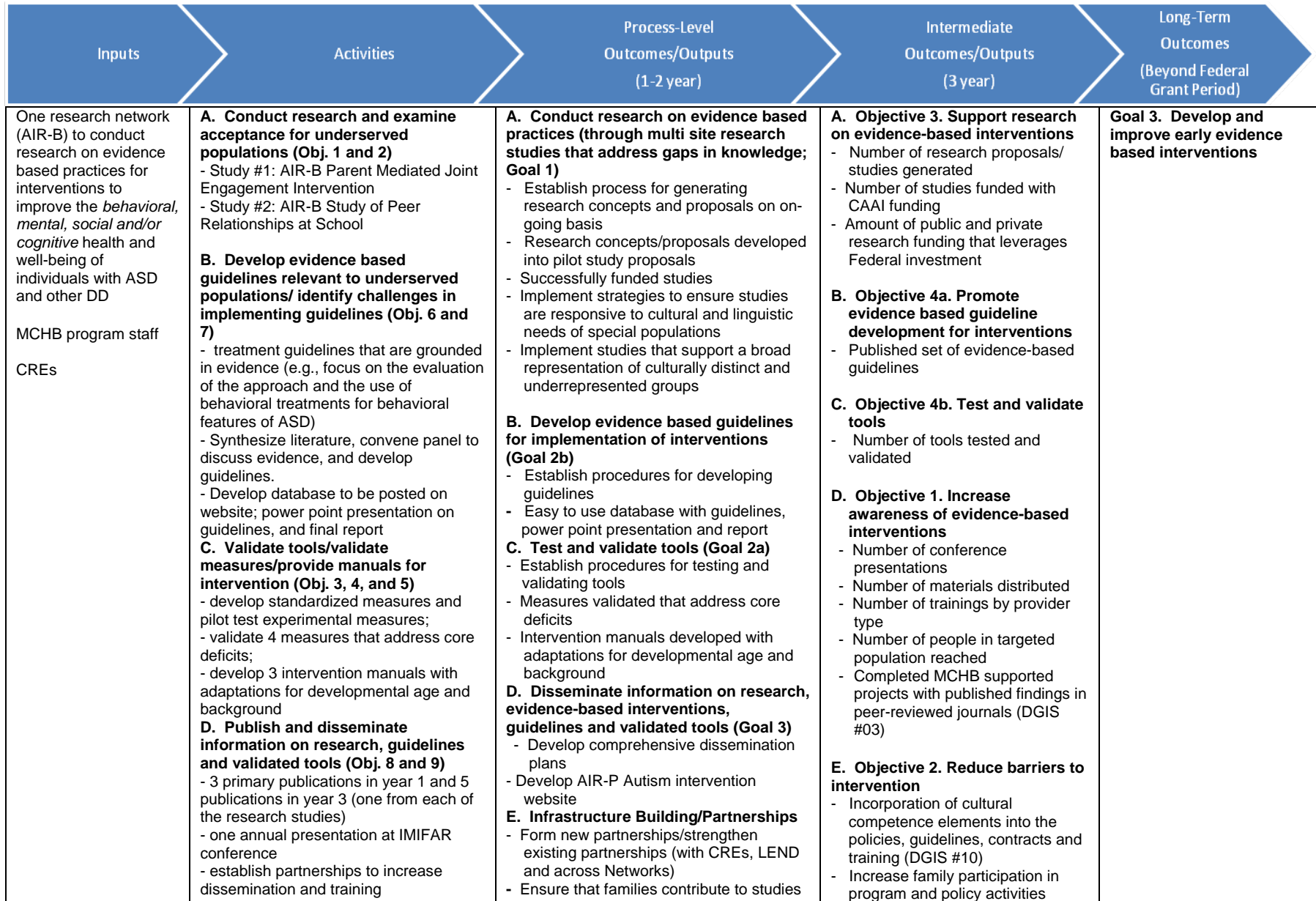
Combating Autism Act Initiative Autism Intervention Research Network Competitions. HRSA-08-142 & HRSA-08-143. Program Guidance, U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Care Bureau.

Combating Autism Act Initiative Autism Intervention Research Network Competitions HRSA-5-UA3-09-001 & HRSA-5-UA3-09-002. Non-Competing Continuation Program Guidance, U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Care Bureau.

Combating Autism Act Initiative R40 MCH Autism Intervention Research Network Competitions. HRSA-09-217. Program Guidance, U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Care Bureau.

ATTACHMENT A
LOGIC MODEL FOR AIR-B

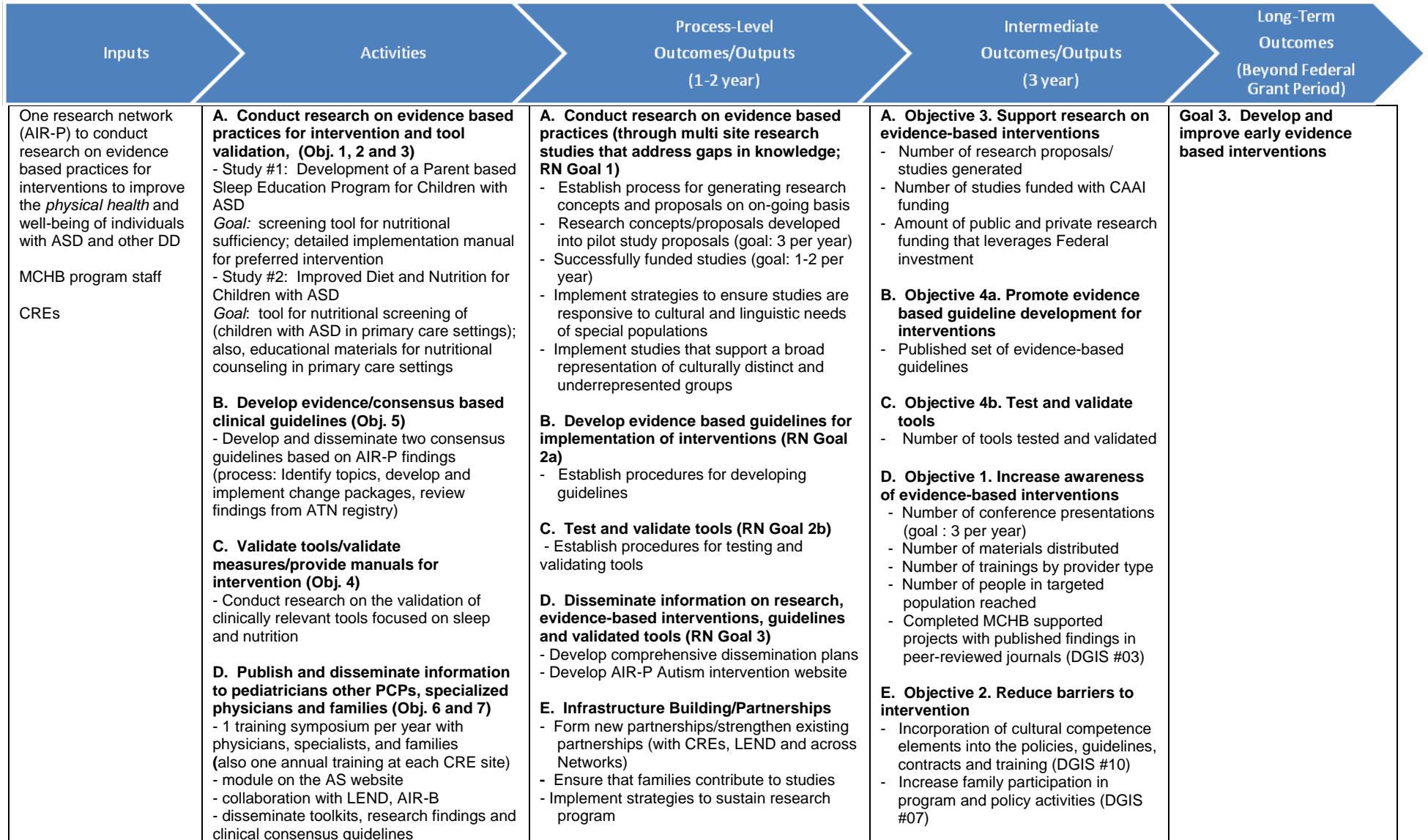
ATTACHMENT A: LOGIC MODEL FOR AIR-B



| | | | | |
|--|---|--|------------|--|
| | <ul style="list-style-type: none">- web development (including multi level searchable databases)- virtual home | <ul style="list-style-type: none">- Implement strategies to sustain research program | (DGIS #07) | |
|--|---|--|------------|--|

ATTACHMENT B
LOGIC MODEL FOR AIR-P

ATTACHMENT B: LOGIC MODEL FOR AIR-P



ATTACHMENT C

CHECKLIST OF RESEARCH ACTIVITIES: AIR-B

CHECKLIST OF RESEARCH NETWORK ACTIVITIES: AIR - B

| | Proposal Reference Page | Description of Proposed Activity | Status (Achieved, Partially Achieved, Not Achieved) |
|--|-------------------------|--|---|
| Research Tasks | | | |
| 1 | 4 | The CAIR-N will entertain studies at all levels of investigation, such as “proof of concept studies”, treatment method piloting, to larger scale randomized, controlled clinical trails. | |
| 2 | 5 | Focus on under-served and under-represented samples of children | |
| 3 | 5 | Parent Mediated Joint Intervention Study: Randomized, multi-site study to test the efficacy of a parent training model of joint attention/joint engagement in ethnically and economically diverse samples of preschool children with ASD | |
| 4 | 7 | Peer Relationships at School Study: Randomized, multi-site study to test two treatment interventions | |
| 5 | 9 | Participants for studies will be recruited across all five sites – 27 subjects per site per year | |
| Validate Tools | | | |
| 1 | 9 | The CAIR-N plans to test and validate a number of tools for use with ASD populations | |
| 2 | 10 | Pilot test rapid experimental measures that can be tested for validity against the standardized measures; 4 measures are proposed for validation that address core deficits | |
| 3 | 10 | Develop 3 intervention manuals with adaptations for developmental age and background diversity | |
| 4 | 11 | There are other possible tools we may validate depending on which concept papers are accepted by the Network Steering Committee | |
| Develop Evidence Based Guidelines | | | |
| 1 | 11 | Proposed interventions for ASD will be identified in the literature which will be abstracted and synthesized used validated procedures, a data based developed | |
| 2 | 12 | We will provide HRSA and expert panel members with scientific evidence (user-friendly access to peer-reviewed literature, evidence tables, relevant forms, and results of the literature synthesis) on approaches to assessment, behavioral, educational, and medical interventions their impact on ASD core and associated symptoms | |
| 3 | 13 | Post comprehensive, linked, and easy-to-query database on ASD website | |
| 4 | 13 | Conduct two-day expert panel to formulate questions for the literature synthesis, discuss evidence, and develop guidelines | |
| 5 | 13 | Develop guideline implementation materials the content of which is detailed on page 14 including executive summary and PowerPoint presentation | |
| 6 | 13 | Prepare and edit a publication ready report of both of the guidelines | |
| 7 | 13 | Consult with network experts, and others including national, state, and local MCH and Title V partners and | |

| | Proposal Reference Page | Description of Proposed Activity | Status (Achieved, Partially Achieved, Not Achieved) |
|--|--------------------------------|---|--|
| | | stakeholders on guidelines | |
| 8 | 13 | Submit guidelines for external review | |
| Dissemination Activities | | | |
| 1 | 14 | Publications aimed at researchers, practitioners, and family and community members | |
| 2 | 14 | Three publications in year 1: a review of intervention science in ASD targeted to a major psychology or behavioral health journal; a summary for professionals on the components of an interdisciplinary intervention plan, and a summary of available interventions for parents and consumers | |
| 3 | 15 | Publications made available through ASD website, downloadable, and printed with some translated into other languages | |
| 4 | 15 | Year three publications 1) evidence-based guideline on social communication core deficits and medical treatments (Year 2); 2) treatment manual from Study 1 (Year 2); 3) treatment manuals from Study 2 (Year 2); 4) reports on primary outcome findings from Study 1 (Year 3); 6) reports on primary outcome findings from Study 2 (Year 3). | |
| 5 | 15 | Annual presentation by CAIR-N researchers at the annual IMFAR Conference which will be videotaped and posted on ASD Website | |
| 6 | 15 | Establish partnerships to increase dissemination | |
| 7 | 16 | Website for ASD intervention and related information | |
| 8 | 16 | Network virtual home containing public and private domain information | |
| Infrastructure Tasks | | | |
| 1 | 5 | Seek additional grant support to supplement or expand research and development efforts | |
| 2 | 20 | Formalize network steering committee as specified in RFA | |
| 3 | 20 | Create publications subcommittee | |
| 4 | 20 | Quality assurance functions | |
| 5 | 23 | Evidence of leveraging Support and Network | |
| Additional Requirements (from Guidance) | | | |
| 1 | 9 | Forge partnerships with researchers, clinicians, educators, advocates, families, State public health programs, and other organizations/agencies critical to improving the health and well-being of individuals with ASD | |
| 2 | 11 | Create Network Steering Committee, establish bylaws and standard operating procedures to govern all aspects of the network | |
| 3 | 12 | Formulate and monitor policies and procedures guiding the research activities, review and approve procedures for data acquisition, analysis and management, oversee communication within the Network and greater scientific community | |
| 4 | 12 | Establish network performance goals and standards and monitor progress of the networks and its research, guideline and tool validation projects | |

| | Proposal Reference Page | Description of Proposed Activity | Status (Achieved, Partially Achieved, Not Achieved) |
|---|--------------------------------|--|--|
| 5 | 13 | Networks will establish protocol specific reports that at a minimum provide enrollment information. The NSC will determine the format of these reports | |
| 6 | 13 | Acknowledge HRSA support in publications | |
| 7 | 14 | Establish central data repository | |
| 8 | 27-28 | Did the NCC enter into agreements to incorporated the various items enumerated on page 27 - 28 | |

ATTACHMENT D

CHECKLIST OF RESEARCH NETWORK ACTIVITIES – AIR P

CHECKLIST OF RESEARCH NETWORK ACTIVITIES: AIR - P

| | Proposal Reference Page | Description of Proposed Activity | Status (Achieved, Partially Achieved, Not Achieved) |
|--|-------------------------|---|---|
| Research Tasks | | | |
| 1 | 6 | Implement a collaborative mechanism to develop innovative research concepts and protocols that will help improve care for children with ASD | |
| 2 | 6 | Carry out a series of pilot studies providing preliminary findings | |
| 3 | 6 | Conduct and develop at least two intervention-focused research projects in areas of sleep, GI, nutritional or neurologic disorders in children with ASD | |
| 4 | 12 | One peer-reviewed publication per research project and three presentations per year. | |
| 5 | 12 | Involve 120 children in Study 1 across two sites in first 18 months; Second 18 months 3 additional sites along with an addition 150 children; plan to expand to all 15 sites; complete study | |
| | 14 | Enroll 100 children/adolescents from each of five sites yearly into Study 2 registry; complete study | |
| Validate Tools | | | |
| 1 | 6 | Conduct research projects on the validation of clinically-relevant tools focused on areas of sleep and nutrition | |
| 2 | 15 | Develop a screening tool for nutritional sufficiency based on Year 1 data (study 2); evaluate the screening tool in selected sites in years 2 and 3 | |
| Develop Evidence Based Guidelines | | | |
| 1 | 6/16 | Develop two consensus based clinical guidelines based on the findings of AIR-P research findings and other existing evidence; the subspecialty subcommittees in two physical health areas will develop consensus guidelines to support the practice of general pediatricians and primary care physicians in caring for children with ASD; manualized sleep program for clinicians (page 18) | |
| 2 | 7 | Collaborate with the Combating Autism Training Programs and other training programs in developing and implementing training and education based on research findings, tools, and clinical consensus guidelines | |
| 3 | 15 | Develop guidelines for clinicians for identifying and counseling for low/no risk children with ASD and develop a one page guide for appropriate family counseling for these children (Phase 2B) | |
| 4 | | Test nutritional screener in primary care sites using the network of pediatric research in office settings or community based primary care practices; develop instructional materials that PCPs can use in counseling families regarding nutrition for their patients with ASD. Pilot study within AIR-P. | |
| Dissemination Activities | | | |
| 1 | 6 | Disseminate toolkits, research findings and clinical consensus guidelines to pediatricians, other primary care providers (PCP), specialty physicians and families | |
| 2 | 7 | Collaborate with the Combating Autism Training Programs and other training programs in developing and | |

| | Proposal Reference Page | Description of Proposed Activity | Status (Achieved, Partially Achieved, Not Achieved) |
|--------------------------------|--------------------------------|--|--|
| | | implementing training and education based on research findings, tools, and clinical consensus guidelines; work with existing training efforts through LEND programs and community practices | |
| 3 | 17 | Publish at least one peer-reviewed article for each AIR-P research project in a main pediatric, pediatric subspecialty, or maternal and child health journal. | |
| 4 | 17 | Present findings at professional conferences such as CAAI, AAP, the American Academy of Child and Adolescent Psychiatry, Child Neurology Society, Society for Developmental and Behavioral Pediatrics, subspecialty conferences, and the International Meeting for Autism Research | |
| 5 | 17 | Plan an informational session for physicians and community practitioners on AIR-P related topics during an annual local training meeting at each CRE site | |
| 6 | 17 | Develop and distribute sleep toolkits and nutritional screeners. Toolkits will be targeted towards providers and families and disseminated through venues such as AAP and AS. | |
| 7 | 17/18 | Participate in a full-day satellite meeting each year for parent-volunteers presenting research presentations, interactive discussions, and dissemination and training strategies | |
| 8 | 18 | AIR-P PIs will present research findings at yearly chapter meetings in each of the CRE local communities | |
| 9 | 18 | AS will create a high quality educational video on sleep hygiene for parents | |
| 10 | 18 | AS will develop a newsletter that focuses on the activities of the AIR-P and collaborative activities with the LEND program and other initiatives funded by the CAA | |
| 11 | 19 | Hold one training symposium per year with 30-60 participants attending, including physicians, specialist, and sub-specialists, and families. | |
| Infrastructure Tasks | | | |
| 1 | 6 | Seek outside funding opportunities to develop full scale implementation and intervention research | |
| 2 | 8 | Steering committee to meet quarterly by teleconference and annually in person | |
| 3 | 8 | Establish subcommittees in each subspecialty area of focus with monthly conference calls and annual meetings | |
| 4 | 18 | Annual conference call between AIR-P leadership and leaders of training programs to provide updates on latest findings to be incorporated into curricula. Collaborate with AIR-B | |
| 5 | 19 | Participate in annual LEND leader conferences and LEND leadership invited to participate in annual ATN meetings | |
| Additional Requirements | | | |
| 1 | 9 | Forge partnerships with researchers, clinicians, educators, advocates, families, State public health programs, and other organizations/agencies critical to improving the health and well-being of individuals with ASD | |
| 2 | 11 | Create Network Steering Committee, establish bylaws and standard operating procedures to govern all aspects of the network | |
| 3 | 12 | Formulate and monitor policies and procedures guiding the research activities, review and approve | |

| | Proposal Reference Page | Description of Proposed Activity | Status (Achieved, Partially Achieved, Not Achieved) |
|---|--------------------------------|--|--|
| | | procedures for data acquisition, analysis and management, oversee communication within the Network and greater scientific community | |
| 4 | 12 | Establish network performance goals and standards and monitor progress of the networks and its research, guideline and tool validation projects | |
| 5 | 13 | Networks will establish protocol specific reports that at a minimum provide enrollment information. The NSC will determine the format of these reports | |
| 6 | 13 | Acknowledge HRSA support in publications | |
| 7 | 14 | Establish central data repository | |
| 8 | 27-28 | Did the NCC enter into agreements to incorporated the various items enumerated on page 27 - 28 | |

ATTACHMENT E
CONTINUATION APPLICATION FORMS

CONTINUATION APPLICATION FORMS

E.1: INCLUSION ENROLLMENT REPORT (from Continuation Application)

Study Title: _____

Total Enrollment: _____ Protocol Number: _____

Grant Number: _____

| PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race | | | | |
|--|-------------------|--------------|--------------------------------|--------------|
| Ethnic Category | Sex/Gender | | | Total |
| | Females | Males | Unknown or Not Reported | |
| Hispanic or Latino | | | | ** |
| Not Hispanic or Latino | | | | |
| Unknown (individuals not reporting ethnicity) | | | | |
| Ethnic Category: Total of All Subjects* | | | | * |
| Racial Categories | | | | |
| American Indian/Alaska Native | | | | |
| Asian | | | | |
| Native Hawaiian or Other Pacific Islander | | | | |
| Black or African American | | | | |
| White | | | | |
| More Than One Race | | | | |
| Unknown or Not Reported | | | | |
| Racial Categories: Total of All Subjects* | | | | * |
| PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative) | | | | |
| Racial Categories | Females | Males | Unknown or Not Reported | Total |
| American Indian or Alaska Native | | | | |
| Asian | | | | |
| Native Hawaiian or Other Pacific Islander | | | | |
| Black or African American | | | | |
| White | | | | |
| More Than One Race | | | | |
| Unknown or Not Reported | | | | |

| | | | | |
|---|--|--|--|----|
| Racial Categories: Total of Hispanics or Latinos** | | | | ** |
| * These totals must agree. ** These totals must agree. | | | | |

E.2: DEMOGRAPHIC CHARACTERISTICS OF PROJECT PARTICIPANTS FOR CLINICAL SERVICES PROJECTS (from Continuation Application Form 7: Project Summary Data)

| | RACE (Indicate all that apply) | | | | | ETHNICITY | |
|---|---------------------------------------|-------|---------------------------|---|-------|--------------------|------------------------|
| | American Indian or Alaska Native | Asian | Black or African American | Native Hawaiian or Other Pacific Islander | White | Hispanic or Latino | Not Hispanic or Latino |
| Pregnant Women | | | | | | | |
| Children | | | | | | | |
| Children with Special Health Care Needs | | | | | | | |
| Women (Not Pregnant) | | | | | | | |
| Other | | | | | | | |
| TOTALS | | | | | | | |

ATTACHMENT F
DGIS FORMS

DGIS FORMS

DGIS #03: The percent of completed MCHB supported projects publishing findings in peer-reviewed journals.

DATA COLLECTION FORM FOR DETAIL SHEET #03

LIST OF PUBLICATIONS RELATED TO THE RESEARCH PROJECT FUNDED OR CO-FUNDED BY MCHB

FUNDED PROJECT #: _____

PROJECT TITLE: _____

PRINCIPAL INVESTIGATOR: _____

GRANTEE/INSTITUTION: _____
(At the time the research was conducted)

TYPE OF PROJECT: Research ____ Training _____ Programmatic _____

LIST OF PUBLICATIONS
Produced by or for the Funded Project
Please attach a reprint of listed article(s) to this form

TITLE OF THE ARTICLE: _____

JOURNAL: _____

VOLUME: _____ NUMBER: _____ SUPPLEMENT: _____ YEAR: _____ PAGE: _____

DGIS #7: The degree to which MCHB supported programs ensure family participation in program and policy activities.

DATA COLLECTION FORM FOR DETAIL SHEET #07

Using a scale of 0-3, please rate the degree to which our grant program has included families into their program and planning activities.

| 0 | 1 | 2 | 3 | Element |
|----------|----------|----------|----------|--|
| | | | | Family members participate on advisory committees or task forces and are offered training, mentoring and reimbursement. |
| | | | | Financial support (financial grants, technical assistance, travel, and child care) is offered for parent activities or parent groups. |
| | | | | Family members participate in the planning, implementation and evaluation of the program's activities. |
| | | | | Families members work with their professional partners to provide training (pre-service, in-service and professional development) to MCH/CSHCN staff and providers. |
| | | | | Family members are hired as paid staff or consultants to the program (a family member is hired for his or her expertise as a family member). |
| | | | | Family members of diverse cultures are involved in all of the above activities. |

0=Not Met

1=Partially Met

2=Mostly Met

3=Completely Met

Total the numbers in the boxes (possible 0-18 score) _____

DGIS #10: The degree to which MCHB supported programs have included cultural competence elements into their policies, guidelines, contracts, and training.

DATA COLLECTION FORM FOR DETAIL SHEET #10

Using a scale of 0-3, please rate the degree to which your grant program has incorporated the following cultural competence elements into your policies, guidelines, contracts and training.

| 0 | 1 | 2 | 3 | Element |
|---|---|---|---|--|
| | | | | CORE FUNCTIONS: Our organization incorporates the following culturally competent core function elements: |
| | | | | 1. Performs needs/assets assessments with the culturally diverse groups we serve. |
| | | | | 2. Collects and analyzes data according to different cultural groups (e.g. race, ethnicity, language). |
| | | | | 3. Designs services to meet the needs of culturally diverse groups (e.g. use of traditional healers, flexible times of services, language services). |
| | | | | 4. Uses data on different groups for program development. |
| | | | | 5. Considers barriers and the provision of appropriate strategies to address them. |
| | | | | 6. Evaluates and monitors quality services (via customer satisfaction surveys, focus groups, chart reviews). |
| | | | | Is there a policy to incorporate cultural competence in the core functions? <i>None</i> __ <i>Informal</i> __ <i>Formal</i> __ <i>In process</i> __ |
| | | | | TRAINING/HUMAN RESOURCES: Our organization incorporates the following culturally competent training/human resource elements: |
| | | | | 1. Employs a culturally diverse and linguistically and culturally competent staff. |
| | | | | 2. Ensures the provision of training, both in orientation and ongoing professional development, for staff, volunteers, contractors and subcontractors in the area of cultural and linguistic competence. |
| | | | | Is there a policy to incorporate cultural competence in training and human resources? <i>None</i> __ <i>Informal</i> __ <i>Formal</i> __ <i>In process</i> __ |
| | | | | COLLABORATION: Our organization collaborates with informal community leaders/groups (e.g. natural networks, informal leaders, spiritual leaders, ethnic media, family advocacy groups) in various aspects of the following categories:: |
| | | | | 1. Program planning |
| | | | | 2. Service delivery |
| | | | | 3. Evaluation/monitoring of services |
| | | | | COLLABORATION: Our organization collaborates with families of culturally diverse groups in various aspects of the following categories: |
| | | | | 1. Program planning |
| | | | | 2. Service delivery |
| | | | | 3. Evaluation/monitoring of services |
| | | | | Is there a policy to support the above mentioned collaborative activities? <i>None</i> __ <i>Informal</i> __ <i>Formal</i> __ <i>In process</i> __ |
| | | | | RESOURCE ALLOCATION: Our organization's allocation of resources adequately meets the unique access, information and service needs of culturally diverse groups in the following program areas: |
| | | | | 1. Planning |

| 0 | 1 | 2 | 3 | Element |
|---|---|---|---|--|
| | | | | 2. Implementation |
| | | | | 3. Evaluation/Monitoring (e.g. customer satisfaction surveys, focus groups) |
| | | | | Is there a policy to support the allocation of fiscal resources for the needs and services for culturally diverse groups? None___ Informal___ Formal___ In process___ |
| | | | | CONTRACTS: Our agency puts language in contracts that addresses our goals to incorporate cultural competence for culturally and linguistically diverse groups in the following areas: |
| | | | | 1. Needs/assets assessments |
| | | | | 2. Outreach |
| | | | | 3. Specialized services |
| | | | | 4. Training for contractors/subcontractors |
| | | | | 5. Sufficient funds to support 1-4 |
| | | | | 6. Reporting requirements for 1-4 |
| | | | | Is there a policy to support monitoring of contractors/ subcontractors? None___ Informal___ Formal___ In process___ |

0=Not Met

1=Partially Met

2=Mostly Met

3=Completely Met

Total the numbers in the boxes (possible 0-69 score) _____

ATTACHMENT G
SEMI-STRUCTURED INTERVIEW GUIDE
AUTISM INTERVENTION RESEARCH NETWORKS

SEMI-STRUCTURED INTERVIEW GUIDE

AUTISM INTERVENTION RESEARCH NETWORKS

The purpose of this interview is to obtain descriptive information about your activities and outcomes for the evaluation of MCHB's Combating Autism Act Initiative. Today, we will be asking you questions on several topic areas which relate to the objectives of the Combating Autism Act Initiative.

Note: This guide is divided into five domains, one for each CAAI goal associated with the Research Program grants. The questions in each domain provide the general topics to cover and not all are applicable to all grantees. As a result, the following guide will be adapted to the activities for a particular grantee. Each discussion will also build on the information that has already been obtained during reviews of program documents.

I. Conduct Research Leading To Evidence-Based Interventions for Children and Adolescents with ASD/DD

Based on all the information we have received from you, we understand that your grant has focused on research leading to improvements in interventions that address the [physical/behavioral] health needs of children and adolescents with ASD and other DD. [provide list of 2 ongoing research studies]. Is our understanding accurate? Are there any other studies you are working on that are funded as part of your CAAI grant?

Probe: What have been the key objectives or goals of your research?

Have you met these objectives or goals?

If yes, how do you know?

If not, why not?

What challenges have you faced implementing this research?

How have your activities evolved during the last [look back period]?

What strategies did you use to develop and fund research concepts and proposals?

Probe: How do you rate and rank these proposals?

We understand that you have a variety of partners and Collaborating Research Entities (CREs). [list 2/3 partners; list 4/15 CREs]
How have the CREs helped you in the research efforts?

How has the Network promoted adoption of this research?

Probe: Where and how has the research been adopted/disseminated?

How effective has the Network been at publishing research findings?

What has been the impact of the research?

Sustainability

What strategies, if any, were implemented to sustain this process after the federal grant period ends?

Probe: Which activities will continue? Which will end?

For those activities that will continue, what will be the source of funding?

Have you secured any outside funding for projects this year?

II. Test and Validate Tools that Can be Used to Improve Outcome Measures

Another area of your grant activities is increasing the number of validated tools for interventions, particularly using those measures that can be completed rapidly and unobtrusively and can be applied in a number of settings by non-researchers. *[provide list of tools/measures that have been validated]*. Is this correct?

Probe: What have been the key objectives or goals of your validated measures and/or tools?

Have you met these objectives or goals?

If yes, how do you know?

If not, why not?

Have these measures/tools been adapted for developmental age and racial/ethnic background of the child?

What steps have you taken to ensure that the measures/tools are relevant to underserved populations?

What challenges did you face in validating the tools/developing the measures?

How has the Network promoted adoption of these measures/tools?

Probe: Where and how have the measures/tools been adopted/disseminated?

How effective has the Network been at publishing research findings related to measures/tools?

What has been the impact of the measures/tools?

III. Develop Evidence Based Guidelines for Implementation of Interventions

Based on the documentation we received, we understand that the Network is focused on the development of treatment guidelines that are grounded in evidence. *[provide list of guidelines/manuals]*. Is our understanding accurate?

Probe: What have been the key objectives or goals of your guidelines?

Have you met these objectives or goals?

If yes, how do you know?

If not, why not?

Have these been adapted for age and racial/ethnic background of the child?

What steps have you taken to ensure that the guidelines are relevant to underserved populations?

What are the challenges the Network faced in developing these guidelines?

How has the Network promoted adoption of these guidelines?

Probe: Where and how have the guidelines been adopted/disseminated?

How effective has the Network been at publishing research findings related to guidelines?

What has been the impact of the guidelines?

IV. Disseminate Information of Research, Guidelines and Validated Tools for ASD/DD Interventions

We also understand that your Network has also focused on dissemination of information for health professionals and families impacted by ASD and other DD. Which efforts have been most successful and why?

Probe: How have the CREs helped to increase dissemination? How effective were they in these activities?

Describe the Network's process for public website development and implementation?

Probe: Did you develop a virtual home (public and private domain)? How successful was the Website?

What are the challenges associated with disseminating information that the Network has faced?

What was the impact of these dissemination activities?

Training symposiums, Training at CREs

We also understand the Network's grant has also focused on training initiatives for [list training target, e.g., providers, parents], and this training has [describe our understanding of their training initiatives]. Is our understanding accurate?

Probe: Did the Network develop its own training materials or did it use materials developed by others? What were the ones developed internally?

Have other organizations offered [provider or family training] at the same time? How has the Network coordinated with them? [ask about other CAAI programs, state public health programs, LEND annual conference]

How successful have these partnerships been?

Grand Rounds, Presentations, Conferences, Speeches

To build awareness, you have also [describe our understanding of ground rounds, speeches and presentations]. Is our understanding accurate?

How successful were these efforts?

Other Outreach Activities

To build awareness, you have also [describe our understanding of their outreach activities]. Is our understanding accurate?

Probe: Did the Network develop its own outreach materials or did it use materials developed by others? What were the ones developed internally? [ask about use of CDC materials]

Have other organizations offered outreach at the same time? How has the Network coordinated with them? [ask about other CAAI programs, state public health programs, LEND annual conference]

How successful have these partnerships been?

V. Reducing Barriers to ASD/DD Interventions

Another objective of the Combating Autism Act is to reduce barriers to evidence based interventions.

What are the main barriers to intervention both across the nation and in your area?

Which of these barriers, if any, does your research work to address?

If the following topics have not been covered during the conversation:

Minority and Underserved Populations

Have any of the Network's efforts addressed service barriers focused on reducing disparities for minority and underserved populations? If yes, please explain.

What progress was made to reducing barriers?

How effective were these activities?

What steps, if any, did you take to ensure the participation of stakeholder groups, including underserved and minority populations, in the design and execution of study protocols?

Have the CREs helped in this effort?

How has the awareness of research increased among various minority and underserved population groups?

Family Involvement

How have families been involved? What, if anything, did you change as a result of family input?

Wrap Up

How successful was the network's approach to research? What worked best? What would you change?

Probe: Successes/positive aspects – shortcomings and negative aspects.

Is there anything that we haven't covered? Thank you for your time. We greatly appreciate your assistance.

ATTACHMENT H

SEMI-STRUCTURED INTERVIEW GUIDE

R40: MCH AUTISM INTERVENTION RESEARCH PROGRAM GRANTEEES

SEMI-STRUCTURED INTERVIEW GUIDE

R40: MCH AUTISM INTERVENTION RESEARCH PROGRAM GRANTEES

The purpose of this interview is obtain descriptive information about your activities and outcomes for the evaluation of MCHB's Combating Autism Act Initiative. Today, we will be asking you questions on several topic areas which relate to the objectives of the Combating Autism Act Initiative.

Notes: This guide is divided into two domains, one for each CAAI goal associated with the R40 Research Program grants. The questions in each domain provide the general topics to cover and not all are applicable to all grantees. As a result, the following guide will be adapted to the activities for a particular grantee. Each discussion will also build on the information that has already been obtained during reviews of program documents.

II. Conduct Research Leading To Evidence-Based Interventions to Improve the Health and Well-Being of Children and Adolescents with ASD/DD

We understand that your grant has focused on research leading to improvements in interventions that address the health of children and adolescents with ASD and other DD. *[provide description of ongoing research study funded]*. Is our understanding accurate? Are there any other studies you are working on that are funded as part of your CAAI grant?

What have been the key objectives or goals of your research?

Have you met these objectives or goals?

If yes, how do you know?

If not, why not?

[For one-year grantees]: What secondary data sources were used to conduct the research?

What challenges have you faced implementing this research?

What study populations were focused on?

Please describe the highlights of your findings.

IV. Disseminate Information to Health Professionals and the Public

How have you promoted adoption of this research?

Probe: What dissemination efforts or activities have been or will be conducted? With what types of health professionals or population groups?

Which dissemination efforts have been most successful and why?

What are the challenges associated with disseminating information?

What, if any, articles or publications have been or will be generated as a result of your R40 grant? *[For each]:* What stage of progress are they in?

What was (or will be) the impact of the research?

Wrap Up

Is there anything that we haven't covered? Thank you for your time. We greatly appreciate your assistance.

ATTACHMENT I

TABLE I.1 SUMMARY OF MCH RESEARCH GRANTEES BY GOALS AND OBJECTIVES

ATTACHMENT I

TABLE I.1: SUMMARY OF MCH RESEARCH GRANTEES BY GOALS AND OBJECTIVES

| Autism Intervention Secondary Data Analysis Studies Program FY2009 Grantees | | |
|--|--|--|
| Grantee | Goal 1: Advance the current knowledge pool leading to improvements in interventions that address the health needs of children and adolescents with ASD and other DD | Goal 2: Disseminate information to health professionals and the public, especially families impacted by ASD and other DD |
| University of Massachusetts Boston | Identify factors associated with and influencing a successful transition into adulthood for young adults with autism spectrum disorders. | <ul style="list-style-type: none"> • Core findings will be presented in a minimum of two <i>journal manuscripts</i>, one addressing findings from analysis of the NLTS2 and one from analysis of the RSA-911, and submitted for refereed review. • Two Data Notes and two <i>Research-to-Practice reports</i> will be developed to support translation of research to practice. |
| University of North Carolina at Chapel Hill | Assess the effectiveness of special education services for children with autism spectrum disorders by measuring the effect of high quality treatment on outcomes. | Publish six papers that will: <ol style="list-style-type: none"> 1) Describe receipt of special education services by autistic children nationwide 2-5) Describe each of the outcomes (CIET) 6) Develop methodology tutorial for special education researchers |
| MCH Autism Intervention Research Program FY2009 Grantees | | |
| Grantee | Goal 1: Advance the current knowledge pool leading to improvements in interventions that address the health needs of children and adolescents with ASD and other DD | Goal 2: Disseminate information to health professionals and the public, especially families impacted by ASD and other DD |
| Brandeis University | Evaluate a Medicaid supportive services waiver program in Massachusetts that uses a participant direction model to choose and manage services for young children with autism spectrum disorder and their families. | <ul style="list-style-type: none"> • Circulate final reports to the MCHB, state Medicaid directors, state offices of intellectual disabilities, and the CMS Office of Research, Development, and Information. • Submit proposals to present findings to the American Association on Intellectual and Developmental Disabilities, the American Psychological Society, the Association of Maternal and Child Health Programs, the Society for Research in Child Development, and the National Medicare and Medicaid Congress. • Submit three articles to peer-reviewed journals: an article on major findings of the Aim II analyses about family and child outcomes to the American Journal on Intellectual and Developmental Disabilities, a waiver-related article to the Health Care Financing Review, and a theoretical article on PD and families with children with ASD to Disability and Society. • Post papers and presentations on the Heller Website. • Work with the Autism Support Centers, the National Autism Center and other local and national parent organizations to design and disseminate written and web-based materials summarizing our findings to families in multiple languages. |

| | | |
|-------------------------------|---|--|
| Boston Medical Center | Determine whether an evidence-based empowerment strategy targeted to mothers of young children with autism spectrum disorders promotes family well-being by decreasing the burden of maternal depressive symptoms and parenting stress and improving maternal social functioning. | <ul style="list-style-type: none"> • Write a minimum of 3 publications which will be submitted to peer reviewed journals • Present findings at 2 national meetings • Present findings to conferences attended by autism services providers and parents of children with ASDs • Post study findings on Autism Speaks website |
| Kennedy Krieger Institute | Evaluate whether parent-mediated intervention and center-based intervention provided by a clinician yield comparable outcomes for minority and underserved toddlers with autism spectrum disorders. | Generate at least 3 peer-reviewed publications. |
| University of New Hampshire | Demonstrate a Family-Centered Transition Planning model designed to empower families and high school students with autism spectrum disorders transitioning to adult life. | <p>Develop peer reviewed articles on:</p> <ol style="list-style-type: none"> 1. Impact of Family-Centered Transition Planning on the Career Maturity, Self-Determination and Healthy Functioning of students with ASD 2. The Impact of Family-Centered Transition Planning on Parental Post-school Expectations for Students with ASD 3. The Impact of Family-centered Transition Planning on High School Transition IEPs. 4. The Experiences of High School Students with ASDF and their families with Family-Centered Transition Planning. <ul style="list-style-type: none"> • Sessions on Family-Centered Transition as part of the Institute on Disability's annual Autism Summer Institute. • Presentations at conferences of the Council on Exceptional Children, the Autism Society of America and the National Rehabilitation Association. • Presentations at the Developmental Disability Family Support annual conferences in NH and ME and the annual conference of the Autism Society of Maine. • A project component implementation manual published by the Institute on Disability. |
| University of Colorado Denver | Develop and evaluate the use of interactive televideo technology to deliver a promising mental health intervention to families of children with autism spectrum disorders who are geographically removed from specialty medical centers. | <ul style="list-style-type: none"> • Conduct outreach workshops in the community and prepare family-friendly recruitment materials. • Conduct 5 workshops around the state to promote awareness of this project and share ideas for interventions to promote coping with families, educational teams, and mental health providers. • Host a web-conference to review our findings and publicize the webcast through various community, university, and national association partners. • Generate two manuscripts from the data captured in this project: one regarding feasibility and acceptability and the other a clinical practice document on lessons learned trying a telehealth application with youth with ASD and their families. |

**TABLE I.2 SUMMARY OF MCH RESEARCH GRANTEES BY
RESEARCH PROJECT**

| Autism Intervention Secondary Data Analysis Studies (SDAS) Program FY2009 Grantees | |
|--|---|
| Grantee/Project Name | Research Summary |
| University of Massachusetts Boston <i>Services and Outcomes for Transition Age Young Adults with Autism Spectrum Disorders: Secondary Analysis of the NLTS2 and RSA 911</i> | <p>Conduct descriptive and predictive analyses of the factors associated with and influencing a successful transition into adulthood for young adults with autism spectrum disorder using secondary data sources. The goal of this project is to identify personal and programmatic factors that are related to positive postsecondary outcomes and understand the differences in services and supports used by young adults with ASD compared to other young adults with disabilities. The project will explore and document the experiences of adolescents and young adults with ASD during the transition from secondary education to adult life using data from the National Longitudinal Transition Survey 2 (NLTS2) and the Rehabilitation Services Administration 911 database (RSA 911).</p> <p>The project will conduct descriptive and predictive analyses to describe the experiences and characteristics of young adults with ASD, the relationships between educational and vocational rehabilitation supports and post-school outcomes, and the relationships between personal characteristics and post school outcomes. Personal characteristics available in both databases include race and ethnicity, family and personal income, health insurance coverage, and co-morbidity with other disabilities. The NLTS2 also includes a wide array of variables that address student and family goals, life planning, self-determination, social supports and expectations for the future.</p> |
| University of North Carolina at Chapel Hill <i>The Effectiveness of Special Education Services for Children with Autism: A National Longitudinal Study</i> | <p>Using the Pre-Elementary Education Longitudinal Study (PEELS), the Special Education Elementary Longitudinal Study (SEELS), and the National Longitudinal Transition Study-2 (NLTS2) this study will address three questions:</p> <ol style="list-style-type: none"> 1) Do children receive high-quality treatment from the schools, as indicated by whether children are taught by appropriately certified teachers; educated in inclusive settings; identified early; and having appropriate plans to make transition to adulthood? 2) If so, which children receive such an education? For example, how does service quality vary by race/ethnicity and gender? Along the autism spectrum? By district? 3) Do these indicators of service quality improve outcomes? <p>These analyses will provide both cross-sectional estimates as well as models that capture the dynamic interplay between service use, a child's functioning and key outcomes and allow us to describe children's receipt of high-quality school services nationwide and to determine patterns (e.g., by age) in who receives those services. These analyses will provide insights into key policy questions, such as the benefits of teacher certification and of early identification. Outcomes considered include key measures of academic, social, behavioral, functional, and motor skills.</p> |

| MCH Autism Intervention Research Program FY2009 Grantees | |
|--|---|
| Grantee/Project Name | Research Summary |
| <p>Brandeis University</p> <p><i>Assessing a Participant Directed Service System for Low Income Children with Autism</i></p> | <p>The project will evaluate a Medicaid supportive services waiver program in Massachusetts that uses a participant direction (PD) model to choose and manage services for young children with autism spectrum disorder (ASD) and their families. The evaluation has two specific aims:</p> <p>(Aim 1) assess how well PD systems are implemented; and (Aim 2) understand the variation in implementation across families and assess what predicts family well-being and child progress.</p> <p>Population: The waiver now serves 100 families with incomes low enough to qualify for Medicaid. Outreach is conducted in 8 languages, and one-fifth of the applicants had a primary language other than English. The clients reside in urban, suburban, and rural areas.</p> <p>Design: The implementation evaluation will include: (1) a staff focus group to define PD program components and weigh their relative importance to success, (2) a survey of about 30 staff to assess implementation of the components, (3) interviews with about 28 staff at high- and low-scoring sites about barriers to and facilitators of implementation, (4) in-depth interviews of 16 families at these sites concerning their experiences with PD, and (5) collection of administrative and cost data. The state will use the findings to revise the PD program in 2010 and we will assess the revision. For aim 2, we will (1) conduct in-home interviews with 77 families who have participated in the waiver program for 18 to 24 months and 30 families who entered the program later and will have participated for about 6 months, (2) access child and family baseline assessment data from the state data base, and (3) using therapists' quarterly progress notes, develop a scale for assessing individual child progress and code data using that scale. A series of multiple regression models will test hypotheses regarding both predictors of utilization and family PD experiences and the influence of the PD experience on child progress and family wellbeing and satisfaction.</p> |
| <p>Boston Medical Center</p> <p>Supporting the Well-being of Families of Young Children with Autism Spectrum Disorders</p> | <p>To determine whether an evidenced-based empowerment strategy, Problem Solving Education (PSE), targeted to mothers of young children with autistic spectrum disorders (ASDs), promotes family well-being by decreasing the burden of maternal depressive symptoms and parenting stress and improving maternal social functioning.</p> <p>Sample: A randomized control trial involving 140 English or Spanish speaking mothers who have children less than 4 years of age with confirmed ASDs. Data collection will occur at the three time points - baseline (T0), 3 months (T3), 6 months (T6).</p> <p>Intervention: Mothers in the intervention group will receive 6 sessions of PSE. Control group subjects will receive usual care. The intervention will be embedded in two settings that provide services to young children with ASDs - Early Intervention (EI) programs and specialty developmental assessment clinics. Randomization will occur independently at EI and developmental assessment clinic sites. PSE sessions will be delivered in the home or at a place determined by the mother as an adjunct to customary services provided by each setting. Mothers in control group will receive the standard of care at the specific recruitment site.</p> <p>The study's primary outcomes are maternal depressive symptoms and parenting stress. Secondary outcomes are maternal functional outcomes measured in 3 domains: 1) problem solving skills; 2) social functioning and 3) behavioral activation. To estimate the effect of the intervention we will conduct an intention-to-treat analysis to compare the difference between intervention and control groups on the major outcome variables. We will conduct both</p> |

| MCH Autism Intervention Research Program FY2009 Grantees | |
|--|--|
| Grantee/Project Name | Research Summary |
| | <p>unadjusted and adjusted analyses, controlling in the latter for stratification variables and individual level characteristics that differ between study groups. Additional exploratory analyses will be conducted to assess effect modification by recruitment site, child functioning, level of maternal distress, and coping style.</p> |
| <p>Kennedy Krieger Institute</p> <p><i>Parent-Mediated vs Center-Based Intervention for Toddlers with ASD: An RCT</i></p> | <p>Early intervention services for toddlers with ASD are highly variable, resulting in disparity across children in the nature of intervention options. This variability in intervention services for toddlers with ASD is due in large part to the general lack of empirical data regarding efficacious interventions for very young children with ASD. Existing intervention studies involving 2-year-olds with ASD primarily have employed descriptive or quasi-experimental designs and have included samples consisting of at least 80% Caucasian children (when ethnicity and race is reported). Thus, the generalizability of findings for toddlers with ASD in general, especially those from diverse ethnic and cultural backgrounds, is unknown. Therefore, research is needed to identify efficacious early interventions for minority and underserved toddlers with ASD in order to reduce disparity of access to high quality intervention and to guide efficient use of public funds. At present, most Part C services for children at risk for ASD are provided in the home where a parent-mediated model is emphasized. Research is needed to evaluate whether parent-mediated intervention and center-based intervention provided by a clinician yield comparable outcomes for minority and underserved toddlers with ASD.</p> <p>Sample: Sixty 2-year-old minority and underserved toddlers with ASD will be randomized to one of the two 6-month intervention conditions: Parent-Mediated, where parents will be trained in responsive, child-contingent interaction strategies to be used at home; or Center-Based, where children receive intervention in a nursery school classroom for 10 hours per week. We anticipate that children in the Center-Based intervention will show greater gains in cognitive and language functioning compared with children in the Parent-Mediated intervention, but gains in joint attention and shared positive affect will be comparable in the two groups. Parents in the Parent-Mediated intervention are expected to utilize more child-contingent, responsive interaction strategies, and show greater gains in self-efficacy, but not reduced levels of stress compared with parents of children in the Center-Based intervention.</p> <p>Design: Data collection methods will include direct child assessment using standardized and experimental measures of social and communication development. Parent measures are questionnaires that assess stress, self-efficacy, and 'buy-in' to the intervention, as well as direct measures of child contingent behavior.</p> |
| <p>University of New Hampshire</p> <p><i>Family-Centered Transition Planning for Students with Autism Spectrum Disorders</i></p> | <p>Young adults with Autism Spectrum Disorders (ASD) frequently transition from high school to adult life lacking the skills and supports needed to participate as full members of their communities. This project demonstrates a Family-Centered Transition Planning model designed to empower families and transitioning students to take a leading role in the process of transition planning:</p> <ol style="list-style-type: none"> 1. The first component involves a series of 6 structured training sessions for the families of transitioning students called SPECS (Specific Planning Encourages Creative Solutions). 2. The second component is facilitating plan development with the individual families following training. A Planning Facilitator will assist transitioning students with ASD and their families to form a group of supportive individuals, including school and adult service representatives and conduct 2 – 3 planning meetings held at the family's home or other chosen location to develop a plan for meaningful community participation following high school, including employment and/or postsecondary education. 3. The third component is facilitation of career exploration activities – such as job shadowing, volunteer work experiences, or investigating colleges – with the |

| MCH Autism Intervention Research Program FY2009 Grantees | |
|---|---|
| Grantee/Project Name | Research Summary |
| | <p>student, family and school, in accordance with each plan.</p> <p>Sample: Forty youth with ASD between the ages of 16 – 18 at enrollment from collaborating high schools in NH and ME, and one parent for each youth.</p> <p>Design: Participants will be randomly assigned to a Year 1 group and a Year 2 group, with the Year 2 group receiving typical high school transition services during Year 1. Data will be collected at enrollment and after 12 months (prior to the initiation of services for the Year 2 group) to measure the impact of Family-Centered Transition Planning. Data will be collected on parent future expectations using a self-report survey. Data will be collected student self-determination using a self-report survey and on student career maturity and healthy functioning using an interview-based survey. Record review will examine the quality of the transition objectives on the high school’s IEP using a document analysis checklist. Semi-structured interviews with students and families will explore their transition experiences using qualitative methods.</p> |
| <p>University of Colorado Denver</p> <p><i>Telehealth Delivery of a Family-Focused Intervention to Reduce Anxiety in Youth with Autism Spectrum Disorders in Rural Colorado</i></p> | <p>Develop and evaluate the use of interactive televideo technology to deliver a promising mental health intervention to families of children with ASD who are geographically removed from specialty medical centers. Given the obstacles faced by rural families of children with autism as they seek specialized care, and the impact of co-occurring psychiatric conditions on child and family functioning, finding innovative ways to link specialists with families of psychiatrically complex youth with ASD is an important research goal. Specific aims of the project are: (1) to refine the policies, procedures, and treatment materials (e.g., Facilitators Manual, Parent Workbook, Youth Workbook) of the Face Your Fears (FYF) intervention package for delivery as a telehealth application (i.e., interactive televideo); (2) to assess the feasibility and acceptability of the telehealth intervention for families of anxious youth with ASD; and (3) to estimate the degree of change and variability of response to the telehealth intervention on youth outcomes (anxiety disorder diagnoses and independent clinician ratings of anxiety severity) and family outcomes (caregiver strain, impact on family, parent mental health, parenting sense of efficacy) using a repeated measures within subjects design.</p> |