

**Health Resources and Services Administration
Maternal and Child Health Bureau**

Autism CARES Act Evaluation

OMB Control No. 0915-0335

Revision

Part A. Justification

A.1 Circumstances That Make Data Collection Necessary

The Health Resources and Services Administration's (HRSA) Maternal and Child Health Bureau (MCHB) is requesting Office of Management and Budget (OMB) continued approval to collect information from grantees funded under MCHB's Combating Autism Act Initiative (CAAI), as reauthorized under the Autism CARES (Collaboration, Accountability, Research, Education, and Support) Act of 2014 (H.R. 4631; Pub. L. 113–157). The reauthorization extended funding for grant programs that received support under the Combating Autism Act (CAA) of 2006 (CAA, P.L. 109–416). The purpose of this information collection is to describe the accomplishments of those grant programs in implementing the provisions of the Autism CARES Act. To build upon work done in previous evaluations, HRSA seeks continued approval to use the updated data collection instruments OMB has already approved (0915-0335, expiration 3/31/2017).

Background

In response to the growing need for research and resources devoted to autism spectrum disorders (ASD) and other developmental disabilities (DDs), the U.S. Congress passed CAA in 2006. The act included funding for the U.S. Department of Health and Human Services' (HHS) HRSA to increase awareness, reduce barriers to screening and diagnosis, promote evidence-based interventions, and train health care professionals to screen for, diagnose or rule out, and provide evidence-based interventions for ASD/DDs. In 2014, the Autism CARES Act was signed into law, reauthorizing funding for CAA's programs for an additional 5 years.

HRSA/MCHB Initiatives

HRSA's activities under this legislation are delegated to MCHB, whose mission is to provide national leadership to reduce disparities, ensure the availability of quality care, and strengthen the Nation's maternal and child health infrastructure. MCHB administers a broad range of programs that promote and support the health of mothers and children and their families. Many of MCHB's discretionary grant programs target specific populations, such as those with low incomes, racial and ethnic minorities, individuals living in rural areas, children with special health care needs, families, and populations with particular medical conditions. MCHB provides grant support for programs that build maternal and child health services capacity such as training health professionals; developing standards of care; and increasing assessment, planning, and quality assurance capabilities.

The overall goal of the Autism CARES Act of 2014 is to enable all infants, children, and adolescents who have, or are at risk of developing, ASD/DDs to reach their full potential by developing a system of services that includes—

1. Screening children as early as possible for ASD/DDs
2. Conducting early, interdisciplinary clinical evaluations to confirm or rule out ASD/DDs
3. Providing early, evidence-based interventions when a diagnosis is confirmed

In alignment with guidance from the legislation, the Autism CARES Act specifies the following objectives:

1. Increase public/provider awareness of ASD/DDs.
2. Reduce barriers to screening and diagnosis.
3. Support research on evidence-based interventions for ASD/DDs.

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.
6. Build system capacity to provide coordinated, comprehensive, and community-based care for children and youth with ASD/DDs.

To achieve these objectives, HRSA/MCHB has provided funding for four grant programs focused on training, research, and improving State systems of care as described briefly below.

Training Programs

Leadership Education in Neurodevelopmental Disabilities (LEND) training programs:

A total of 53 LEND programs received funding to provide trainees from diverse professional disciplines with high-quality interdisciplinary education that emphasizes the integration of services from State and local agencies and organizations, private providers, and communities and the use of innovative practices to enhance cultural competency and family-centered care.

Developmental-Behavioral Pediatrics (DBP) training programs:

A total of 10 DPB programs received funding to enhance the behavioral, psychosocial, and developmental aspects of pediatric care.

Research Programs

Autism Intervention Research (AIR) Networks:

Five autism intervention networks focus on intervention research, guideline development, and information dissemination. The Autism Intervention Research Network on Physical Health (known as AIR-P) focuses on physical/medical health interventions, the Autism Intervention Research Network on Behavioral

Health (known as AIR-B) focuses on behavioral, mental, social, and/or cognitive health interventions. The Developmental-Behavioral Pediatrics Research Network (known as DBPNet) focuses on collaborative, interdisciplinary research that advances clinical practice, supports research training, and promotes optimum health of children with ASD/DDs. The Health Care Transitions Research Network (known as HCT-RN), a collaborative network new to this evaluation, focuses on the health, family, and social needs of adolescents and young adults on the autism spectrum. The Healthy Weight Research Network (known as HW-RN) works to improve the Nation's understanding of factors contributing to the possible increased risk of overweight and obesity among children with ASD/DDs.

R40 Maternal and Child Health (MCH) Research Multiyear Grant Program: Ten MCH grantees were funded to support research on evidence-based interventions to improve the health and well-being of children and adolescents with ASD/DDs.

R40 MCH Autism Intervention Secondary Data Analysis Studies (known as SDAS)

Program: Twelve MCH grantees were funded to support research on evidence-based interventions to improve the health and well-being of children and adolescents with ASD/DDs, using the exclusive analysis of existing secondary data.

Improving State Systems of Care

State Implementation Grants/State Innovation in Care Integration Grantees: Nine States were awarded CAAI State Implementation grants in 2013 or 2014 and four states were awarded Planning grants in 2013. The State Implementation grants provide grantees with the funding needed to implement existing State plans for improving access to comprehensive, coordinated health care and related services for children and youth with ASD/DDs. The State Autism Planning Grants will allow grantees to develop plans for improving access to care for children

and youth with ASD/DDs. Four States were awarded Autism CARES State Innovation in Care Integration grants in 2016. While the ultimate goals of the 2016 and 2013–2014 planning and implementation grants are similar, their specific objectives vary greatly.

Resource Centers

Interdisciplinary Technical Assistance Center (ITAC): One grantee received funding to serve as the technical assistance and resource center to the LEND and DBP grantees through operating ITAC on Autism and Developmental Disabilities.

State Public Health Autism Resource Center (SPHARC): One grantee was funded through a cooperative agreement with MCHB to provide technical assistance to the State Implementation grantees through operating SPHARC.

Use of Information for Policy and Program Objectives

The Autism CARES Act mandates that the HHS Secretary provide to Congress an interagency report documenting the progress of HRSA/MCHB, the National Institutes of Health, and the Centers for Disease Control and Prevention in implementing the provisions of this act. For HRSA's part, the agency has hired a contractor to assess and report on the progress of the grant programs funded through MCHB's Autism CARES Act. To gather the requisite information for that report, the contractor plans to collect data from all grantees. MCHB and Congress will use that information to make decisions about future funding of these programs and to assess program priorities.

A.2. Purpose and Use of the Information

The information needed for this study will be derived from both primary data collection and existing performance measure data provided by grantees to MCHB. Primary data collection

methods will include semistructured interviews and questionnaires. Existing data sources include the annual grantee performance measures, which have been cleared through the Discretionary Grants Information System (DGIS) OMB number 0915-0298. Additional performance data for the training grantees will be obtained through the National Information Reporting System (NIRS), a Web-based data reporting and retrieval system maintained by the Association of University Centers on Disabilities (AUCD) that enables grantees to manage data on their training programs, projects, activities, and products and helps them comply with Federal reporting requirements.

The information to be collected from each grant program is described below. Since the last OMB submission (OMB No. 0915- 0335, expiration 3/31/2017), some changes have been made to the interview protocols to improve efficiency and ensure they address MCHB's mission and research questions. For a complete table of specific changes made to the data collection instruments, see attachment B.

Training Programs (LEND and DBP)

LEND Semistructured Interview Protocol (attachment C)

During semistructured interviews, LEND directors and/or LEND program staff from 53 programs will be asked questions about their Autism CARES grant-funded activities pertaining to the following areas:

- Training professionals to use valid and reliable screening and diagnostic tools for ASD/DDs
- Reducing barriers to ASD/DD screening and diagnosis
- Increasing awareness about ASD/DDs

- Contributing to research on evidence-based practices

The LEND interview protocol will include questions about the technical assistance provided by AUCD, the extent to which that assistance contributed to the grantee's successes, and the effectiveness of AUCD as a source of information and a forum for disseminating information. These interviews will be conducted by telephone.

DBP Semistructured Interview Protocol (attachment D)

During semistructured interviews, DBP directors and/or program staff from 10 programs will be asked questions about their Autism CARES grant-funded activities and accomplishments pertaining to each of the following areas:

- Training professionals to provide screening, diagnosis, and coordination of care for ASD/DDs
- Research related to ASD/DDs, including efforts to translate research into practice
- Increasing awareness of ASD/DDs
- Reducing barriers and improving systems of care for children with ASD/DDs and their families

The DBP interview protocol will include questions about the technical assistance provided by AUCD, the extent to which that assistance contributed to the grantees' successes, and the effectiveness of AUCD as a source of information and a forum for disseminating information. These interviews will be conducted by telephone.

Research Programs

Research Network and R40 Semistructured Interview Protocols (attachments E and F)

During semistructured interviews, principal investigators from approximately 27 programs will be asked about their research activities pertaining to the following:

- Evidence-based interventions for ASD/DDs
- Efforts to test and validate tools used for ASD interventions
- Development of evidence-based treatment guidelines

The interviews will include questions about the grantees' efforts to disseminate research findings, treatment guidelines, and information about validated ASD intervention tools. Other questions will focus on how the Research Network's work may be addressing barriers to service for underserved populations. These interviews will be conducted by telephone.

Research Network Questionnaire (attachment G)

This questionnaire, which will be administered via email to inform the semistructured interviews described above (attachment E), will collect information about the following:

- Number of research proposals developed and funded by the network
- Grantees' progress in developing evidence-based guidelines for ASD interventions
- Grantee's efforts to develop and validate tools for ASD screening and intervention
- Methods used to disseminate information about new research findings, clinical guidelines, and tools

The questionnaire will also ask the principal investigators to describe any collaborations or partnerships they have formed with other agencies or entities, their efforts to address minority and underserved populations in their research, and their efforts to develop and mentor new investigators. These interviews will be conducted by telephone.

State Implementation Grants

State Implementation Grant Semistructured Interview Protocol (attachments J and K)

During the semistructured interviews, approximately 13 grantees will be asked to describe the following:

- Their efforts to build awareness of ASD/DDs among target populations
- Their efforts to address service barriers, including activities related to screening, medical homes, and referral systems
- Training initiatives
- Activities related to building a statewide infrastructure for comprehensive, coordinated, and community-based systems of care

Grantees will be asked to assess the support provided by the SPHARC and the extent to which that support facilitated their success in implementing statewide improvements in care. Since there will be a new round of grantees awarded mid-way through the evaluation, attachment J is designed to address the current grantees and attachment K is for the new grantees. These interviews will be conducted by telephone.

Resource Centers

Semistructured Interview Protocol: ITAC (attachment H)

During the semistructured interview, a key representative from ITAC will be asked to describe how the center has provided technical assistance to the LEND and DBP grant programs, disseminated information to grantees, and promoted collaboration across grant programs. These interviews will be conducted by telephone.

Semistructured Interview Protocol: SPHARC (attachment I)

To supplement the performance measure data and the information collected from the State Implementation grantees, a one-time telephone interview with a representative from the SPHARC will be conducted to gather information on the SPHARC's efforts to support and assist States in developing a system of care to improve the health of individuals with ASD/DDs and in fostering collaborations and disseminating resources among State grantees.

This information collection request seeks approval for the eight semistructured interview protocols (attachments C, D, E, F, H, I, J, K) and the questionnaire (attachment G).

The questionnaire will gather information primarily about quantifiable outputs and outcomes, whereas the interviews will gather more descriptive information about each grant program's activities, challenges encountered during the grant, examples of successes, and results of collaborative efforts within and across grant programs. The questionnaire and interview data will be analyzed and summarized in a final report for MCHB.

Who Will Use the Information?

The information gathered through this data collection effort will inform MCHB and its stakeholders on grantee activities and inform HHS's Interagency Report to Congress, which requires "a description of the progress made in implementing the provisions of the Combating Autism Act of 2006." (For a full list of the legislative requirements, see attachment A.)

A.3. Use of Information Technology and Burden Reduction

Questionnaire data for the Research program will be collected via email. All semistructured interviews will be conducted by telephone.

A.4. Efforts To Identify Duplication and Use of Similar Information

There are no other HRSA/MCHB data collection activities that are qualitatively measuring the progress of Autism CARES Act grantees in meeting the objectives of Autism CARES. The evaluation team will be using NIRS data, DGIS data, and progress reports, already collected by MCHB from the grantees, to capture the full extent of Autism CARES Act activities. The in-depth interviews aim to address any gaps of the other data collection tools.

A.5. Impacts on Small Businesses or Other Small Entities

This activity does not impact small entities.

A.6. Consequences of Collecting the Information Less Frequently

The information described here will be collected one time only. If the data are not collected, HRSA and HHS will not have sufficient information to provide the mandated Report to Congress.

A.7. Special Circumstances Relating to the Guideline of 5 CFR 1320.5

This data collection request is fully consistent with the guidelines in 5 CFR 1320.5(d)(2).

A.8.A Comments in Response to the *Federal Register Notice*

The notice required by 5 CFR 1320.8(d) was published on October 24, 2016 on pages 73117 – 73118 of the Federal Register Vol. 81, No. 205. No comments were received.

A.8.b Efforts To Consult Outside Agency

To obtain input on the availability of data, clarity of instructions, and the proposed data elements to be collected, MCHB consulted with the program officers from each funded program. Table 1 lists all persons who were consulted and offered input on the interview protocols and/or the questionnaires.

Table A.1. Persons Consulted on Data Collection Instruments

Instrument	Name	Affiliated Entity	Title	Contact Information (Telephone Number Email Address)
LEND interview protocol	Robyn Schulhof	HRSA	Senior Public Health Analyst	301.443.0258 RSchulhof@hrsa.gov
DBP interview protocol	Rita Maldonado	HRSA	Public Health Analyst	301-443-3622 RMaldonado@hrsa.gov
ITAC interview protocols	Robyn Schulhof	HRSA	Senior Public Health Analyst	301.443.0258 RSchulhof@hrsa.gov
State Implementation interview protocols	Leticia Manning	HRSA	Public Health Analyst	301-443-8335 LManning@hrsa.gov
Research Network and R40 interview protocol	Robin Harwood	HRSA	Health Scientist	301-443-3888 RHarwood@hrsa.gov
SPHARC interview protocol	Debra Wagler	HRSA	Public Health Analyst	301-443-5467 DWagler@hrsa.gov

A.9. Explanation of Any Payment or Gift to Respondents

Respondents will not be remunerated or compensated.

A.10. Assurance of Confidentiality Provided to Respondents

No personally identifiable information will be collected. Only program data will be collected, which is aggregate in nature.

A.11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

A.12. Estimates of Hour Burden Including Annualized Hourly Costs

The burden estimates for respondents appear in table 2. These estimates are based on previous experience with instruments included in the prior OMB submissions. It is estimated there will be an average of two individuals participating in each interview. Participants may include the project director and principal investigator from each grant program. The questionnaire for the Research programs will be completed by research assistants for the principal investigator.

Wage rates are based on May 2015 national occupational and wage estimates from the Bureau of Labor Statistics. For the interviews with ITAC, the Training programs and Research program grantees, the cost estimates are based on the national mean hourly wage for a medical scientist. For the interviews with the State Implementation program principal investigators and SPHARC, the cost estimates are based on the national mean hourly wage for medical and health services managers. For the Research program questionnaires, the cost estimates are based on the national mean hourly wage for social science research assistants.

Table A.2. Estimated Hour and Cost Burden of the Data Collection

Grant Program/Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Hours per Response	Total Hour Burden	Wage Rate	Total Hour Cost
LEND Interview Protocol	53	2	106	1	106	44.66	4733.96
DBP Interview Protocol	10	2	20	1	20	44.66	893.20
State Implementation Program Interview Protocol	9	2	18	1	18	50.99	101.98
State Innovation in Care Integration State Grantees	4	1	4	1	4	22.00	88.00
Research Network Interview Protocol	5	2	10	1	10	44.66	446.60

Research Program R40 Interview Protocol	10	1	10	1.5	15	44.66	669.90
Research Network Questionnaire	5	1	5	1	5	22.00	110.00
Resource Center: ITAC Interview Protocol	1	2	2	1	2	44.66	89.32
Resource Center: SPHARC Interview Protocol	1	2	2	1	2	50.99	101.98
Total	98		177		182		7,234.94

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital or startup costs associated with data collection.

A.14. Annualized Cost to Federal Government

The total cost to the Government for collecting these data is estimated to be the portion of the 3-year contract that is devoted to the evaluation data collection and analysis efforts, at \$240,000.

The cost is estimated to include approximately 20 percent of the Federal project officer’s time (estimated for an O-4 PHS Commissioned Officer), at approximately \$13,000. The total estimated cost is approximately \$253,000.

A.15. Explanation of Program Changes or Adjustments

The current burden inventory is 110 hours. This request is for 182 hours, an increase of 72 hours. The burden has been increased to include an average of two people per interview since some grantees wanted an opportunity for multiple people to respond to the interview questions to share perspectives. For a complete understanding of changes made to the interview protocols since previous OMB submissions, refer to the Summary of Interview Protocol Changes document.

A.16. Plans for Tabulation and Publication and Project Time Schedule

All data collection must begin by September 2017 to ensure inclusion of the data in the June 2018 final report. The proposed schedule for the information collection appears in table 3.

Table A.3. Estimated Time Schedule for Data Collection, Analysis, and Publication

Activity	Time Schedule
Develop data collection tools	June 2016
Receive OMB approval	By August 2017 (anticipated)
Questionnaires administered and collected <ul style="list-style-type: none">• Research Network questionnaire	September–December 2017
Interviews scheduled and conducted	September–December 2017
Data analysis	Fall 2017 to winter 2018
Final report to HRSA	June 2018
Final fact sheets	September 2018

Final reports will be submitted to MCHB in June 2018. The results will be summarized in four factsheets submitted to MCHB in September 2018.

A.17. Reason(s) Display of OMB Expiration Date Is Inappropriate

All data collection materials will display the OMB expiration date.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

HRSA certifies that the collection of information encompassed by this request complies with 5 CFR 1320.9 and the related provision of 5 CFR 1320.8(b)(3).

Attachments to Supporting Statement

Attachment A: Public Law 113–157, 128 Stat. 1831 §42 U.S.C. 280i§

Attachment B: List of Changes to Interview Protocols

Attachment C: LEND Semistructured Interview Protocol

Attachment D: DBP Semistructured Interview Protocol

Attachment E: Research Network Semistructured Interview Protocol

Attachment F: R40 Semistructured Interview Protocol

Attachment G: Research Network Questionnaire

Attachment H: ITAC Semistructured Interview Protocol

Attachment I: SPHARC Semistructured Interview Protocol

Attachment J: State Implementation Grant Program Semistructured Interview Protocol

Attachment K: State Innovation in Care Integration Grantee Program Semistructured Interview Protocol