

**HEALTH RESOURCES AND SERVICES
ADMINISTRATION
MATERNAL AND CHILD HEALTH BUREAU**

Combating Autism Act Initiative Data Collection

Part A

November 24, 2013

Contents

PART A.	JUSTIFICATION.....	1
A.1.	Circumstances that Make Data Collection Necessary.....	1
A.2.	Purpose and Use of the Information.....	4
A.3.	Use of Information Technology and Burden Reduction.....	8
A.4.	Efforts to Identify Duplication and Use of Similar Information.....	8
A.5.	Impacts on Small Businesses or Other Small Entities.....	8
A.6.	Consequences of Collecting the Information Less Frequently.....	8
A.7.	Special Circumstances Relating to the Guideline of 5 CFR 1320.5.....	8
A.8.	Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency.....	9
A.9.	Explanation of Any Payment or Gift to Respondents.....	9
A.10.	Assurance of Confidentiality Provided to Respondents.....	9
A.11.	Justification for Sensitive Questions.....	9
A.12.	Estimates of Hour Burden Including Annualized Hourly Costs.....	9
A.13.	Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	10
A.14.	Annualized Cost to Federal Government.....	10
A.15.	Explanation for Program Changes or Adjustments.....	10
A.16.	Plans for Tabulation and Publication and Project Time Schedule.....	11
A.17.	Reason(s) Display of OMB Expiration Date is Inappropriate.....	11
A.18.	Exceptions to Certification for Paperwork Reduction Act Submissions.....	11
ATTACHMENT A	PUBLIC LAW 112-32, 125 STAT. 361 §42 U.S.C.§1	
ATTACHMENT B	LEND SEMI-STRUCTURED INTERVIEW PROTOCOL	
ATTACHMENT C	DBP SEMI-STRUCTURED INTERVIEW PROTOCOL	
ATTACHMENT D	RESEARCH NETWORK SEMI-STRUCTURED INTERVIEW PROTOCOL	
ATTACHMENT E	R40 INTERVIEW PROTOCOL	
ATTACHMENT F	RESEARCH NETWORK QUESTIONNAIRE	
ATTACHMENT G	STATE IMPLEMENTATION GRANT PROGRAM SEMI-STRUCTURED INTERVIEW PROTOCOL	
ATTACHMENT H	STATE IMPLEMENTATION GRANT PROGRAM QUESTIONNAIRE	
ATTACHMENT I	AUCD SEMI-STRUCTURED INTERVIEW PROTOCOL	
ATTACHMENT J	AMCHP SEMI-STRUCTURED INTERVIEW PROTOCOL	

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) approval to collect information from grantees funded under MCHB's Combating Autism Act Initiative (CAAI), as reauthorized under the Combating Autism Reauthorization Act of 2011 (CARA, P.L. 112-32).¹ The reauthorization extended funding for grant programs that received support under the Combating Autism Act 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 CARA.

Background

In response to the growing need for research and resources devoted to autism spectrum disorders (ASD) and other developmental disabilities (DD), the U.S. Congress passed the CAA in 2006. The Act included funding for the U.S. Department of Health and Human Services (HHS) Health Resources and Services Administration (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 and other DD. In 2011, the CARA was signed into law, reauthorizing funding for the CAA's programs for an additional 3 years at the existing funding levels.

HRSA/MCHB Initiatives

HRSA's activities under this legislation are delegated to MCHB, whose mission is to provide national leadership to reduce disparities, assure 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 low-income, racial and ethnic minority, rural, children with special health care needs, families, as well as populations with particular medical conditions. In addition, 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.

Under the authority of the CAA, MCHB established the CAAI in 2008 and was provided reauthorization to continue CAAI activities in 2011. The overall goal of the CAAI is to enable all infants, children, and adolescents who have, or are at risk of developing, ASD/DD to reach their full potential by developing a system of services that includes:

¹ A copy of the legislation can be found in Attachment A.

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

Additionally, in alignment with guidance from the legislation, the CAAI specifies the following objectives:

1. Increase public/provider awareness of ASD and other DD;
2. Reduce barriers to screening and diagnosis;
3. Support research on evidence-based interventions for ASD and other DD;
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; and
6. Build system capacity to provide coordinated, comprehensive, and community-based care for children and youth with ASD and other DD.

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

Training Programs

- Leadership Education in Neurodevelopmental Disabilities (LEND) training programs: A total of 43 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: Three autism intervention networks focus on intervention research, guideline development and information dissemination. The Autism Intervention Research Network on Physical Health (AIR-P) focuses on physical/medical health interventions, the Autism Intervention Research Network on Behavioral Health (AIR-B) focuses on behavioral, mental, social, and/or cognitive health interventions, and the Developmental Behavioral Pediatrics Research Network (DBPNet) focuses on collaborative, interdisciplinary research that advances clinical practice, supports research training, and optimizes the health of children with ASD/DD.

-
- R40 MCH Autism Intervention Research Program: Fourteen MCH grantees were funded to support research on evidence-based interventions to improve the health and well-being of children and adolescents with ASD and other DD.
 - R40 MCH Autism Intervention Secondary Data Analysis Studies (SDAS) Program: Six MCH grantees were funded to support research on evidence-based interventions to improve the health and well-being of children and adolescents with ASD and other DD, utilizing the exclusive analysis of existing secondary data.

Improving State Systems of Care

- State Implementation Grants: A total of 22 States have been awarded CAAI State Implementation or Planning grants. 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 and other DD. The State Autism Planning Grants will allow grantees to develop plans for improving access to care for children and youth with ASD and other DD.

Resource Centers

- National Interdisciplinary Training Resource Center: The Association of University Centers on Disabilities (AUCD) received funding to serve as the technical assistance and resource center to the LEND and DBP grantees.
- State Public Health Coordinating Resource Center: The Association of Maternal and Child Health Programs (AMCHP) was funded through a cooperative agreement with MCHB to provide technical assistance to the State Implementation Grantees.

Use of Information for Policy and Program Objectives

The Combating Autism Act, continued under CARA, mandated that the Secretary of the Department of Health and Human Services (DHHS) provide to the Congress an interagency report documenting the progress of HRSA/MCHB, NIH and CDC 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 Combating Autism Act Initiative. In order 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 derive from both primary data collection and existing performance measure data provided by grantees to MCHB. Primary data collection methods include semi-structured 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 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.

Training Programs (LEND and DBP)

DGIS Performance Measures 09, 10 and 59 (OMB # 0915-0298)

LEND Semi-structured interview protocol (Attachment B):

LEND Directors and/or LEND program staff will be asked to answer questions about their CAAI grant-funded activities pertaining to the following areas: training professionals to use valid and reliable screening and diagnostic tools for ASD and other DD; reducing barriers to ASD screening and diagnosis; increasing awareness about ASD and other DD; and contributing to research on evidence-based practices. Additionally, 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 Semi-structured interview protocol (Attachment C):

DBP Directors will be asked to answer questions about their CAAI grant-funded activities and accomplishments pertaining to each of the following areas: training professionals to provide screening, diagnosis, and coordination of care for ASD/DD; research related to ASD/DD, including efforts to translate research into practice; increasing awareness of ASD and other DD; reducing barriers and improving systems of care for children with ASD/DD and their families. Additionally, the DBP 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.

NIRS CAAI Module. This module is one component in the Training programs' performance measurement system that obtains information on autism-related activities and outputs, such as number of trainees enrolled in autism-related didactic or clinical training.

Research Programs

DGIS Performance Measure # 3 (OMB # 0915-0298): The percent of completed MCHB supported projects that are publishing findings in peer-reviewed journals.

Research Network and R40 semi-structured interview protocols (Attachments D and E):

Principal Investigators will be asked about their research activities pertaining to evidence-based interventions for ASD and other DD, their efforts to test and validate tools used for ASD interventions, and the development of evidence-based treatment guidelines. Additionally, the interviews will include questions about the grantee's 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.

Research Network Questionnaire (Attachment F):

This questionnaire will collect information about the number of research proposals developed and funded by the network, their progress in developing evidence-based guidelines for ASD interventions, their efforts to develop and validate tools for ASD screening and intervention, and the 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.

State Implementation Grants

DGIS Performance Measures #16, 24, 31, 37, and 41 (OMB # 0915-0298)

State Implementation Grant semi-structured interview protocol (Attachment G):

Grantees will be asked to describe: their efforts to build awareness of ASD and other DD among target populations and more specifically, their use of CDC Learn the Signs, Act Early materials; their efforts to address service barriers, including activities related to screening, medical homes, and referral systems; training initiatives; and activities related to building a Statewide infrastructure for comprehensive, coordinated and community based systems of care. Additionally, grantees will be asked to assess the support provided by the Coordinating Resource Center, and the extent to which that support facilitated their success in implementing State-wide improvements in care.

State Implementation Grant Questionnaire (Attachment H): The questionnaire will collect quantitative and qualitative data pertaining to: State grantees' development and dissemination of informational materials to increase awareness of ASD and other DD among professionals and the public; ASD-related trainings that were developed and/or implemented by State grantees using CAAI funds; efforts to monitor screening rates and diagnostic practices, including any documented changes in screening rates or wait times for diagnostic evaluations; efforts to improve systems of care, using MCHB's quality indicators.

Resource Centers

DGIS Performance Measures #24, 26, 27, and 59 (OMB # 0915-0298)

Semi-structured interview protocol: Training Resource Center (Attachment I): The National Interdisciplinary Training Resource Center is charged with providing technical assistance to the LEND and DBP grant programs, disseminating information to grantees, and promoting collaboration across grant programs. The study will gather information about AUCD's efforts in these areas through a one-time in-depth interview with a key representative from AUCD.

Semi-structured interview protocol: State Public Health Coordinating Resource Center (Attachment J): To supplement the performance measure data and the information collected from the State Implementation grantees, a one-time interview with a representative from the State Public Health Coordinating Resource Center will be conducted in the summer of 2014. This interview will gather information on the Coordinating Resource Center's efforts to support and assist States in developing a system of care to improve the health of individuals with autism spectrum disorders (ASD) and other developmental disabilities.

This information collection request seeks approval for the six semi-structured interview protocols (Attachments B, C, D, G, I, J) and the two questionnaires (Attachments F and H).

The questionnaires will primarily gather information about quantifiable outputs and outcomes, whereas the interviews will gather more descriptive information about each grant program's activities, challenges they encountered during the grant, examples of their 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 HRSA and for Congress.

Who will use the information?

The information gathered through this data collection effort will inform the DHHS' Inter-agency Report to Congress, which requires "a description of the progress made in implementing the provisions of the Combating Autism Act of 2006." (For full list of the legislative requirements, see Appendix A).

A.3. Use of Information Technology and Burden Reduction

Questionnaire data for the Research and the State Implementation grant programs will be collected via an online survey tool. All semi-structured interviews will be conducted by phone.

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

There are no other HRSA/MCHB data collection activities that are measuring the progress of CAAI grantees in meeting the objectives of the CARA. The information being collected is not available elsewhere.

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 the DHHS 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 in the *Federal Register* on August 23, 2013, Volume 78, Number 164, pages 52,536 – 52,537. 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 grantees and/or the program officers from each funded program between April and October 2013. Table 1 below lists all persons who were consulted and offered input on the interview protocols and/or the questionnaires.

Table 1. Persons consulted on data collection instruments

Instrument	Name	Affiliated entity	Title	Contact Information Telephone Number Email address
LEND, DBP and AUCD interview protocols	Jamie Perry	AUCD	MCHB Technical Assistance Director	301-588-8252 jperry@aucd.org
	Robyn Schulhof	MCHB	Senior Public Health Analyst	301-443-0258 rschulhof@hrsa.gov
State Implementation interview protocol and questionnaire	Leolinda Parlin	HI Pediatric Assn, Research and Education Foundation	Co-Principal Investigator	808-282-6348 leolinda@resqconsultants.com
	Toni G. Wall	ME DHHS	Director, CSHN Program	207-287-5350 toni.g.wall@maine.gov
Research Network and R40 interview protocol	Hae Young	MCHB	Senior Public Health Analyst	301-443-2127 hpark@hrsa.gov
AMCHP interview protocol	Treeby Brown	AMCHP	Associate Director, Children's & Adolescent Health	202-266-3053 tbrown@amchp.org

There were no major problems that could not be resolved during consultation.

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 are shown in Table 2. These estimates are based on previous experience with instruments included in the prior OMB submission, as well as comments received from those individuals listed in Table 1. We plan to interview the Principal Investigator or Project Director from each grant program. The questionnaires for the Research Programs and the State Implementation grants will be completed by Research Assistants for the Principal Investigator.

Wage rates were determined based on May 2012 national occupational and wage estimates from the Bureau of Labor Statistics. For the interviews with AUCD, the Training programs and Research program grantees, the cost estimates are based on the national mean hourly wage for a Medical Scientist.² For the interviews with the State Implementation Program Principal Investigators and AMCHP, the cost estimates are based on the national mean hourly wage for health services managers³. For the Research and State Implementation program questionnaires, the cost estimates are based on the national mean hourly wage for social science research assistants⁴.

² Occupation code 19-1040. See http://www.bls.gov/oes/current/oes_nat.htm#19-0000

³ Occupation code 11-9111.

⁴ Occupation code 19-4061.

Table 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	43	1	43	1	43	\$41.85	\$1,799.55
DBP Interview Protocol	10	1	10	1	10	\$41.85	\$418.50
State Implementation Program Interview Protocol ⁵	13	1	13	1	13	\$47.34	\$615.42
State Implementation Program Questionnaire	13	1	13	1	13	\$19.60	\$253.50
Research Network Interview Protocol	3	1	3	1	3	\$41.85	\$125.55
Research Program R40 Interview Protocol	20	1	20	.75	15	\$41.85	\$627.75
Research Network Questionnaire	3	1	3	1	3	\$19.60	\$58.80
Resource Center: AUCD Interview Protocol	1	1	1	1	1	\$41.85	\$41.85
Resource Center: AMCHP Interview Protocol	1	1	1	1	1	\$47.34	\$47.34
Total	107		107				\$3,988.26

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 three year contract that is devoted to the evaluation data collection and analysis efforts at \$240,000. In addition, the cost is estimated to include approximately 20% of the federal project officers’ time estimated for an O-5 PHS Commissioned Officer is approximately \$15,000. The total estimated cost is approximately \$255,000.

⁵ Although a total of 22 State grants have been awarded to date, States that were awarded grants in 2008 and 2009 were interviewed during the previous evaluation. We are seeking clearance to interview only the 13 States that were awarded grants in 2011.

A.15. Explanation for Program Changes or Adjustments

The current evaluation will use the same design and data collection methods as the prior evaluation, with some minor updates to the interview protocols based on program revisions. Many of the grantees, however, have changed since the prior study, and other CAAI-supported programs that were not previously subject to formal evaluation will be included in the current evaluation. Specifically, the evaluation will include the two Resource Centers that are charged with providing grantees with technical support and promoting coordination across grant programs. These two Centers- AUCD and AMCHP, were not formally evaluated in the prior study. Also, the MCH Autism Intervention Research program now includes three components: the Autism Intervention Research Network on Physical Health (AIR-P), the Autism Intervention Research Network on Behavioral Health (AIR-B) and a third, new program, the Developmental Behavioral Pediatrics Research Network (DBPNet). Whereas the prior evaluation included the AIR-P and AIR-B Networks, the current evaluation has been expanded to include DBP-Net. Finally, some of the grantees that were part of the previous evaluation no longer have funding and therefore, they will not be part of the current data collection effort. The table below illustrates the number of new or continuing grantees who are part of the current evaluation, by grant program.

	Previous grantees not in current evaluation	New or continuing grantees included in current evaluation
LEND	2	43
DBP	5	10
Research Program Networks		3
R40 grantees	7	13

Also, though the total number of grantees has increased since the prior evaluation, the estimated burden level is lower. This change in estimated burden is based on our experience from the last data collection effort. We had anticipated that we might need to speak with up to six team members from each grant, to ensure that the full range of questions could be answered. However, during the interview process, we realized that the Principal Investigator of each grant was sufficiently knowledgeable about all aspects of the grant to address all research questions. The current request, therefore, assumes just one respondent per grant.

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

All data must be collected by September 2014 to ensure inclusion in the March 2015 Report to Congress. The proposed schedule for the information collection is show below in Table 2.

Table 2. Estimated Time Schedule for Data Collection, Analysis and Publication

Activity	Time Schedule
Develop data collection tools	June 2013
Receive OMB approval	March/April 2014 (anticipated)
Interviews scheduled and conducted	Spring/Summer 2014
Questionnaires administered and collected	July 2014

<ul style="list-style-type: none"> • Research Network Questionnaire • R40 Program Questionnaire • State Questionnaire 	
Data Analysis	Summer/Fall 2014
Final Report to HRSA	March 2015
Final Report to Congress	March 2015

Final reports will be submitted to HRSA/MCHB in March 2015. Additionally, the results will be published in a Report to Congress in March 2015.

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).