collection includes blood, urine, and saliva. The postmortem collection includes the brain, spinal cord, cerebral spinal fluid (CSF), bone, muscle, and skin.

In addition to fulfilling the two-part Congressional mandate, the Registry is designed to be a tool for ALS researchers. Now that the Registry has matured, ATSDR has made data and specimens available to approved researchers and has added a respondent type. Researchers can request access to specimens, data, or both collected by the National ALS Registry for their research projects. ATSDR will review applications for scientific validity and human subjects' protection and make data/specimens available to approved researchers. ATSDR is collaborating with ALS service organizations to conduct outreach activities through their local chapters and districts as well as on a national level. They provide ATSDR with information on their outreach efforts in support of the Registry on a monthly basis.

There are no costs to the respondents other than their time. Participation in this proposed information collection is completely voluntary. The total number of burden hours requested is 1,946 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Person with ALS	ALS Case Validation Questions	1,670	1	2/60	56
	ALS Case Registration Form	1,500	1	10/60	250
	Voluntary Survey Modules	750	1	85/60	1,063
	Disease Progression Survey*	750	3	5/60	188
	ALS Biorepository Specimen Processing Form and In-Home Collection.	325	1	30/60	163
	ALS Biorepository Saliva Collection	350	1	10/60	59
Researchers	ALS Registry Research Application Form	36	1	30/60	18
	Annual Update	24	1	15/60	6
ALS Service Organization.	Chapter/District Outreach Reporting Form	135	12	5/60	135
	National Office Outreach Reporting Form	2	12	20/60	8
Total					1,946

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[FR Doc. 2019–10836 Filed 5–23–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–1171; Docket No. CDC–2019–0036]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Study to Explore Early Development (SEED) Phase 3. This study evaluates potential risk factors for Autism Spectrum Disorders (ASD) and the behavioral and health characteristics of children with autism by conducting a case control study to compare them with children who have other developmental disabilities and children from the general population.

DATES: CDC must receive written comments on or before July 23, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0036 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Lead, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.
- *Instructions:* All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

*Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Study to Explore Early Development (SEED) Phase 3—Extension—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Autism spectrum disorders (ASD) are group of neurodevelopmental disorders characterized by qualitative impairments in social interaction, and communication and stereotyped behaviors and interests. Recent systematic population surveys and routine monitoring systems in the U.S. and other countries indicate the prevalence to be 1–2%. Apart from the identification of some rare genetic conditions that are commonly associated with autism, causal mechanisms for the disorder remain largely unknown.

The Children's Health Act of 2000 mandated CDC to establish autism surveillance and research programs to address the number, incidence, and causes of autism and related developmental disabilities. Under the provisions of this act, NCBDDD funded five Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) through program announcements in FY2001 and FY2002; CDC's NCBDDD served as the sixth CADDRE site.

For the first funding cycle (2001–2006), each CADDRE grantee had three core objectives: To develop a protocol for a multi-site collaborative epidemiologic study focused on autism (which was eventually named the Study to Explore Early Development [SEED]); to conduct surveillance of autism and other developmental disabilities; and to conduct site-specific investigator initiated studies on autism. In FY 2006, through a second CADDRE funding cycle, five grantees were awarded. The CADDRE activities for the second funding cycle (2006–2011) were limited to implementation of the first phase of SEED (subsequently known as SEED 1). CDC served as the sixth CADDRE SEED 1 site during this period. A second phase of SEED (SEED 2) was funded under a third funding cycle (2011–2016). Five CADDRE grantees received the awards. Again, CDC served as the sixth SEED 2 site.

A third phase of SEED (SEED 3) was funded in July 2016. Five extramural sites were funded. Together with the CDC, they are implementing the SEED 3 collaborative protocol. The SEED 3 protocol for identification of study participants, recruitment, and study data collection flow is similar to the protocols for SEED 1 and 2. CDC obtained approval to collect information for SEED 3 in 2017 (OMB 0920–1171). The current request is to obtain an extension of this approval so that data collection may continue beyond the current expiration date of 3/31/2020.

While all SEED phases have the same research goals and the same basic study design, data collection was greatly streamlined and revised between SEED 1, SEED 2, and SEED 3. Many study instruments and data collection components included in the SEED 1 protocol are not included in the SEED 3 protocol; two instruments included in the SEED 3 protocol were developed subsequent to SEED 1 to capture an abbreviated version of information that had been included on some of the discontinued SEED 1 forms and to capture some additional information overlooked in the SEED 1 protocol; and instruments included in all phases of SEED underwent review and minor revision subsequent to SEED 1 to address ambiguities and difficulties experienced during SEED 1 data collection. No additional changes are requested from the SEED 3 protocol that initially obtained OMB approval. Implementing this phase of SEED will increase the total SEED pooled sample size for investigation of high priority hypotheses. Maintaining the same basic study design and general protocol integrity will ensure that data pooling can be achieved across SEED phases.

Families will be identified from each of the three groups: Autism Spectrum Disorder (ASD), other developmental delay or disorder comparison group (DD), and a second comparison group of children randomly drawn from the entire study cohort population (POP). It is expected that the six SEED 3 study sites will enroll a total of 2,106 children and complete the study protocol. The data collection will take approximately nine hours 10 minutes (ASD group); five hours 30 minutes (POP group); two hours 45 minutes (DD group) to complete, which includes: (1) Maternal telephone interview with questions about maternal reproductive history and pregnancy with the index child, (2) parent-completed questionnaires about parental and child health and child development, (3) in-person child developmental evaluation, (4) maternal and child anthropometry measurements, and (5) biosampling from biological parents and child. There are no costs to participants other than their time. The total estimated annual burden hours are 7,118.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Mother, ASD workflow. *All potential participants sent mailing.*	Invitation Packet/Response Card	1,718	1	10/60	286
Mother, ASD workflow. *Potentially eligible with contact by study staff.*	Invitation Call Script and Social Communication Questionnaire.	859	1	30/60	430
Mother, ASD workflow. *Eligible, consented, and enrolled; assigned to the ASD workflow based on enrollment intake.*	Enrollment Packet	469	1	20/60	156
Mother, ASD workflow. *Completed this study step.*	Follow-up Phone Call Script and Checklist and Pregnancy Reference Form.	422	1	15/60	106

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Mother, ASD workflow. *Completed this study step.*	Maternal Interview Call	422	1	1	422
Mother, ASD workflow. *Completed this study step.*	Self-Administered Forms	375	1	105/60	656
Mother, ASD workflow. *Completed this study step.*	Follow-up Call 2	375	1	20/60	125
Mother, ASD workflow. *Completed this study step.*	Clinic/Home Visit—Developmental Assessment, saliva collection, overall consent.	328	1	225/60	1,230
Father, ASD workflow. *Completed this study step.*	Clinic/Home Visit—Saliva Collection	164	1	15/60	41
Child, ASD workflow. *Completed this study step.*	Clinic/Home Visit—Developmental Assessment.	328	1	135/60	738
Mother, POP workflow. *All potential participants sent mailing.*	Invitation Packet/Response Card	1,466	1	10/60	244
Mother , POP workflow. *Potentially eligible with contact by study staff.*	Invitation Call Script and Social Communication Questionnaire.	733	1	30/60	367
Mother , POP workflow. *Eligible, consented, and enrolled; assigned to the POP workflow based on enrollment intake.*	Enrollment Packet	334	1	20/60	111
Mother, POP workflow. *Completed this study step.*	Follow-up Phone Call Script and Checklist and Pregnancy Reference Form.	301	1	15/60	75
Mother, POP workflow. *Completed this study step.*	Maternal Interview Call	301	1	1	301
Mother, POP workflow. *Completed this study step.*	Self-Administered Forms	267	1	105/60	467
Mother, POP workflow. *Completed this study step.*	Follow-up Call 2	267	1	20/60	89
Mother, POP workflow. *Completed this study step.*	Developmental Assessment, saliva collection, overall consent.	234	1	50/60	195
Father, POP workflow. *Completed this study step.*	Clinic/Home Visit—Saliva Collection	117	1	15/60	29
Child, POP workflow. *Completed this study step.*	Clinic/Home Visit—Developmental Assessment, saliva collection.	234	1	90/60	351
Mother, DD workflow. *All potential participants sent mailing.*	Invitation Packet/Response Card	641	1	10/60	107
Mother, DD workflow. *Potentially eligible with contact by study staff.*	Invitation Call Script and SCQ	321	1	30/60	161
Mother, DD workflow. *Eligible, consented, and enrolled; assigned to the DD workflow based on enrollment intake.*	Enrollment Packet	175	1	20/60	58
Mother, DD workflow. *Completed this study step.*	Follow-up Phone Call Script, and Checklist and Pregnancy Reference Form.	158	1	15/60	40
Mother, DD workflow. *Completed this study step.*	Maternal Interview Call	158	1	1	158
Mother, DD workflow. *Completed this study step.*	Self-Administered Forms	140	1	55/60	128
Mother, DD workflow. *Completed this study step.*	Follow-up Call 2	140	1	20/60	47
Total					7,118

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[FR Doc. 2019–10839 Filed 5–23–19; 8:45 am]

BILLING CODE 4163–18–P