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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[30Day-19-1171]**

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Study to Explore Early Development (SEED) Phase 3 to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on May 24, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) 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;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) 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 submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

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 a 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 largely remain 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 10 hours

35 minutes (ASD group); six hours 55 minutes (POP group); two hours 30 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)
Mother, ASD workflow <i>All potential participants sent mailing</i>	Invitation Packet/Response Card (Attachment 10a,d,g)	1,718	1	10/60
Mother, ASD workflow <i>Potentially eligible with contact by study staff</i>	Invitation Call Script and Social Communication Questionnaire (Attachment 11a) (Attachment 3)	859	1	30/60
Mother, ASD workflow <i>Eligible,</i>	Enrollment Packet (Attachment	469	1	20/60

<i>consented, and enrolled; assigned to the ASD workflow based on enrollment intake</i>	t 12a, c, d)			
Mother, ASD workflow Completed this study step	Follow-up Phone Call Script and Checklist (Attachment 13) and Pregnancy Reference Form and 5 a, b)	422	1	15/60
Mother, ASD workflow Completed this study step	Maternal Interview Call (Attachment 4)	422	1	1
Mother, ASD workflow Completed this study step	Self-Administered Forms (Attachment 6a-e, 6f or 6g, 6h-i, 6k-l, and 6o-p)	375	1	105/60
Mother, ASD workflow Completed this study step	Follow-up Call 2 (Attachment 14)	375	1	20/60
Mother, ASD workflow Completed this study step	Clinic / Home Visit - Developmental Assessment (Attachment 7b,c, g), saliva collection (Attachment 8a-d), overall	328	1	225/60

	consent (Attachment 15a)			
Father, ASD workflow <i>Completed this study step</i>	Clinic / Home Visit - Saliva Collection (Attachments 8b-d)	164	1	15/60
Child, ASD workflow <i>Completed this study step</i>	Clinic / Home Visit - Developmental Assessment (attachment 7a, 7d or 7e or 7f) and saliva collection (8a-d)	328	1	135/60
Mother, POP workflow <i>All potential participants sent mailing</i>	Invitation Packet/Res ponse Card (Attachments 10c, 10f, and 10g)	1,466	1	10/60
Mother , POP workflow <i>Potentially eligible with contact by study staff</i>	Invitation Call Script (Attachment 11c) and Social Communication Questionnaire (Attachment 3)	733	1	30/60
Mother , POP workflow <i>Eligible, consented, and enrolled;</i>	Enrollment Packet (Attachments 12a, c, d)	334	1	20/60

<i>assigned to the POP workflow based on enrollment intake</i>				
Mother, POP workflow Completed this study step	Follow-up Phone Call Script and Checklist (Attachment 13) and Pregnancy Reference Form Attachments 5a and 5b)	301	1	15/60
Mother, POP workflow Completed this study step	Maternal Interview Call (Attachment 4)	301	1	1
Mother, POP workflow Completed this study step	Self-Administered Forms (Attachment 6a-e, 6f or 6g, 6h-i, 6k, 6n-p)	267	1	105/60
Mother, POP workflow Completed this study step	Follow-up Call 2 (Attachment 14)	267	1	20/60
Mother, POP workflow Completed this study step	Developmental Assessment saliva collection (Attachment 8a-d), overall consent (Attachment 15c)	234	1	50/60
Father, POP workflow Completed	Clinic / Home Visit - Saliva	117	1	15/60

<i>this study step</i>	Collection (Attachments 8b-d)			
Child, POP workflow <i>Completed this study step</i>	Clinic / Home Visit - Developmental Assessment Attachment 7a-c), saliva collection (Attachment 8a-d)	234	1	90/60
Mother, DD workflow <i>All potential participants sent mailing</i>	Invitation Packet/Response Card (Attachments 10b, 10e, and 10g)	641	1	10/60
Mother, DD workflow <i>Potentially eligible with contact by study staff</i>	Invitation Call Script (Attachment 11b) and SCQ (Attachment 3)	321	1	30/60
Mother, DD workflow <i>Eligible, consented, and enrolled; assigned to the DD workflow based on enrollment intake</i>	Enrollment Packet (Attachment 12b-d)	175	1	20/60
Mother, DD workflow <i>Completed this study step</i>	Follow-up Phone Call Script (Attachment 13) and Checklist and	158	1	15/60

	Pregnancy Reference Form (Attachments 5a and 5b)			
Mother, DD workflow Completed this study step	Maternal Interview Call (Attachment 4)	158	1	1
Mother, DD workflow Completed this study step	Self-Administered Forms (Attachments 6a-d, 6j, 6m, and 6o-p)	140	1	55/60
Mother, DD workflow Completed this study step	Follow-up Call 2 (Attachment 15b)	140	1	20/60

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