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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-17ADR; Docket No. CDC-2017-0042]

Proposed Data Collections 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 to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the Study to Explore Early Development, Teen Follow-Up Study (SEED Teen).

DATES: Written comments must be received on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2017-0042 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.

- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 6501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of the information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Registry concerning each proposed collection of the

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 OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on:

- (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;
- (b) the accuracy of the agency's estimate of the burden of the proposed collection of information;
- (c) ways to enhance the quality, utility, and clarity of the information to be collected;
- (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and
- (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to

develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Study to Explore Early Development, Teen Follow-Up Study (SEED Teen) - New - National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Autism spectrum disorder (ASD) is a neurodevelopmental disorder characterized by impairments in social interaction and communication and stereotyped behaviors and interests. The U.S. prevalence of ASD is estimated at 1% to 2%. In addition to the profound, lifelong impacts on individuals' functioning given the core deficits in social-communication abilities, a high proportion of children with ASD also have one or more other developmental impairments such as intellectual disability or attention-deficit-hyperactivity-disorder and children with ASDs have higher than expected prevalences of health conditions such

as obesity, asthma and respiratory disorders, eczema and skin allergies, migraine headaches, and gastrointestinal symptoms and disorders.

Historically, young children have been the focus of ASD research: diagnosis and symptom detection at young ages, prenatal or early-life risk factors, and the effect of early intervention programs. Meanwhile, the number of children diagnosed with ASD each year has steadily increased and, as children age, the prevalence of adults diagnosed with ASD will likewise increase for several decades. Despite this ongoing demographic shift –which some have called “the autism tsunami”– there has been relatively little research on ASD in adolescence and adulthood.

While there is research showing that the majority of ASD diagnoses made in early childhood are retained in adolescence with mostly stable in symptom severity, there are major gaps in our understanding of the health, functioning, and experiences of adolescents with ASD and other developmental disabilities. Many of these topics are especially relevant to public health: adolescents and adults with ASD have been shown to have frequent health problems, high healthcare utilization and specialized service needs, high caregiving burden, require substantial supports to perform daily activities, are likely to be bullied, or isolated from society, and are likely to have food allergies

or put on restrictive diets of questionable benefit. Many of these problems emerge after early childhood, and more studies are needed to estimate the frequency, severity, and predictive factors for these important outcomes in diverse cohorts of individuals with autism and other developmental conditions.

SEED Teen is a follow-up study of children who participated in the first phase of the SEED case-control study (SEED 1) in 2007-2011 when they were 2 to 5 years of age. SEED includes one of the largest cohorts of children assembled with ASD. Children will be identified from four SEED sites in Georgia, Maryland, North Carolina, and Pennsylvania. Three groups of children will be included: children with ASD, children with other developmental (non-ASD) conditions (DD comparison group), and children from the general population who were initially sampled from birth records (POP comparison group).

The children and parents previously enrolled in SEED 1 represent a unique opportunity to better understand the long-term trajectory of children identified as having ASD at early ages. Mothers or other primary caregivers who participated in SEED 1 will be re-contacted when their child is 13-17 years of age and asked to complete two self-administered questionnaires (SEED Teen Health and Development Survey and the Social Responsiveness Scale) about their child's health, development, education, and current functioning. Information from this study

will allow researchers to assess the long-term health and functioning of children with ASD and other developmental disabilities, family impacts associated with ASD and other DDs, and service needs and use associated with having and ASD and other DDs, particularly during the teen years.

We estimate that 1,410 SEED families are potentially eligible to participate in SEED Teen. Reading the letter and other materials in the invitation mailing will take approximately five minutes. We estimate that a minimum of 60% of parents/caregivers sent the invitation mailing or will be successfully contacted and participate in the invitation call (approximately 15 minutes). We estimate that 80% of the families who participate in the invitation call will meet the eligibility criteria for SEED Teen and 70% of those will enroll in SEED Teen. We assume all enrolled families will complete the follow-up call to confirm data collection packet receipt (approximately 10 minutes) and will review the materials in the data collection packet. Finally, we estimate that 90% of enrolled parents/caregivers will complete two self-administered questionnaires (SEED Teen Health and Development Survey and the Social Responsiveness Scale) and two supplemental consent forms. The two questionnaires will take approximately 60 minutes to complete, plus an additional 5 minutes to read and sign the informed consent. Therefore, we estimate the total burden hours

are 911. There are no costs to participants other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Eligible families who were enrolled in SEED 1	Invitation Packet	1,410	1	5/60	118
Eligible families who were enrolled in SEED 1	Invitation Call Script	846	1	15/60	212
Families who agreed to participate in SEED Teen	Follow-up Call Checklist	474	1	10/60	79
Families who agreed to participate in SEED Teen	Data Collection Packet	474	1	5/60	40
Families who agreed to participate in SEED Teen	SEED Teen Health and Development Survey	427	1	40/60	284

Families who agreed to participate in SEED Teen	Social Responsiveness Scale	427	1	20/60	142
Families who agreed to participate in SEED Teen	Supplemental Consent Forms	427	1	5/60	36
TOTAL					911

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