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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-21IK; Docket No. CDC-2021-0107]

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) Follow-up Studies. This follow-up study will allow CDC to better understand the developmental trajectory of children with autism spectrum disorder, their health outcomes and co-occurring conditions at older ages, and the associated early predictors of these outcomes, including intellectual abilities.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0107 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, 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 copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: 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 (https://www.federalregister.gov/)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;
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; and
5. Assess information collection costs.

Proposed Project

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

Background and Brief Description

In 2016, an estimated one in 54 children, eight years of age living in 11 communities across the United States, had autism spectrum disorder (ASD), a developmental disability that can cause significant social, communication, and behavior challenges. Total annual costs associated with ASD have been estimated between $11.5 - $60.9 billion, yet major gaps in knowledge remain about risk factors for ASD, and associated challenges and needs for persons with ASD and their families. Additionally, while most research on ASD has focused on children, ASD is considered a lifelong condition, and although an estimated 70,000 to 111,000 youth with ASD turn 18 years of age annually, little is known about the transition to adolescence and adulthood for persons with ASD. Despite the call to address transition and lifespan issues in the Autism CARES Acts of 2014 and 2019, only 2% of ASD funding from 2008 to 2018 was spent on lifespan issues.

The 2016-2017 Interagency Autism Coordinating Committee (IACC) Strategic Plan highlighted the need for more information

about the services and support needed to maximize the quality of life for people on the autism spectrum, especially as individuals with ASD progress into adulthood.

The current information collection request is to conduct longitudinal follow-up studies of SEED 1-3 participants at older ages, thereby addressing the priorities established in the Autism CARES Acts of 2014 and 2019, and the need for research highlighted in the IACC Strategic Plan. Given the size of the original SEED birth cohorts and the wealth of baseline information collected, a follow-up study of participants can help us address the research gaps described above. The information collected from this study will allow us to better understand the developmental trajectory of children with ASD, their health outcomes and co-occurring conditions at older ages, and the associated early predictors of these outcomes, including intellectual abilities.

The data collected in this study also provides the opportunity to obtain important self-reported measures of well-being among young adults with ASD. Recent evidence suggests that individuals with ASD with average to above average levels of intellectual functioning may still struggle with activities of daily living. Yet, adults with special needs are often required to have an intellectual disability in order to qualify for services. This data will allow investigators to describe the gap between intellectual ability and daily living skills in adolescents with ASD to inform public policies on eligibility

for services. Additionally, because most SEED 1 participants will reach young adulthood (i.e., age 18 years) in years 2021-2026, data collected through this study will provide an opportunity to assess changes in service access and utilization that may occur following high school exit. This period is particularly challenging for young adults with ASD who can experience poor outcomes across multiple domains (e.g., employment, education, social engagement, independent living, and access to health and mental health care services in association with the loss of well-integrated school-based services). Hence, through surveying SEED 1 participants before and after their anticipated exit from high school, data collected through this study could provide important information on the loss of services and emerging issues that can inform service delivery and programs on the support needed to achieve greater independence.

Initial follow-up surveys of SEED participants will be conducted with the parents of the children who previously participated in SEED because it is the parents who provided consent for follow-up studies. However, many emerging issues surrounding the transition to adulthood among adolescents with ASD require self, rather than parental report (e.g., self-reported symptoms of anxiety, depression, quality of life, social camouflaging, gender identity, sexuality, and relationships). Children who originally participated at age 2-5 years, who are now adolescents and young adults, will be

contacted through their parents and asked if they wish to provide informed consent for participation in surveys.

CDC requests OMB approval for an estimated 6,193 annual burden hours. There are no costs to respondents other than their time to participate.

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 Hours
Parent	Review of invitation letter and call script for first follow-up survey	5,850	1	10/60	975
Parent	First follow-up core survey of SEED 1-3 parents	3,900	1	40/60	2,600
Parent	First follow-up survey supplement for parents of children	1,300	1	20/60	433
Parent	First follow-up survey supplement for parents of adolescents	1,300	1	20/60	433
Parent	First follow-up	1,300	1	20/60	433

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
	survey supplement for parents of adults				
Parent	Second follow-up survey of SEED 1 parents	1,105	1	10/60	184
Adult Child	Invitation and informed consent script	520	1	10/60	87
Adult Child	Second follow-up survey of SEED 1 adult children	520	1	30/60	260
Children age 8-22 years or their parents	Parents or adult children receiving informed consent or assent script	472	1	10/60	79
Children age 8-22 years	In-person assessment of intellectual abilities	472	1	90/60	708
TOTAL					6,193

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

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