Supporting Statement Part A

The Study to Explore Early Development (SEED) Follow-up Study

New

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Goal of the project: The goal of this project is to gain knowledge about the expression of autism spectrum disorder (ASD) from childhood through early adulthood that can inform efforts to improve the health and functioning of individuals with ASD as they mature. This will be completed through longitudinal follow-up of previous participants of the Study to Explore Early Development (SEED), a multi-phase, multi-site, case-control study of children originally identified at age 2-5 years with ASD, other developmental disabilities (DD), or from the general population (POP). Information will be obtained on these participants through early adulthood on their health and functioning, service use and needs, and the impact of ASD on their families.

Intended use of the resulting data: Information on the characteristics and needs of persons with ASD as they mature and their families will inform strategies to prevent the often-debilitating outcomes associated with ASD, as well as strategies to improve the health and functioning of individuals with ASD as they mature. Data obtained through this information collection may improve our understanding of which co-occurring conditions are most prevalent; increase our understanding of the needs of individuals with ASD, and how these needs change with age and can be best met at different points in development; and inform research and public health policies. Specifically, information collected will provide data to inform policies on eligibility for services and public health outreach efforts that could provide opportunities for education, employment, and social connection to improve the health, functioning, and quality of life among persons with ASD and their families.

Methods to be used to collect: The SEED Follow-up Study will collect information from families through surveys on the health and functioning of individuals during childhood, adolescence, and young adulthood, and in-person assessments of cognitive abilities.

The subpopulation to be studied: Guardians of children, adolescents, and young adults with ASD, other developmental disabilities (DD), and from the general population (POP) age 6 to 22 years, who initially participated in SEED when their children were age 2-5 years, will be invited to participate in follow-up surveys. Guardians of the original SEED participants who are now young adults will be invited to complete an additional survey, and the young adults will also be asked to complete their own survey. A subset of original SEED child participants, now age 8-22 years will be invited to participate in an in-person assessment of cognitive abilities.

How the data will be analyzed: Data from this information collection will be combined with data from the original SEED data set to characterize when changes occur over time and the factors associated with these changes among persons identified at age 2-5 years with ASD, other DDs or from the general population. Statistical testing will include generalized estimating equations (GEE) for repeated measures analysis GEE and mixed-effects models.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This Information Collection Request is submitted under the classification “New.” The length of data collection requested for OMB-PRA approval is 3 years.

The National Center on Birth Defects and Developmental Disabilities (NCBDDD) at CDC is making this information collection request as authorized by Section 301(a) [42 U.S.C. Section 241(a)] and 317C of the Public Health Service Act [42 U.S.C. 247b-4], as amended (**Attachment 1a**); Pub. Law No. 106-310, Children’s Health Act of 2000 (**Attachment 1b**); Pub. Law No. 109-416 (**Attachment 1c**), Combating Autism Act of 2006; Pub. Law No. 113-157, Autism CARES Act of 2014 (**Attachment 1d**); and the Pub. Law No. 116-60, Autism CARES Act of 2019 (**Attachment 1e**).

Background

The Study to Explore Early Development (SEED) was established to address the Children's Health Act of 2000 (Pub. Law No. 106-310; **Attachment 1b**), which mandated CDC to conduct ASD surveillance and implement research programs to address the number, incidence, and causes of ASD and related developmental disabilities. Under this legislation, CDC's National Center on Birth Defects and Developmental Disabilities funded a network of university centers to develop and implement SEED, a multi-phase, multi-site, case-control study comparing children ages 2-5 years with ASD, to children with other non-ASD developmental disabilities (DD), and from the general population (POP). Through further congressional mandates [Pub. Law No. 109-416 (**Attachment 1c**), Combating Autism Act of 2006; Pub. Law No. 113-157, Autism CARES Act of 2014 (**Attachment 1d**); and the Pub. Law No. 116-60, Autism CARES Act of 2019 (**Attachment 1e**)], SEED has been continued for three phases (SEED 1: 2006-2011, SEED 2: 2011-2016, and SEED 3: 2016-2021). The OMB control numbers are 0920-0741 for SEED 1, and 0920-1171 for SEED 3; please note SEED 2 inadvertently received a clinical exemption and thus did not go through OMB review. A follow-up pilot study of SEED 1 participants, known as SEED Teen (OMB control number 0920-1219), was also conducted during the same time as SEED 3.

In 2016, an estimated 1 in 54 children 8 years of age living in 11 communities across the United States had autism spectrum disorder (ASD) [1], 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 (2011 US dollars) [2], yet major gaps in knowledge remain about risk factors for ASD, and associated challenges and needs for persons with ASD and their families [3]. 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 [4], little is known about the transition to adolescence and adulthood for persons with ASD [5]. Despite the call to address transition and lifespan issues in the Autism CARES Acts of 2014 and 2019 (**Attachment 1d-e**), only 2% of ASD funding from 2008-2018 was spent on lifespan issues [6]. The 2016-2017 Interagency Autism Coordinating Committee (IACC) Strategic Plan highlighted the need for more information about the services and supports needed to maximize the quality of life for people on the autism spectrum, especially as individuals with ASD progress into adulthood [6].

This information collection is being funded through cooperative agreement CDC-RFA-DD21-001. It is a longitudinal follow-up of participants who participated in SEED Phases 1, 2, and 3. Each phase of SEED was funded by CDC through the following cooperative agreements: CDC-RFA-DD06-003 (Phase 1, 2007-

2012), CDC-RFA-DD11-002 (Phase 2, 2012-2016), and CDC-RFA-DD16-001 (Phase 3, 2017-2021). SEED Teen was also funded through cooperative agreement CDC-RFA-DD16-001 as a pilot for the proposed follow-up study in order to show feasibility for implementing the currently proposed information collection.

2. Purpose and Use of the Information Collection

The purpose of this information collection is to conduct longitudinal follow-up studies of SEED 1-3 participants as they mature, 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.

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. 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, sexuality, and relationships). Hence children who originally participated at age 2-5 years, and are now young adults, will be contacted through their parents and asked if they wish to provide informed consent for participation in surveys. Thus, the information 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 [7-10]. Yet, adults with special needs are often required to have an intellectual disability in order to qualify for services. This information collection 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, the information collected 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 (i.e., employment, education, social engagement, independent living, and access to health and mental health care services [11, 12] in association with the loss of well-integrated school-based services [13, 14]. Hence, surveying SEED 1 participants before and after their anticipated exit from high school, will provide important information on the loss of services and emerging issues that can inform service delivery and programs on the supports needed to achieve greater independence.

Information on the characteristics and needs of persons with ASD as they mature and their families will inform strategies to prevent the often-debilitating outcomes associated with ASD, as well as strategies to improve the health and functioning of individuals with ASD as they age. Data obtained through this information collection may improve our understanding of which co-occurring conditions are most prevalent; increase our understanding of the needs of individuals with ASD, and how these needs change with age and can be best met at different points in development; and inform research and public health policies. Specifically, information collected will provide data to inform public policies on eligibility for needed services and public health outreach efforts that could provide opportunities for education, employment, and social connection to improve the health, functioning, and quality of life among persons with ASD and their families.

3. Use of Improved Information Technology and Burden Reduction

SEED will apply information technology broadly to collect data efficiently, to assure both the quality of the collected data and the privacy and security of the collected data, and to minimize the burden to the study participants. All data will be collected using advanced information technology, unless participants specifically request the use of paper surveys.

SEED Follow-up participants will have the options to complete the study instruments online, on paper, or by telephone with a study team member. Study staff will encourage participants to complete the study instruments online, when possible, to maximize the use of information technology and automate skip patterns. For online administration, participants will receive a weblink and responses to questions will be automatically recorded in the database. In the case of missing or inconsistent responses, study staff may follow up with participants by phone.

Participants who prefer a telephone interview will schedule this interview with a study staff member. During the telephone interview, study staff will record responses from the participant for each study instrument directly into the REDCap system.

If participants indicate they are unable to complete the survey online or by phone, they will be given the option to complete the study instruments by mail. For those who choose to complete the survey via mail, study staff will mail the study instruments and prepaid return envelope. Study staff will enter data from the paper study instruments directly into the REDCap system. In the case of missing or inconsistent responses, study staff may follow up with participants by phone.

4. Efforts to Identify Duplication and Use of Similar Information

No similar data are gathered or maintained by CDC or are available from other sources known to CDC.

ASD is considered a lifelong condition and an estimated 70,000 to 111,000 youth with ASD turn 18 years of age annually [14]. Yet little is known about the transition to adolescence and adulthood for persons with ASD. In fact, the most recent data from the Interagency Autism Coordinating Committee (IACC) shows that only 3% of autism research dollars were focused on adults or "lifespan" issues (https://iacc.hhs.gov/apps/portfolio-analysis-web-tool/questions). In a 2019 report to Congress [6], the Office of Autism Research Coordination at the National Institutes of Health noted that "Additional information is needed to understand how to best meet the service needs of adults with autism as they continue their education, enter the workforce, seek appropriate housing, and otherwise live their lives to their maximum potential." (Report to Congress on Activities Related to Autism Spectrum Disorder and Other Developmental Disabilities (hhs.gov): https://iacc.hhs.gov/publications/report-to-congress/2018/report_to_congress_2018.pdf.

A recent systematic review of the literature conducted at CDC (manuscript in preparation), suggests there are a limited number of studies to date that assess longitudinal outcomes among children diagnosed with ASD in early childhood; those that exist are highly heterogeneous and have small samples sizes (N<100) [15-19]. Additionally, these studies lack relevant comparison groups to determine whether longitudinal changes in outcomes among children with ASD differ from those observed in children with other developmental disabilities or from the general population. In contrast, SEED has collected data from over 6,000 children identified as having ASD, DD, or from the general population and anticipates that roughly half of this sample will be participating in the longitudinal follow-up study. Approximately 1,000 will be from the ASD group (Table 1).

TABLE 1

Study	**Eligible Pool**	**Contacted (%)**	**Enrolled (%)**	**Completed sample size (%)**	**Time between follow-up**
SEED Teen (Pilot CDC study, OMB control number 0920-1219)	1674	1620 (97%)	1039 (64%)	867 (83%)	9-13 years
SEED Follow-up (currently proposed information collection)	6362	6174 (97%)	3951 (64%)	3703 (93%) (estimated)	2-16 years
Dudley et al. (2019) [15]	1710	529 (31%)	354 (67%)	274 (77%)	40 years
Smith et al. (2008) [16]	406	310 (76%)	262 (85%)	149 (57%)	2 years
Baghdadli et al. (2019) [17]	362	343 (95%)	281 (82%)	219 (78%)	3 years
Lounds et al. (2007) [18]	220	203 (92%)	168 (83%)	140 (83%)	4.5 years
Bal et al. (2019) [19]	214	140 (65%)	132 (94%)	98 (74%)	1, 6, & 10 years

In CDC's review of the literature key areas of research were also identified that are missing and needed to address the following key questions:

<u>Key Questions (KQ)</u>
KQ1: What are the changes or differences in health-related outcomes between children, adolescents, and young adults with ASD?
KQ2: What is the stability or variability in ASD-related symptomatology and functioning between children, adolescents, and young adults with ASD?
KQ3: Do service needs change or does access to needed services change between childhood, adolescence, or young adulthood?

Additionally, CDC further refined this search to focus on papers that examined key outcomes among children, adolescents, and adults with ASD including:

1. Physical Health – studies that examined bodily health and well-being such as obesity, diabetes, or physical activity.

2. Mental Health – studies that examined co-occurring psychiatric and mental health conditions and symptoms such as depression or anxiety.
3. Services Utilization – studies that examined health and mental health service use and/or need.
4. Employment and Post-Secondary Education – studies that examined outcomes related to work or schooling after leaving high school.
5. ASD-related Symptoms – studies that examined outcomes related to common characteristics and/or symptoms of autism spectrum disorder such as social deficits, repetitive behavior, executive function, or motor abilities.
6. Social Relationships – studies that examined social functioning including peer engagement and interaction, platonic relationships (i.e., friendship), and/or romantic relationships.
7. Autonomy – studies examining functional independence and skills including adaptive behavior, daily living skills, quality of life, and living situations.

From this literature review, authors concluded there is insufficient data available to address these important outcomes. Hence the SEED Follow-up Study will fill a critical gap.

5. Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will not be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

This information collection will fill gaps in our understanding of how autism affects young adults as they transition into adulthood. Understanding information about the services and supports needed will help maximize the quality of life for people with ASD and other developmental disabilities. The consequence of not collecting the information would be to have insufficient information to guide policies and the implementation of services and supports that can improve the quality of life for individuals with ASD and other developmental disabilities as they progress into adulthood.

For the first follow-up, each respondent will be asked to respond once. This information has not been collected previously. There are no legal obstacles to reduce the burden.

In addition to gaining information on the health and development of SEED 1-3 children as they age (through the first follow-up), this study also includes a second follow-up of SEED 1 parents and their young adult children who have recently graduated high school or aged-out of the school system (i.e., typically this occurs when child reaches 21 years old in most states in the U.S.).

A short (10 minute) repeat survey of caregivers of SEED 1 is essential for detecting changes in services before to after exit from high school. Although high school exit is a pivotal transition for all young adults, prior evidence suggests that life after high school exit is particularly challenging for young adults with ASD who often experience a precipitous loss of access to well-integrated school-based health and mental health care services [20] and limited employment and educational opportunities [21, 22]. The second follow-up survey for caregivers of SEED 1 participants will include questions about their child's loss or change in services, vocational training and support, transition to post-secondary education, daily activities, and social participation following high school exit. Information gathered from these questions will inform service delivery and programs about the supports needed to achieve greater independence in young adulthood.

The second follow-up survey for young adults (i.e., self-report survey) will include similar questions to those included in the caregiver-report survey about changes in service use and needs after high school exit; however, many additional issues that emerge during the transition to adulthood require self- rather than caregiver-report. Therefore, the self-report survey for young adults will also include questions on key outcomes such as anxiety and depression symptoms, suicidality, quality of life, social camouflaging, sexuality, and romantic relationships.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A copy of the agency's 60-day Federal Register Notice is attached (60-day Federal Register Notice, **Attachment 10**). The notice, as required by 5 CFR 1320.8 (d), was published on October 4, 2021. No public comments were received in response to this notice.

B. From July 1, 2021, to June 30, 2022, the following list of representatives from several organizations outside of CDC were consulted and asked to review the data collection instruments for this study (see Table 2 below). During this period, we consulted these representatives to ensure the data collection was not duplicative and that the study design, data elements, and instruments were appropriate. The principal investigators (PIs) at each of the SEED sites played an integral role in the design and development of the study. Additionally, CDC consulted with the following partner organizations: Autism Science Foundation, Autistic Self Advocacy Network, Autism Society, and Autism Speaks.

TABLE 2

Name	Title	Agency	Contact Information
Carolyn DiGuiseppi, MPH, MD, PhD	Principal Investigator for CO SEED	University of Colorado Anschutz Medical Center	Colorado School of Public Health University of Colorado Anschutz Medical Campus 13001 East 17th Place Campus Box B-119 Aurora, CO 80045 Office: Colorado School of Public Health Fitzsimons Building, Room W3138 13001 East 17th Place Aurora, CO 80045 303-724-4415 Carolyn.DiGuiseppi@cuanschutz.edu
Cordelia	Principal	University of	University of Colorado School of

Robinson Rosenberg, PhD, RN	Investigator for CO SEED	Colorado Anschutz Medical Center	Medicine Mail Stop C234, Anschutz Medical Campus, Education 2 South 13121 East 17th Ave, Room L28-5124 Aurora, CO 80045-2570 (303) 724-7680 cordelia.rosenberg@cuanschutz.edu
M. Daniele Fallin, PhD	Principal Investigator for MD SEED	Johns Hopkins University	3400 N. Charles Street Baltimore, MD 21218-2680 410-955-3463 dfallin@jhu.edu
Christine Ladd-Acosta, PhD	Principal Investigator for MD SEED	Johns Hopkins University	Department of Epidemiology 615 N. Wolfe Street, W6509 Baltimore, MD 21205 443-287-5180 claddac1@jhu.edu
Robert Fitzgerald, MPH, PhD	Principal Investigator for MO SEED	Washington University at St. Louis	Campus Box 1054 1 Brookings Drive St. Louis, MO 63130-4862 314-286-0151 fitzgeraldr@wustl.edu
Julie Daniels, MPH, PhD	Principal Investigator for NC SEED	University of North Carolina at Chapel Hill	Office of Sponsored Research Chapel Hill, NC 27599-5023 919-966-7096 julie_daniels@unc.edu
Maureen Durkin	Principal Investigator for WI SEED	University of Wisconsin Madison	21 N Park Ave, Suite 6301 Madison, WI 53715-1218 608-263-7507 maureen.durkin@wisc.edu
Alison Singer, MBA	President	Autism Science Foundation	3 Continental Road Scarsdale, NY 10583 914-552-1580 asinger@autismsciencefoundation.org
Alycia Halladay	Chief Science Officer	Autism Science Foundation	3 Continental Road Scarsdale, NY 10583 914-552-1580 ahalladay@autismsciencefoundation.org
Greg Robinson	Policy Analyst	Autistic Self Advocacy Network	PO Box 66122 Washington, DC 20035 202-558-4864 grobinson@autisticadvocacy.org
Chris Banks	President/Chief Executive Officer	Autism Society	6110 Executive Boulevard, Suite 305 Rockville, MD 20852 800-328-8476 cbanks@autism-society.org
Kim Musheno	Vice President	Autism Society	6110 Executive Boulevard, Suite 305

	Public Policy		Rockville, MD 20852 800-328-8476 kmusheno@autism-society.org
Adrienne Cornwall	Director, Science Communication	Autism Speaks	1060 State Road, Second Floor Princeton, NJ 08540 646-385-8500 adrienne.cornwall@autismspeaks.org
Stuart Spielman	Senior Vice President, Advocacy	Autism Speaks	1060 State Road, Second Floor Princeton, NJ 08540 646-385-8500 sspielman@autismspeaks.org

9. Explanation of Any Payment or Gift to Respondents

Respondents will receive $30 for completing the first follow-up survey. For the second follow-up survey, caregiver respondents will receive $5 and young adult respondents will receive $20. The IRB approval of the study (see CDC IRB Approval Letter, **Attachment 11**) included the review and approval of this level of remuneration.

Families included in SEED have young children and children with ASD or other developmental disabilities presenting challenges above and beyond what parents of typically developing children face. In general, tokens of appreciation have been found to be important for encouraging participation in federal research especially for more reluctant responders [23, 24, 25], including populations that SEED is specific designed to include (i.e., minorities and mothers with lower education, literacy, or income) [26]. Other studies of caregivers with more intensive caregiving responsibilities have shown the importance of retention strategies given that participating in even simple activities that can be challenging in the face of financial constraints, childcare duties, and fatigue [27, 28]. Thus, finding sufficient periods of uninterrupted time can be challenging, especially for many SEED families of children with ASD and other developmental disabilities or delays.

10. Assurance of Confidentiality Provided to Respondents

The proposed data collection will have minimal effect on the respondent’s privacy. All data on individuals participating in this information collection will remain confidential – as a Federally funded research study collecting sensitive information, this study is covered by a Federal Certificate of Confidentiality from the Department of Health and Human Services which, in most circumstances, affords the study and the participant additional protection from involuntary disclosure of identifiable information.

The exposure of the identity of study participants will be carefully avoided by using a participant identification number to encode the participant identity on data collection forms. The linkage of the identification number and the participant personal identifiers will be provided by the participant tracking system for this study. Only limited study staff will have access to the tracking system with identifiers and the identification number to link personal information to the study data collected.

Institutional Review Board Approval

The SEED Follow-up protocol (CDC Protocol 7409.0, "Study to Explore Early Development (SEED) Follow up Studies") received human subjects' approval by CDC IRB on May 18, 2022. A copy of the approval letter is included as **Attachment 11**.

A. The purpose of the SEED Follow-up Study is to collect information about the expression of autism spectrum disorder (ASD) from childhood through early adulthood. CDC, in collaboration with seven university partner institutions, previously conducted a multi-phase, multi-site case control study of pre-school aged children (2-5 years) to examine risk factors and behavioral characteristics of children with ASD. The SEED Follow-up Study will conduct longitudinal follow-up of the original SEED participants and their families. It will include surveys of caregivers to assess the developmental trajectories of their children, and to identify problems and service needs that may emerge during childhood, adolescence, and young adulthood. Additionally, it will include surveys of the children from SEED 1 who will be young adults, and it will include an in-person assessments of cognitive abilities among SEED 1-2 participants.

Only SEED staff and their research partners will have access to their personal information. Results from the study will not be linked to their name. Findings will only be linked to the study ID assigned to the family when they first participated in SEED. This link will be maintained in a database that is kept on a secure server. Participants will be encouraged to complete study materials online so that there are no paper copies, but all study forms will be kept locked in the offices of study staff, and once hard copy documents have been scanned and uploaded by study staff, they will be shredded.

Participants are notified of what data will be collected from them and how these data will be used when study staff are obtaining verbal informed consent for enrollment in the SEED Follow-up Study. They will be notified that participation is voluntary and that they can choose not to participate at any time or to skip any questions they do not want to answer. They may drop out of the study at any time without penalty. In addition, they will be informed that any information that they give the study staff about themself or their family will be kept private. Enrolled participants will also receive a written participant information sheet indicating what information will be collected and how it will be protected.

At CDC, SEED F/U data will be maintained thought a system that complies with all current (and future, with updates to the system as required) CDC security requirements and is located in a HIPAA-compliant data center with full redundant power and security measures. Finally, staff and investigators from each site will be required to sign a SEED Confidentiality and Data Use Acknowledgement Form (**Attachment 9**) prior to accessing SEED data and agree to house on institutional servers with similar security.

10.1 Privacy Impact Assessment

(i) Overview of the Data Collection System

CDC will develop a participant tracking and data entry system for SEED F/U that complies with all current (and future, with updates to the system as required) CDC security requirements for such web-based applications and is located in a HIPAA-compliant data center with full redundant power and security measures. The primary system will only be accessed by study staff. A second system will be used to collect survey responses directly from participants. This second system will not have personally identifiable information. Data from this second system is linked to data in the primary system via a family ID. Participants will have the options to complete the study instruments online, on paper, or on the phone with a study team member.

(ii) Items of Information to Be Collected

The following types of data will be collected:

1) Survey data from individual caretakers related to their child who participated in the original SEED study (co-occurring symptoms and conditions; use of health services and community supports; developmental characteristics; child safety; family and financial impacts related to their child; independence of their child; employment and educational attainment of their child);

2) Survey data from the children who participated in SEED and will be age ≥18 years during study implementation (quality of life, anxiety and depression, suicidality; sexuality and relationships; resiliency; and educational attainment and employment);

3) Existing contact information obtained from participants during earlier phases of the SEED study, along with updated information and PII obtained during data collection, including the following elements:
    - Caregiver first/last name
    - Caregiver address
    - Caregiver home phone number
    - Caregiver work phone number
    - Caregiver mobile phone number
    - Caregiver primary phone number
    - Caregiver email address
    - Young adult first/last name
    - Young adult address
    - Young adult home phone number
    - Young adult work phone number
    - Young adult mobile phone number
    - Young adult primary phone number
    - Young adult email address

Contact information will be obtained from study records from the original SEED study and will be updated during enrollment. Additional PII to be collected during enrollment will include child DOB for verification of age in weeks, necessary for standardizing age-specific developmental measures.

Only limited CDC personnel will have access to the information for the full set of participants. Additionally, because the information was collected during previous phases by institutions receiving funds from CDC through a cooperative agreement, individuals from these institutions will provide and be able to access contact information for their own participants through a secure file transfer site (CDC’s Secure Access Management System, or SAMS).

10.2 Privacy Impact Assessment Information

B. Yes, this data collection effort is subject to the CDC Privacy Act System in accordance with CDC's System of Records Notice (SORN) #09-20-0136 Epidemiologic Studies and Surveillance of Disease Problems, Department of Health and Human Services/CDC/National Center for Infectious Diseases. (See Privacy Impact Assessment, **Attachment 12**).

C. All electronic data will be collected in the participant tracking and data entry system that will be developed by CDC. This system will comply with all current (and future, with updates to the system as required) CDC security requirements for such web-based applications and is located in a HIPAA-compliant data center with full redundant power and security measures. All study materials (hard copy surveys) will be properly filed, maintained, and secured in locked containers, file cabinets, or rooms. Access to locked storage areas will be limited to study staff who have completed confidentiality training. Once hard copy documents have been scanned and uploaded by study staff, they will be shredded.

D. Prior to collection of survey data, informed consent will be obtained verbally from caregivers of SEED 1-3 participants, and from the children from SEED 1 who are now young adults. This language is included as part the Enrollment Call Script and Consent guides for the first and second follow-up surveys (**Attachment 2c**, first follow-up survey of SEED 1-3 caregivers; **Attachment 6b**, second follow-up survey of SEED 1 caregivers; **Attachment 7b**, second follow-up of survey SEED 1 young adults). Assessments of cognitive abilities will be carried out during in-person visits, during which the following written documents will be obtained: written informed consent from the caregiver (**Attachment 8c**) and written assent from the minor child (**Attachment 8d**); or written informed consent from the young adult (**Attachment 8e**).

E. Participants will be reminded that their participation is voluntary and that they may choose not to answer a question at any time or may withdraw from the study at any time without penalty. Should they decide to withdraw from the study, they will still receive a gift card as a token of appreciation. The study staff will also verbally present relevant information about the study to the participants to further enable them to make informed decisions about their involvement in the study. Respondents will be informed during the invitation and enrollment process that all information collected will be kept private, that any information presented will be in aggregate, and that their name(s) will never be used in any report. This information will be reviewed with respondents during the process of obtaining verbal informed consent; in addition, all of this information on privacy protections will also be made available to the respondents in a participant information sheet (**Attachments 2d, 6c, and 7c**) that will be sent to them via email or mail.

11. Justification for Sensitive Questions

Some topics covered in the data collection activities may be sensitive for some participants. However, these questions are essential to meeting the goals of the information collection.

SEED Follow Up study instruments (**Attachments 2, 3, 4, 5, and 6**) include questions on sensitive topics for parents, including bullying and discrimination, family and financial impacts, and parental expectations. Parents are told that they may choose to skip any question(s) that make them uncomfortable. In addition, CDC will utilize staff who have experience with participants who are emotionally vulnerable and will provide training on how to address sensitive situations that may arise during their contacts with participants.

The second follow-up self-report survey for young adults (**Attachment 7**) includes questions of a sensitive or personal nature, including those about sexual education and behavior, romantic relationships and sexual orientation, substance use, unwanted sexual contact, and suicidal thoughts or behaviors. Previous research indicates that individuals with a disability are significantly more likely to experience unwanted sexual contact and sexual violence than individuals without a disability [29, 30, 31]. This finding extends to individuals with ASD [32]. Similarly, previous research indicates that individuals with ASD are more likely than those without ASD to be at risk for suicide. A systematic review of 16 epidemiologic studies suggested that people with ASD were 3.3 times as likely than those without ASD to be at risk for suicide (defined as suicidal thoughts, suicide attempt, or suicide) [33]. Risk for suicide is increasing among those with ASD more than those without ASD [34]. In fact, suicide has been found to be the leading cause of premature death among individuals with ASD in Sweden [35]. Hence including questions on these topics on the young-adult survey is essential for informing prevention strategies.

Participants will be reminded during the informed consent process that all answers are kept private and will not be shared with anyone without their written consent. They may also skip any questions that make them feel uncomfortable. Passive referral for a positive endorsement of these questions will be provided numerous times throughout the study period. Specifically, for all participants, resources for unwanted sexual contact, suicidal thoughts or behaviors, and anxious or depressed symptomology (which are correlated with suicidal thoughts and behaviors) will be offered two times throughout the SEED Follow Up study: (1) contact phone numbers and weblinks for the National Sexual Assault Hotline, National Suicide Prevention Lifeline, and National Alliance for Mental Illness (NAMI) will be listed in the participant information sheet for young adult survey participants and; (2) a separate resource brochure will be made available for young adults. These same contact numbers and weblinks will be included in some SEED newsletters that are made available to participants.

12. Estimates of Annualized Burden Hours and Costs

Estimated Annualized Burden Hours

The following information collection instruments will be implemented for the SEED Follow-up Study:

- A first follow-up survey, including a core survey for all SEED 1-3 caregivers (**Attachment 2**), and supplements (middle childhood [**Attachment 3**], adolescent [**Attachment 4**], and young adult [**Attachment 5**]) based on when the family first participated in SEED;
- A second follow-up survey, including a survey of SEED 1 caregivers (**Attachment 6**) and SEED 1 children, who originally participated at 2-5 years, but are now young adults (**Attachment 7**); and
- An in-person assessment from 3 of the 8 original study sites (Colorado, Georgia, and Maryland) of children age >8 years whose caregivers completed the first follow-up survey (**Attachment 8**).

To estimate sample numbers, the SEED Teen study (OMB control number 0920-1219) served as a pilot for this information collection. In this pilot, contact was established with approximately 97% of eligible participants. Of those contacted, 60% completed the study. Therefore, of the approximately 6,362 eligible participants from SEED 1-3, we estimate we will establish contact with 97% of the participant pool (6,171 participants) and that up to 60% of these participants will complete the core component of the first follow-up survey (3,703 participants). Since data collection will take place over 3 years, we anticipate approximately 1,234 participants will complete the survey each year.

Given the SEED 1-3 cohorts are roughly similar in size, and the age-specific supplements will be administered at the same time as the core survey, we anticipate roughly 1/3 of participants who completed the core survey (N=1,234) will complete each of the age-specific supplements (middle childhood, adolescent, and early adult), for a total of 411 participants per year for each supplement.

For the second follow-up survey, we expect a response rate of 85% for the caregivers of SEED 1 participants who completed the first follow-up survey. This is based on our recent experience with the SEED Teen study, in which 84% of participants who enrolled completed the study. Therefore, we anticipate that roughly 85% of the 1,234 SEED 1 participants who completed the first survey, or 1,049 participants, will complete the second follow-up survey overall, for a total of 350 participants each year.

For the second follow-up young adults, who were child participants in SEED 1, we will be contacting participants through the sample pool of parents who completed the first follow up survey. Hence, we will have the same starting pool of 1,234, but we anticipate a lower response rate (40%) due to the need to obtain consent from the adult child, and because some of the adult children will not have the capacity to complete the survey. We therefore anticipate a final sample of 494 overall and 165 each year.

For the in-person assessment, we will invite the children who meet the following 4 criteria: (1) caregivers completed the core and supplemental surveys included in the first follow-up; (2) child completed the developmental assessment in SEED 1 or SEED 2 and had a final study classification of ASD or DD; (3) family's participation in SEED 1 or SEED 2 was in CO, GA, or MD, as these are the only sites funded for this aspect of data collection; and (4) the participants does not have uncorrected vision or hearing loss. The eligible sample pool meeting these criteria is approximately 982 participants. Previous SEED analyses [36] found that 70% of children whose mother completed a telephone interview completed an in-person developmental evaluation. Therefore, we estimate that 70% of the eligible sample will complete the in-person assessment of cognitive abilities (N=687 Total), for an annual sample of 229 participants.

The total number of annualized burden hours for this information collection request is estimated to be 2,089 hours.

A.12.A. Estimated Annualized Burden Hours

Type of Respondent	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**
Caregiver	Review of enrollment call script and consent for first follow-up survey **(Attachment 2c)**	2,057	1	10/60	343
Caregiver	First follow-up core survey of SEED 1-3	1,234	1	40/60	823

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
	caregivers **(Attachment 2f-h)**				
Caregiver	First follow-up survey supplement for caregivers of children (**Attachment 3a-b)**	411	1	20/60	137
Caregiver	First follow-up survey supplement for caregivers of adolescents **(Attachment 4a-b)**	411	1	20/60	137
Caregiver	First follow-up survey supplement for caregivers of young adults **(Attachment 5)**	411	1	20/60	137
Caregiver	Review of enrollment call script and consent **(Attachment 6b)**, and Second follow-up survey of SEED 1 caregivers **(Attachment 6d)**	350	1	10/60	58
Caregiver and Adult Child	Review of enrollment call script and consent by caregivers **(Attachment 6b)** and young adults **(Attachment 7b)**	165	1	10/60	27
Adult Child	Second follow-up survey of SEED 1 adult children **(Attachment 7e-h)**	165	1	30/60	82
Children aged 8-22 years and their caregivers	Review of enrollment and informed consent or assent (**Attachment 8c-e)**, In-person assessment of intellectual abilities **(Attachment 8f-g)**	229	1	90/60	344
TOTAL					**2,089**

Estimated Annualized Burden Costs

There are no costs to respondents other than their time.

Annualized burden costs are summarized in the table below. The hourly wage estimates are based on the U.S Bureau of Labor Statistics, May 2020 National Occupational Employment and Wage Estimates (available at http://www.bls.gov/oes/current/oes_nat.htm). The mean hourly wage rate for all occupations ($27.07) was used.

For the first follow-up survey, caregivers will receive $30 as a token of appreciation for his or her time to review and complete the first follow-up survey and supplement.

For the second follow-up survey, each caregiver participant will receive $5 and each adult child will receive $20 gift.

For the in-person assessment of intellectual abilities, the caregiver of the child or the adult child being evaluated will receive a $45 gift card.

A.12.B. Estimated Annualized Burden Costs

Type of Respondent	**Form Name**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Caregiver	Review of invitation materials, plus enrollment call script and consent for first follow-up survey **(Attachment 2a-d)**	343	$27.07	$ 9,280
Caregiver	First follow-up core survey of SEED 1-3 caregivers **(Attachment 2f-h)**	823	$27.07	$22,273
Caregiver	First follow-up survey supplement for caregivers of children (**Attachment 3)**	137	$27.07	$3,712
Caregiver	First follow-up survey supplement for caregivers of adolescents **(Attachment 4)**	137	$27.07	$3,712
Caregiver	First follow-up survey supplement for caregivers of young adults **(Attachment 5)**	137	$27.07	$ 3,712
Caregiver	Review of enrollment call script and consent **(Attachment 6b)**, and Second follow-up survey of SEED 1 caregivers **(Attachment 6d)**	58	$27.07	$1,578
Caregiver and Adult Child	Review of enrollment call script and consent by caregivers **(Attachment 6b)** and young adults **(Attachment 7b)**	27	$27.07	$742
Adult Child	Second follow-up survey of SEED 1 adult children **(Attachment 7e-h)**	82	$27.07	$ 2,227

Children aged 8-22 years and their caregivers	Enrollment and informed consent or assent script (**Attachment 8b-e),** In-person assessment of intellectual abilities **(Attachment 8f-g)**	344	$27.07	$9,299
TOTAL		**2,429**	$27.07	**$63,221**

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents (other than their time to participate) associated with either capital and startup efforts or operation and maintenance of services for this project.

14. Annualized Cost to the Government

The average annualized cost to the Government to collect this information is $3,934,173 for this 3-year OMB approval period that is requested.

		Total
Federal Government Personnel Costs	CDC Principal Investigator	$67,000
	CDC Project Officer	$90,000
	CDC Co-Principal Investigator	$56,000
	CDC Co-Principal Investigator	$67,000
	CDC Health Scientist	$56,000
	Subtotal for Government Personnel Costs	**$336,000**
Cooperative Agreement Costs	Five awards to SEED Follow-up sites	**$1,478,021**
Central Survey Contract Costs	Single award to central contractor for database and central survey center	**$2,120,152**
Total Government Costs		**$3,934,173**

15. Explanation for Program Changes or Adjustments

This is a new information collection; therefore, program changes or adjustments do not apply at this time.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will commence 1 month after OMB approval is obtained and is expected to continue for 3 years. Data cleaning, analytic preparation and quality checks of all SEED analytic data files (including harmonization of SEED Follow-up data with data from SEED 1, 2, 3, and Teen) will take up to 1 year following data collection. Data analysis will begin as soon as the analytic files are finalized.

A.16.—Project Time Schedule

Activity	Timeframe	
Identify and Recruit Participants	Invitation letters sent to potential participants	Immediately after OMB approval
	Data collection begins	1 month after OMB approval
	Complete data collection	3 years after OMB approval
Prepare for data analysis	Finalize data cleaning and data entry	4.5 years after OMB approval
	Prepare analytic data files and harmonize all SEED data files	5 years after OMB approval
Data analysis	Begin data analysis	5 years after OMB approval
Manuscript development	Prepare first manuscript	5.5 years after OMB approval
	Publish first manuscript	6 years after OMB approval

17. Reason(s) Display of OMB Expiration Date Is Inappropriate

Not applicable – The OMB expiration date will be displayed on necessary materials and documents.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.