

- Full Name
- Organizational Affiliation
- Complete Mailing Address
- Citizenship
- Phone Number or Email Address

The public is also welcome to listen to the meeting via Adobe Connect. Pre-registration is required by clicking the links below.

WEB ID for October 30, 2017: (100 seats) <https://adobeconnect.cdc.gov/e7yrlzismvq/event/registration.html>.

WEB ID for October 31, 2017: (100 seats) <https://adobeconnect.cdc.gov/e4icit9ctcz/event/registration.html>.

Dial in number: 888-324-3809 (100 seats).

Participant code: 3293468.

DATES: The meeting will be held on October 30, 2017, 10:00 a.m. to 5:00 p.m., ET; October 31, 2017, 8:30 a.m. to 3:30 p.m., ET.

ADDRESSES: Centers for Disease Control and Prevention (CDC), Global Communications Center, Building 19, Auditorium B3, 1600 Clifton Road NE., Atlanta, Georgia 30329.

FOR FURTHER INFORMATION CONTACT: Dometa Ouisley, Office of Science and Public Health Practice, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop D-44, Atlanta, Georgia 30329, Telephone: (404) 639-7450; Facsimile: (404) 471-8772; Email: OPHPR.BSC.Questions@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: This Board is charged with providing advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health (ASH), the Director, Centers for Disease Control and Prevention (CDC), and the Director, Office of Public Health Preparedness and Response (OPHPR), concerning strategies and goals for the programs and research within OPHPR, monitoring the overall strategic direction and focus of the OPHPR Divisions and Offices, and administration and oversight of peer review for OPHPR scientific programs. For additional information about the Board, please visit: <http://www.cdc.gov/phpr/science/counselors.htm>.

Matters To Be Considered: The agenda for day one of the meeting will include discussions that will cover briefings and BSC deliberation on the following topics: Interval updates from OPHPR Divisions and Offices; updates from the Biological Agent Containment working group; overview of OPHPR division roles and responsibilities during complex emergencies; and Preparedness Updates from Liaison Representatives.

Day two of the meeting will cover briefings and BSC deliberation on the following topics: OPHPR Office of Policy, Planning and Evaluation Stories Project; Public Health Preparedness and Response Social Media and Communications Metrics; Incident Management Training Development Program updates, OPHPR Practice-based Research Agenda and Synthesis and Translation of Public Health Preparedness and Response Research. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Claudette Grant,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2017-20082 Filed 9-20-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-17ADR]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 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 will be 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 303.

There are no costs to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Eligible families who were enrolled in SEED 1	Invitation Packet	470	1	5/60
Eligible families who were enrolled in SEED 1	Invitation Call Script	282	1	15/60
Families who agreed to participate in SEED Teen.	Follow-up Call	158	1	10/60
Families who agreed to participate in SEED Teen.	Data Collection Packet	158	1	5/60
Families who agreed to participate in SEED Teen.	SEED Teen Health and Development Survey	142	1	40/60
Families who agreed to participate in SEED Teen.	Social Responsive-ness Scale	142	1	20/60
Families who agreed to participate in SEED Teen.	Supplemental Consent forms	142	1	5/60

Leroy A. Richardson,
*Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.*

[FR Doc. 2017–20067 Filed 9–20–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5526]

**Department of Health and Human Services, Supply Service Center et al.;
 Withdrawal of Approval of 27
 Abbreviated New Drug Applications**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 27 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: *Applied Date:* October 23, 2017.